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Care Interventions for People Living With Dementia and Their Caregivers

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None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help healthcare decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of healthcare services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of healthcare in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new healthcare technologies and strategies. The National Institute on Aging (NIA) of the National Institutes of Health (NIH) requested this report from the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center (EPC) Program. The report was presented April 15, 2020, at the Health and Medicine Division, National Academies of Sciences, Engineering, and Medicine public meeting on Care Interventions for Individuals with Dementia and Their Caregivers.

The reports and assessments provide organizations with comprehensive, evidence-based information on common medical conditions and new healthcare technologies and strategies. They also identify research gaps in the selected scientific area, identify methodological and scientific weaknesses, suggest research needs, and move the field forward through an unbiased, evidence-based assessment of the available literature. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for healthcare quality improvement projects throughout the Nation. The reports undergo peer review and public comment prior to their release as a final report.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the healthcare system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program.

If you have comments on this systematic review, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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Key Informants and Technical Expert Panel

The role of the Key Informants was filled by the Health and Medicine Division (HMD) Committee of the National Academies of Sciences, Engineering, and Medicine (NASEM) that will use the report to help develop its own consensus report on which care interventions are supported by sufficient evidence to be widely disseminated and implemented to NASEM and the NIA. (An overview of the NASEM conflict of interest policies can be found at https://www.nationalacademies.org/about/institutional-policies-and-procedures/conflict-of-interest-policies-and-procedures) Because the HMD committee would not see the draft key questions, the population, intervention, comparator, outcomes, and study timing and setting (PICOTS) to specify the key questions, and analytic framework until the KQs were posted for public comment, a panel of content experts from federal agencies acted as proxy Key Informants prior to posting. The proxy Key Informants disclosed any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest.

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Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The Task Order Officer and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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Care Interventions for People Living With Dementia (PLWD) and their Caregivers

Structured Abstract

Objective. To understand the evidence base for care interventions for people living with dementia (PLWD) and their caregivers, and to assess the potential for broad dissemination and implementation of that evidence.

Data sources. We searched Ovid Medline, Ovid Embase, Ovid PsycINFO, CINAHL, and the Cochrane Central Register of Controlled Trials (CENTRAL) to identify randomized controlled trials, nonrandomized controlled trials, and quasi-experimental designs published and indexed in bibliographic databases through March, 2020.

Review methods. We searched for nondrug interventions targeting PLWD, their informal or formal caregivers, or health systems. Two investigators screened abstracts and full-text articles of identified references for eligibility. Eligible studies included randomized controlled trials and quasi-experimental observational studies enrolling people with Alzheimer's disease or related dementias or their informal or formal caregivers. We extracted basic study information from all eligible studies. We assessed risk of bias, and summarized results for studies not judged to be NIH Stage Model 0 to 2 (pilot or small sample size studies) or to have high risk of bias. We grouped interventions into categories based on intervention target.

Results. We identified 9217 unique references, of which 627 unique studies with an additional 267 companion articles were eligible. We classified interventions into 37 major categories. With few exceptions, we did not combine data quantitatively due to variability of interventions, comparison groups, outcomes measured, and study timing. Low-strength evidence shows that an intensive multicomponent intervention for informal caregiver support, with education, group discussion, in-home and phone support, and caregiver feedback (i.e. discrete adaptations of REACH II), may improve informal caregiver depression at 6 months. Low-strength evidence also shows that collaborative care models (i.e. Care Ecosystems or discrete adaptations of the ACCESS models) may improve quality of life for PLWD and health system-level markers, including improvements in guideline-based quality indicators and reducing emergency room visits. The literature does not allow for further determination of whether the very small to small average effects in quality of life applied to all enrolled PLWD or if larger effects were concentrated in an unidentified subgroup. For all other interventions and outcomes, we found the evidence insufficient to draw conclusions. Insufficient evidence does not mean that the intervention is determined to be of no value to PLWD or their caregivers. Rather, it means that due to the uncertainty of the evidence, we could not draw meaningful conclusions at this time.

Conclusions. Despite hundreds of studies, very little evidence supports widespread dissemination of any general care approaches for PLWD or caregivers. This review demonstrates the need for larger, longer-term, and more rigorous studies of interventions.

Contents

Tables

Figures

Appendixes

Evidence Summary

Main Points

- An intensive multicomponent intervention with education, group discussion, in-home and phone support sessions, and caregiver feedback for informal caregiver support (i.e. discrete adaptations of REACH II), may improve informal caregiver depression and quality of life at 6 months. (low-strength evidence)
- Collaborative care models (i.e. Care Ecosystems or discrete adaptations of the ACCESS models) may improve PLWD quality of life. (low-strength evidence) The literature does not allow for further determination of whether the very small to small average effects applied to all enrolled PLWD or if larger effects were concentrated in an unidentified subgroup.
- Collaborative care models (i.e. discrete adaptations of the ACCESS model) may improve system-level markers, including guideline-based quality indicators and reduction in emergency department visits. (low-strength evidence)
- For all other outcomes and interventions, we found the evidence was insufficient because the uncertainty of the evidence was too high to draw conclusions.
- We found little information to determine whether interventions are equally appropriate for or have been successfully adapted to other race/ethnic cultures within the United States, rural communities/communities with low resources, or specific populations of PLWD, such as people with Down syndrome or complex presentations of dementias.

Background and Purpose

The aging of the U.S. population and the concurrent rise in the number of adults living with dementia underscore the urgent need for a systematic review of the available evidence for care interventions for people living with dementia (PLWD) and their formal and informal caregivers. The National Institute on Aging (NIA) commissioned such a review from the Evidence-based Practice Center Program at the Agency for Healthcare Research and Quality (AHRQ). Dementia affects about 5 million U.S. adults 65 years and older (with disparities by race and ethnicity), and that number may grow to almost 14 million by 2060.[1, 2]

The goal is to understand the evidence base for effective care interventions, and to assess the potential for broad dissemination and implementation of that evidence. Subsequently, a NASEM committee of experts, established at the request of the NIA, will use the evidence findings delivered in this report to help develop its own independent recommendations regarding which care interventions are supported by sufficient evidence to be widely disseminated and implemented, as well as to identify research gaps.

Methods

The methods for this systematic review follow the Agency for Healthcare Research & Quality (AHRQ) Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[9] See the review protocol (https://effectivehealthcare.ahrq.gov/products/care-interventions-pwd/protocol) and the full report of the review for additional details. We searched Ovid Medline, Ovid Embase, Ovid PsycINFO, CINAHL, and the Cochrane Central Register of Controlled Trials (CENTRAL) to identify randomized controlled trials, nonrandomized controlled trials, and quasi-experimental designs published and indexed in bibliographic databases through October, 2019.

Results

We identified 9217 unique references, 894 of which were eligible for our review, comprising 627 unique studies with an additional 267 companion publications. We sorted eligible studies into 37 major intervention categories. Approximately 60 percent of the literature emerged from research conducted outside of the United States.

While the literature was highly diverse, we found little information to determine whether interventions are equally appropriate for or have been successfully adapted to other race/ethnic cultures within the United States, with only a handful of studies providing sufficient inclusion of African-American or Hispanic/Latino populations. Interventions for rural communities were found to be even more rare in the literature. Additionally, the many countries in which care interventions were evaluated were almost exclusively high-resource, with very few low-resource countries represented. Finally, few studies gathered the granular detail necessary for a deeper understanding of the applicability of the interventions. Many important groups were rarely studied, including people with Down syndrome, who are living longer and who overall experience higher rates of dementia than the general population, and individuals with complex presentations of dementia.

We found low-strength evidence that one multicomponent intervention for informal caregiver support, REACH II (comprised of education, group discussion, in-home and phone support sessions, and caregiver feedback), may improve caregiver depression.[3-5] Collaborative care models based on the ACCESS or Care Ecosystems models may improve quality of life for PLWD[6-9] and health system-level markers, including improvements in guideline-based quality indicators[7, 8] and reducing emergency room visits.[6] For all other interventions and outcomes, we found the uncertainty of the evidence was too high to draw conclusions. The vast majority of studies had small sample size, were pilots that had not undergone traditional efficacy testing, and/or had high risk of bias, and provided insufficient evidence to draw conclusions.

Limitations

As stated, the goal of the review was to understand the evidence base for effective care interventions for PLWD and their caregivers in order to assess the potential for broad dissemination and implementation of that evidence. All decisions about the review methodology followed from this goal, which has implications for our findings. Therefore, some specific approaches for a particular intervention, or even whole classes of interventions, may not have been captured. Similarly, we may have missed some community services and support approaches such as tool kits, referral services and links, or awareness-raising outreach.

Because we excluded studies with fewer than 10 participants per study arm, we may not have identified some interventions with only very preliminary research. Our approach to risk of bias assessment was generous, relative to how risk of bias is assessed in more targeted systematic review topics. This is in part due to the unusually varied studies included in this review as well as the complexity of the condition and the care approaches.

Furthermore, included studies had methodological problems such as low subject retention, widely varying measures of success, and relatively small size trials that may have lacked the power to detect benefits. These problems stem from well-recognized challenges in researching these populations; therefore, we erred on the side of assessing a body of research as insufficient rather than ineffective. Additionally, given the progressive nature of dementia and the anticipated increase in care needs over time, it may be difficult to identify improvement in caregiver burden. The goal may in fact be to slow the rate of burden—and studies may be underpowered to detect such a small effect.

Finally, given the breadth of the topic, our systematic review is naturally reductionist in nature. That is, small but true differences may exist between many of the categories we summarized into our outcomes.

Implications and Conclusions

Ultimately, we uncovered very little evidence to support interventions and programs for active, widespread dissemination because evidence was insufficient to draw conclusions about the effects of the vast majority of interventions studied.

Dementia care research has been slow to incorporate key elements of rigorous intervention design. Until relatively recently, many dementia care intervention studies were not held to reporting standards (e.g. the Consolidated Standards of Reporting Trials [CONSORT] statement), pre-registration of trials, data safety and monitoring boards, or other standards more common in other areas of clinical science. As a direct result, despite a few positive findings, our global conclusions, largely similar to past reviews,[10] are that the amount of high-quality evidence is insufficient to draw firm conclusions about interventions.

In order for federal funders and stakeholders to expedite the translational pipeline of idea development to implementation, as they aim to do, critical improvements are needed in dementia care research. Only with such improvements will we be able to draw clearer, less ambiguous conclusions related to efficacy.

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Chapter 1. Introduction

Background

The aging of the U.S. population and the concurrent rise in the number of adults living with dementia underscore the urgent need for a systematic review of the available evidence for care interventions for people living with dementia (PLWD) and their formal and informal caregivers.[1] The National Institute on Aging (NIA) has commissioned such a review from the Evidence-based Practice Center Program at the Agency for Healthcare Research and Quality (AHRQ). The goal is to understand the evidence base for effective care interventions, and to assess the potential for broad dissemination and implementation of that evidence.

Dementia affects about 5 million U.S. adults 65 years and older (with disparities by race and ethnicity), and that number may grow to almost 14 million by 2060.[1-3] A further 200,000 individuals under age 65 have some form of early-onset dementia.[1] As a clinical syndrome and a disability, dementia is characterized by an acquired cognitive deficit that interferes with independence in daily activities.[4] Alzheimer's disease is the most common form of progressive dementia and, grouped with Lewy body, frontotemporal, vascular, and mixed forms, it has been referred to as AD/ADRD (i.e., Alzheimer's disease [AD] and Alzheimer's disease related dementias [ADRD]).[5] Dementia can lower an individual's quality of life, burden caregivers (even those who find caregiving very rewarding), increase institutionalization, and increase costs to families and society.[6] Agitation, aggression, and other behavioral disturbances are common, especially late in the disease course.[7]

The significant public health implications of dementia led to the 2011 passage of the National Alzheimer's Project Act, an effort to create a national research strategy to accelerate scientific discovery of curative treatments, preventive approaches, and effective strategies to manage and alleviate the many clinical symptoms of AD/ADRD. The National Alzheimer's Project Act has spurred considerable federal investment; the National Institutes of Health (NIH) funding for AD/ADRD research has more than tripled since 2015.[8] (See https://report.nih.gov/categorical_spending.aspx

In addition to attracting new investigators, the NIA and other federal agencies have leveraged funding increases to initiate and/or contribute to several important, complementary, large-scale efforts to improve the design and delivery of care for PLWD. Among these are the first ever National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers. This 2017 summit generated a number of recommendations to advance the science of dementia care and catalyzed several important actions, including a substantial investment in several Funding Opportunity Announcements, one of which resulted in award of the NIA IMbedded Pragmatic Alzheimer's disease (AD) and AD Related Dementias (AD/ADRD) Clinical Trials (IMPACT) Collaboratory. The IMPACT Collaboratory is designed to provide technical assistance and pilot grant support to "embed" dementia care trials within health care systems across the United States, a decadal review of the state of behavioral and social science research (including but not limited to AD/ADRD care intervention research) commissioned by the National Academies of Sciences, Engineering and Medicine (NASEM), as well as other efforts.

While these initiatives are designed for rapid advancement of the science of dementia, this systematic review of the available evidence for care interventions for PLWD and their formal and informal caregivers will provide valuable information about the efficacy or effectiveness of certain types of strategies/interventions. This review also pinpoints areas that require greater attention when evaluating, disseminating, or implementing certain dementia care and caregiver interventions.

Dementia has no known cure, but both drug and nondrug interventions are available to treat symptoms, support function, and improve quality of life. Nondrug interventions have been recommended as first-line treatments for behavioral and psychological symptoms of dementia (BPSD), but pharmacological treatment options such as antipsychotics are also available.[9] And although nondrug interventions are generally presumed safe, few trials have reported information on their harms or other unintended consequences. (Drugs and over-the-counter supplements to treat clinical Alzheimer's-type dementia and behavioral and psychological symptoms of dementia are being addressed by a separate AHRQ systematic review; please see https://effectivehealthcare.ahrq.gov/products/alzheimers-type-dementia/research.)

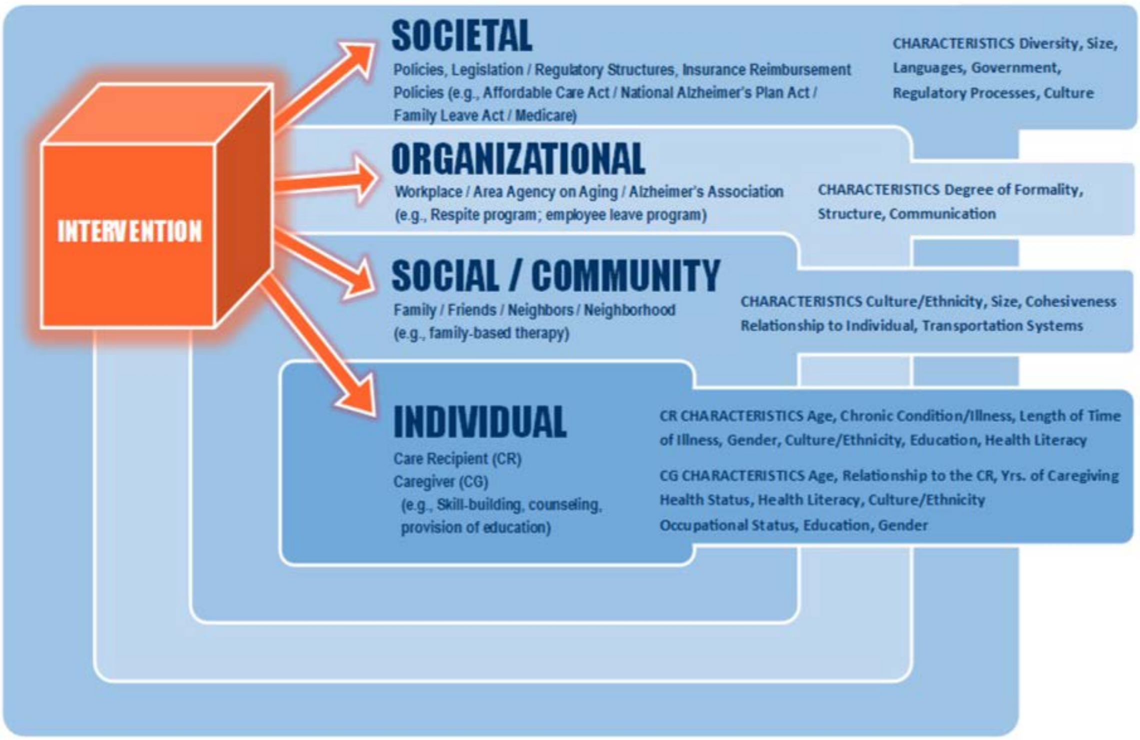
Dementia care is costly, and more than 83 percent of community-residing older adults who need it rely on help from family members.[10] In 2017, informal (unpaid) caregivers for PLWD provided an estimated 17 billion hours of care at an economic value of $232.1 billion, and about two-thirds of informal caregivers are women.[11] Caregiving for dementia is multifaceted and can be both rewarding and burdensome, sometimes simultaneously. Many surveys suggest that, for some, caregiving instills confidence, provides lessons on dealing with difficult situations, and increases feelings of closeness to the care recipient.[12] However, evidence also suggests that caregivers have lower self-ratings of physical health, elevated levels of stress hormones, higher rates of chronic disease, and impaired health behaviors. Therefore, many research teams have developed and tested interventions for supporting the health and well-being of informal caregivers. Some examples include social support, therapeutic counseling, skills training, respite, and combined approaches.[13] Additionally, many frontline paid caregivers, such as home health aides in home-based settings or certified nursing assistants in institutional settings, lack adequate training and support for this difficult work.[12] A recent NASEM report recommended an increase in federal requirements for training of direct care workers—from 75 hours to 120 hours—along with more focus on knowledge and skills related to caring for PLWD.[14]

Care interventions for PLWD encompass a broad range of activities that support, enhance, or otherwise help the care recipient. Likewise, care interventions comprise an array of options that, as noted by the NASEM committee's feedback on the framing and parameters for this review [https://www.nationalacademies.org/our-work/care-interventions-for-individuals-with-dementia-and-their-caregivers], "contribute to a person's well-being, happiness, identity, privacy, capacity, autonomy, or authority. They can be supports, services, programs, accommodations, or practices that include behavioral, environmental, technological, and psychological methods or approaches. They may be delivered by healthcare, social services, and other community organizations or caregivers with the intention of having a direct impact on either a person with dementia or their caregiver or both."

Necessarily, then, interventions addressing care for PLWD and their caregivers can be complicated and multifaceted. Unfortunately, no consensus has been reached on classification systems for types of interventions, and investigators are left to categorize interventions themselves, based on varied criteria. In our own effort to categorize interventions for this review, we identified two basic intervention groups: 1) interventions testing a type of care that is aimed at improving the health and well-being of PLWD and/or their caregivers (e.g., interventions that use music or essential oils to help calm the care recipient, or respite care that provides a break for the caregiver and 2) interventions testing the manner in which care is delivered in order to improve effectiveness, efficiency, and/or accessibility and availability of care (e.g., staff training for caregivers, coordination of care). This review refers to interventions testing a type of care as care interventions, and interventions testing the manner in which care is delivered as care delivery interventions.

Intervention complexity also stems from the diversity of PLWD (e.g., younger adults with Down syndrome or other genetic risk factors, younger and middle-aged adults with frontotemporal dementia, and older adults with AD, from very early to advanced stages) as well as different caregiver populations (e.g., spousal caregivers, adult child caregivers, paid caregivers). Intervention designs may be straightforward and aimed at supporting a single, well-defined group, such as formal or informal caregivers, or they may be very complex and target several levels of a system simultaneously, from a care system (e.g., health care or social services) to family units or caregiver/PLWD dyads to individual formal or informal caregivers. (See Figure 1.1) Furthermore, complexity in outcomes may arise because interventions targeting one level of a system, such as PLWD, may benefit other individuals, such as caregivers, or other levels of the system, such as reduced use of healthcare services for an accountable care organization.

Figure 1.1. Framework for care interventions



Abbreviations: CG=caregiver; CR=care recipient
Source: NASEM, 2016, *Families caring for an aging America*. p. 163.

Given these complexities, our review aims to specify intervention characteristics that link to benefits. Unfortunately, informal and formal caregivers may not always be easily characterized according to the levels outlined in Figure 1; paid caregivers may be hired as independent contractors by family of a PLWD, whereas unpaid volunteers may be affiliated with a larger organization. Nonetheless, information regarding relationships between PLWD and caregiver characteristics and outcomes will help clinicians, care providers, and other stakeholders make decisions about the best interventions for their specific circumstances or PLWD.

Assessing whether a care intervention is ready for broad implementation is challenging. For this review, we were guided by the NIH Stage Model for Behavioral Interventions.[15] This model provides a conceptual framework of intervention research development, ranging from basic science research (Stage 0) to new intervention creation (Stage 1), research-setting efficacy (Stage 2), “real-world” community-clinic efficacy (Stage 3), broad community-based effectiveness (Stage 4), to eventually dissemination and implementation research (Stage 5). This model not only describes the stages of behavioral intervention development, but also supports eventual implementation. While the stages are not a direct assessment of implementation readiness, the model suggests that interventions at Stage 3 or higher are more likely to be ready for broad dissemination. Interventions at Stage 4 that use pragmatic study designs move research closer to “real world” conditions and population levels.

Scope and Key Questions

This review examines a large number of nondrug care interventions targeted at PLWD, their informal and formal caregivers, and the larger health systems, including collaborative or integrated care. The intended audience is similarly broad, from PLWD and their families, to care services and support providers, to research organizations and policymakers at national, local, state, tribal, and federal levels.

Given such a wide range of stakeholders, we have prioritized the readability and usability of our review by striving for plain language and avoiding technical and field-specific jargon as much as possible throughout this report. We acknowledge that the wide readership for these findings makes communication challenging. Stakeholder groups differ in how they define and address terms and concepts related to care interventions for PLWD and their caregivers, and some of these differences may be philosophical. Additionally, individual members of stakeholder groups may differ on these matters. This report cannot resolve the rich and nuanced discussions that would be needed to come to a wide-ranging consensus about which terms to use and where. Therefore, we have opted to use the terms most commonly found within the studies we identified for this review. Our choice reflects our priority to communicate the evidence base in the clearest and most accessible way to the largest number people. In no way does our choice of terms reflect any particular philosophical position. We recognize that the various perspectives among readers may lead to different interpretations of our report. Our intention is to honor all perspectives and value all audiences.

The review specifically focuses on AD/ADRD, informal and formal caregivers, and the effect of interventions on outcomes for people or systems beyond the intended intervention target. We *did not exclude* any care setting. However, because the purpose is to inform readiness for dissemination, the review *does not include* education interventions conducted in educational settings. Because of the interest in daily caregiving, we also *did not include* workplace-based training programs that targeted professional staff (such as physicians and registered nurses) rather than auxiliary staff.

Key Questions

The key questions (KQs) are structured to organize the literature by the intervention target and grouped such that outcomes for PLWD and caregivers were examined regardless of the intervention target. The KQs are further specified by the populations, interventions, comparators, outcomes, timing, and settings (PICOTS) laid out in Table 1.1.

Care Interventions for Behavioral and Psychological Symptoms of Dementia (BPSD) in People Living With Dementia (PLWD)

- KQ1: For people living with dementia **(PLWD),** what are the benefits and harms of care interventions aimed at treating the behavioral and psychological symptoms of dementia (BPSD) in PLWD?
  - KQ1a: What evidence is available on how outcomes differ by **PLWD** characteristics?
  - KQ1b: What evidence is available on how outcomes differ by informal and/or formal **PLWD Caregiver** characteristics?
  - KQ1c: Which intervention characteristics or components are associated with effectiveness?
- KQ2: For informal and/or formal **PLWD Caregivers,** what are the benefits and harms for care interventions aimed at treating BPSD in **PLWD**?
  - KQ2a: What evidence is available on how outcomes differ by **PLWD** characteristics?
  - KQ2b: What evidence is available on how outcomes differ by informal and/or formal **PLWD Caregiver** characteristics?
  - KQ2c: Which intervention characteristics or components are associated with effectiveness?

Care Interventions for Quality of Life, Function, or Non-BPSD Symptoms in PLWD:

- KQ3: For people living with dementia **(PLWD),** what are the benefits and harms for care interventions aimed at improving quality of life, function, or non-BPSD symptoms in **PLWD**?
  - KQ3a: What evidence is available on how outcomes differ by **PLWD** characteristics?
  - KQ3b: What evidence is available on how outcomes differ by informal and/or formal **PLWD Caregiver** characteristics?
  - KQ3c: Which intervention characteristics or components are associated with effectiveness?
- KQ4: For informal and/or formal **PLWD Caregivers,** what are the benefits and harms for care interventions aimed at improving quality of life, function, or non-BPSD symptoms in **PLWD**?
  - KQ4a: What evidence is available on how outcomes differ by **PLWD** characteristics?
  - KQ4b: What evidence is available on how outcomes differ by informal and/or formal **PLWD Caregiver** characteristics?
  - KQ4c: Which intervention characteristics or components are associated with effectiveness?

Care Interventions for Quality of Life and Health Outcomes for Informal and Formal PLWD Caregivers:

- KQ5: For people living with dementia **(PLWD),** what are the benefits and harms for care interventions aimed at supporting the quality of life and health outcomes of the informal **PLWD Caregivers**?
  - KQ5a: What evidence is available on how quality of life and outcomes differ by **PLWD** characteristics?

  - KQ5b: What evidence is available on how quality of life and outcomes differ by informal or formal **PLWD Caregiver** characteristics?
  - KQ5c: Which intervention characteristics or components are associated with effectiveness?
- KQ6: For informal and/or formal **PLWD Caregivers,** what are the benefits and harms for care interventions aimed at supporting the quality of life and health outcomes of the informal **PLWD Caregivers**?
  - KQ6a: What evidence is available on how quality of life and outcomes differ by **PLWD** characteristics?
  - KQ6b: What evidence is available on how quality of life and outcomes differ by informal and/or formal **PLWD Caregiver** characteristics?
  - KQ6c: Which intervention characteristics or components are associated with effectiveness?
- KQ7: For people living with dementia **(PLWD),** what are the benefits and harms for care interventions aimed at supporting the quality of life and health outcomes of the formal **PLWD Caregivers**?
  - KQ7a: What evidence is available on how quality of life and outcomes differ by **PLWD** characteristics?
  - KQ7b: What evidence is available on how quality of life and outcomes differ by informal and/or formal **PLWD Caregiver** characteristics?
  - KQ7c: Which intervention characteristics or components are associated with effectiveness?
- KQ8: For informal and/or formal **PLWD Caregivers,** what are the benefits and harms for care interventions aimed at supporting the quality of life and health outcomes of the formal **PLWD Caregivers**?
  - KQ8a: What evidence is available on how quality of life and outcomes differ by **PLWD** characteristics?
  - KQ8b: What evidence is available on how quality of life and outcomes differ by informal and/or formal **PLWD Caregiver** characteristics?
  - KQ8c: Which intervention characteristics or components are associated with effectiveness?

Interventions for How Care Is Delivered:

- KQ9: For people living with dementia **(PLWD),** what are the benefits and harms for care delivery interventions?
  - KQ9a: What evidence is available on how outcomes differ by **PLWD** characteristics?
  - KQ9b: What evidence is available on how outcomes differ by informal and/or formal **PLWD Caregiver** characteristics?
  - KQ9c: Which intervention characteristics or components are associated with effectiveness?
- KQ10: For informal and formal **PLWD Caregivers,** what are the benefits and harms for care delivery interventions?
  - KQ10a: What evidence is available on how outcomes differ by **PLWD** characteristics?
  - KQ10b: What evidence is available on how outcomes differ by informal and/or formal **PLWD Caregiver** characteristics?

- KQ10c: Which intervention characteristics or components are associated with effectiveness?

Dissemination and Implementation Research:

- Guiding Question 1: What is the state of the empirical evidence on implementation of interventions that have at least low-strength evidence for “real-world” benefits and harms (i.e., NIH Stage Model for Behavioral Intervention Development Stages 3-5)?

Note that in Table 1.1, outcomes are loosely organized to correspond with the levels shown in Figure 1.1. Importantly, we based our final organization of outcomes according to the outcomes examined and measures used in eligible studies, as well as the intentions of the authors.

Table 1.1. PICOTS

Element	PLWD	PLWD Caregiver
Population	**PLWD**, including individuals with possible or diagnosed AD/ADRD. PLWD Subgroups: Age, sex, sexual orientation/gender identity, race/ethnicity, education, socioeconomic status, prior disability, age at diagnosis, dementia type, dementia severity [e.g. stage of dementia (early stage, moderate, or severe), level of cognitive impairment rate of cognitive decline], family/household characteristics, health insurance, geographic location (e.g. urban, rural), setting type	**Informal PLWD Caregivers**, such as spouses, family, friends, and volunteers Informal PLWD Caregiver Subgroups, including age, sex, sexual orientation/gender identity, race/ethnicity, family history of dementia, education, socioeconomic status, employment status, relationship with PLWD, living distance from PLWD, dementia care training, general health status, caregiving networks, setting type **Formal PLWD Caregivers**, such as certified nursing assistants (CNAs), home health aides, auxiliary workers, personal care aides, hospice aides, promotoras or promotores, and community health workers Formal PLWD Caregiver Subgroups, including age, sex, race/ethnicity, education, job position, skill, training, general health status, setting type
Intervention	KQ 1-4. Any nondrug care intervention intended to benefit PLWD **except** interventions to treat conditions other than dementia, including but not limited to CPAP, and those that use supplements/natural products. (See list of example intervention types in Appendix A.) Guiding Question: Any quality improvement or implementation science study that informs the dissemination or implementation of a care intervention at least low-strength evidence for “real-world” benefits and harms (i.e., NIH Stage Model for Behavioral Intervention Development Stages 3-5)	KQ 5-6. Any care intervention intended to support informal PLWD caregivers’ well-being **except** interventions to treat health conditions unrelated to providing care to PLWD. KQ 7-8. Any care intervention intended to support formal PLWD caregivers’ well-being except interventions to treat health conditions unrelated to providing care to PLWD. KQ 9-10. Any care delivery intervention to improve how care is delivered IF the training intervention is incorporated as on-going operational procedures into the structure or processes of the organization. Interventions carried out by higher education organizations or professional organizations to provide training toward licensed professionals, and continuing education for degreed health professionals are also excluded. (See list of example intervention types in Appendix A.)

Element	PLWD	PLWD Caregiver
		Guiding Question: Any quality improvement or implementation science study that informs the dissemination or implementation of a care intervention at least low-strength evidence for “real-world” benefits and harms (i.e., NIH Stage Model for Behavioral Intervention Development 3-5)
Comparator	Inactive Comparator: No intervention, usual care, waitlist, attention control Active Comparator: Different intervention	Inactive Comparator: No intervention, usual care, waitlist, attention control Active Comparator: Different intervention
Outcomes (Generally organized to correspond with Figure 1.1 Framework for care interventions)	Quality of life and subjective well-being Burden of care* Satisfaction with care Perceived Support Expenditures/financial burden (informal caregivers) Health-related outcomes: Psychological health (e.g., depression, anxiety) Neuropsychiatric symptoms (including apathy, aggression, and agitation) Function (e.g., ADL, IADL, ability to care for one’s self, ability to recreate/socialize Weight loss Sleep problems Use of restraints Use of anti-psychotics Harm reduction (e.g. driving, firearms) Palliative care/hospice outcomes: Completion of advanced directives Comfort during dying process Concordance with preferred location of death Social/Community level outcomes: Engagement in community activities, Perceived inclusion Safety/perceived safety Utilization of healthcare service outcomes: Admission to nursing home Access to care and services ICU and ED usage Hospital admission and readmission Primary, Specialty, Long-term Care usage Quality of care and services (e.g., overutilization of unnecessary antibiotics, other quality care metrics.) Societal costs, including caregiving time/time spent on activities Harms, including isolation, loneliness, perceived stigma, suicidal ideation or suicide, elder abuse (e.g., physical harm,	Quality of life and subjective well-being Burden of care* Satisfaction with care for PLWD (informal caregivers) Perceived Support Expenditures/financial burden (informal caregivers) Health-related outcomes: Psychological health (e.g., depression, anxiety) Immune function (e.g., inflammation or cortisol) Sleep problems Weight loss due to stress Health behaviors (e.g., exercise, substance use) Caregiving self-efficacy Confidence to manage caregiver tasks Social/Community level outcomes (informal caregivers): Engagement in community activities, Perceived inclusion Safety/perceived safety Turnover and retention (formal caregivers) Utilization of healthcare service (e.g., physician visits, antidepressant or antianxiety medication usage) Societal costs including caregiving time/time spent on activities Harms, including isolation, loneliness, perceived stigma, caregiver PTSD

Element	PLWD	PLWD Caregiver
	abuse, neglect, exploitation, family violence)	
Timing	No minimum duration or followup	No minimum duration or followup
Setting	Any setting; no exclusion based on geographic location or setting. Includes home, home health care, adult day care, acute care settings, social service agencies, nursing homes, assisted living, memory care units, hospice, rehabilitation centers/ skilled nursing facilities, long-distance caregiving, and nonplace-based settings	Any setting; no exclusion based on geographic locations or setting. Includes home, home health care, adult day care, acute care settings, social service agencies, nursing homes, assisted living, memory care units, hospice, rehabilitation centers/ skilled nursing facilities, long-distance caregiving, and nonplace-based settings

*****We are obligated to use the proper names of measurement tools, such as the Zarit Caregiver Burden Scale, when used in a specific study. **Abbreviations:** AD=Alzheimer's disease; ADL=activities of daily living; ADRD= Alzheimer's disease related dementias; BPSD=behavioral and psychological symptoms in dementia; CNA= certified nursing assistants; CPAP=continuous positive airway pressure; ED=emergency department; IADL=instrumental activities of daily living; ICU=intensive care unit; KQ=key question; MCI=mild cognitive impairment; NIH=National Institutes of Health; PICOTS=population, intervention, comparator, outcome, timing, setting; PTSD=post-traumatic stress disorder; PLWD=person with dementia; RCT=randomized controlled trial

Analytic Framework

Figure 1.2 is a traditional analytic framework, illustrating the relationships between interventions and outcomes. Due to limited space, not all baseline characteristics or outcomes listed in Table 1.1 are specifically listed in Figure 1.2.

Figure 1.2. Analytic framework

Abbreviations: KQ=key question; PLWD=People living with dementia; SES=socioeconomic status

Report Organization

This report provides, in Chapter 2, details intended to familiarize readers with the methods used to conduct this systematic review. Chapter 3 presents the overall results of the search for the review's eligible studies. Beginning in Chapter 4, results are organized by the intervention target, then by outcome. Due to the breadth and complexity of the interventions, we also present for each result section a brief description of the intervention as well as the intervention's research context, especially regarding how the eligible studies may or may not represent how that particular body of research has progressed along the NIH Stage Model. A glossary of terms for the report is provided in Table 1.2

Results Chapters are structured to present each pair of KQs, keeping the PLWD and caregiver outcomes together for each intervention. And, as discussed earlier, we have categorized interventions as either care interventions (which test the effects of a specific type of care) or care delivery interventions (which test the effects of different manners in which care is delivered). We present the care interventions addressed in KQs 1-8 in Chapters 4 – 7, and the care delivery interventions addressed in KQs 8 – 9 in Chapter 8. Readers interested in considering potential implementation costs and investments (of technologies, support materials, and personnel required for intervention implementation) to suit their unique settings and contexts may find this separation helpful. Chapter 9 provides a brief response to the Guiding Question 1. The report then concludes with the Discussion in Chapter 10.

Table 1.2 Glossary of terms

Term	Description
Analytic set	For the purposes of this review, the **analytic set** is the set of studies that underwent synthesis. It consists of the studies not judged to be pilots or have a high potential for bias that might have interfered with the ability of the study to answer its research question.
Care delivery intervention	**Care delivery interventions** aim to improve the manner in which care is delivered, including the scheduling of staff and tasks as well as the ways in which staff and tasks are interdependent. Care delivery interventions can change the tasks that are performed, the set of staff who perform the tasks, or the way the staff work together. While much of this change is implemented through education and training, care delivery interventions differ from the type of education and training targeted at improving already established roles and tasks.
Care intervention	**Care interventions** contribute to a person's well-being, happiness, identity, privacy, capacity, autonomy, or authority. They can be supports, services, programs, accommodations, or practices that include behavioral, environmental, technological, and psychological methods or approaches. They may be delivered by health care, social services, and other community organizations or caregivers with the intention of having a direct impact on either a person with dementia or their caregiver or both.
Eligible study	An **eligible study** is one that meets the initial study criteria that were defined in advance regarding the type of study that would be included in the systematic or comparative effectiveness review.
Evidence map	An **evidence map** is the result of a systematic search of a defined topic area that can facilitate evidence-informed decision making or identify gaps in knowledge and future research needs.
Explanatory studies	**Explanatory studies** aim to test whether an intervention works under optimal situations.
Exploratory study	**Exploratory studies** are preliminary research designed to clarify the exact nature of the problem to be solved.
Formal caregiver	**Formal caregivers** are paid caregivers, such as certified nursing assistants (CNAs), home health aides, auxiliary workers, personal care aides, hospice aides, promotoras or promotores, and community health workers.
Heterogeneity	**Heterogeneity** is a word that signifies diversity in something. A classroom consisting of people from lots of different backgrounds would be considered having the quality of heterogeneity. Likewise, a wide range of study designs in a group of studies would be considered heterogeneous.
Informal caregiver or Caregiver/Care Partner (CG/P)	For the purposes of this review, **Informal caregivers** are spouses, family, friends, and volunteers providing care to one or more PLWD. Informal caregivers are typically unpaid. While caregiver has been a term commonly used in the literature, some people prefer the term “care partner.”
People Living With Dementia (PLWD)	For the purposes of this review, **People Living With Dementia (PLWD)** is a term/ abbreviation that refers to individuals living with Alzheimer’s disease or Alzheimer’s disease related dementias.
Person-centered	**Person-centered**, in this context, is a way of designing interventions with consideration for the needs of the people using health and social services in planning, developing and monitoring care.
Pragmatic studies	**Pragmatic studies or trials** are designed to evaluate the effectiveness of interventions in real-life routine practice conditions.
Preliminary studies	A **preliminary study** is an initial exploration of issues related to a proposed intervention.
Protocol	A **protocol** is set of steps or procedures for health systems or units providing the care. They can also specify the tools and tasks that need to be carried out, and they help processes to be understood by staff regardless of staff’s tenure or experience.

Term	Description
Pilot study	A **pilot study** is a small-scale test of the methods and procedures to be used on a larger scale in a future study.
Risk of bias	**Risk of bias** is the extent to which the design and conduct of a study are likely to have prevented bias in the results.
Small sample	**Sample size** is a count of the individual people or observations in any statistical setting, such as a scientific experiment or a public opinion survey. Too small a sample yields unreliable results, while an overly large sample requires a significant commitment of time and resources.

Chapter 2. Methods

The methods for this systematic review followed the Agency for Healthcare Research and Quality (AHRQ) Methods Guide for Effectiveness and Comparative Effectiveness Reviews (available at https://effectivehealthcare.ahrq.gov/topics/cer-methods-guide/overview). This systematic review also reports in accordance with the Preferred Items for Reporting in Systematic Reviews and Meta-Analyses (PRISMA),[16] A Measurement Tool to Assess Systematic Reviews (AMSTAR 2),[17] and any relevant extension statements.

The topic of this review was initially developed by the National Institute on Aging (NIA) in consultation with AHRQ. The role of the Key Informants was filled by the NASEM committee, which, as noted earlier, will use the review to help develop its own recommendations regarding which interventions are ready for dissemination and implementation on a broad scale. However, the NASEM committee did not see the draft key questions (KQs), PICOTS, and analytic framework until the KQs were posted for public comment; therefore, a panel of content experts from federal agencies acted as proxy Key Informants, providing input on the KQs to be examined. Federal content experts were drawn from the NIA, the Department of Veterans Affairs, The Department of Defense, the Center for Disease Control and Prevention, the Office of the Assistant Secretary for Planning and Evaluation, and the Administration for Community Living within the Department of Health and Human Services. The NASEM committee also served as Technical Experts, providing high-level content and methodological expertise throughout development of the review protocol. The final protocol is posted on the EHC website at https://effectivehealthcare.ahrq.gov/products/care-interventions-pwd/protocol.

Study Selection

Studies were included in the review based on the PICOTS framework outlined above in Table 1.1 and the study-specific inclusion criteria described in Table 2.1.

Table 2.1. Study inclusion criteria

Category	Criteria for Inclusion
Study Enrollment	Adults with possible or diagnosed AD/ADRD. No age requirement is made, that is, early onset disease that may be experienced by people with Down syndrome or other genetic risk factors are included. Study populations may include adults with mild cognitive impairment (MCI) if 15% or less of total sample, or must report results for dementia population separately.
Study Objective	KQ 1-2: Evaluate benefits and harms of care interventions for BPSD symptoms in PLWD KQ 3-4: Evaluate benefits and harms of care interventions for quality of life, function, or non-BPSD symptoms in PLWD KQ 5-6: Evaluate benefits and harms of care interventions for quality of life and health outcomes of informal caregivers for PLWD KQ 7-8: Evaluate benefits and harms of care interventions for quality of life and health outcomes of formal caregivers for PLWD KQ 9-10: Evaluate benefits and harms of care delivery interventions that address how care is delivered KQ subquestions: Evaluate possible effect modifiers of intervention benefits and harms
Study Design	RCTs, and prospective studies with concurrent comparator arms, and at least 10 participants per arm at study analysis. Interrupted time series with at least 3 measures both pre- and post-intervention (therefore excluding simple controlled before/after studies without comparator arm).

Outcomes	Outcomes listed in Table 1. Actual outcome measures will be defined by study authors. Common measures are provided in Appendix A. We will only include studies with immune function, turnover, or retention of caregivers if the study also includes another PLWD or quality outcomes; that is, we will not include the study if it only examines turnover or retention as an intermediate outcome in isolation.
Publication type	Published in peer-reviewed journals and grey literature with full text available (if sufficient information to assess eligibility and risk of bias are provided). Letters and conference abstracts are excluded due to the inability of such short publications to provide the information needed to fully describe the interventions.
Language of Publication	English only, due to resource limitations

Abbreviations: AD=Alzheimer's disease; ADRD= Alzheimer's disease related dementias; BPSD=behavioral and psychological symptoms in dementia; KQ=key question; MCI=mild cognitive impairment; PLWD=person with dementia; RCT=randomized controlled trial

The following discussion about the review search processes is organized by type of research question—first the KQs, then the guiding question.

For the KQs, we searched Ovid Medline, Ovid Embase, Ovid PsycInfo, CINAHL, and the Cochrane Central Register of Controlled Trials (CENTRAL) to identify studies published and indexed in bibliographic databases. The search algorithm included relevant controlled vocabulary and natural language terms for the concepts of Alzheimer's disease (AD) and related dementias (ADRD) (Appendix A).

We reviewed bibliographic database search results for studies relevant to our PICOTS framework and study-specific criteria. Search results were downloaded to EndNote. Two reviewers independently reviewed titles and abstracts to identify studies meeting PICOTS framework and inclusion/exclusion criteria. Two reviewers independently performed full-text screening to determine if inclusion criteria were met. Differences in screening decisions were resolved by consultation between reviewers, and, if necessary, consultation with a third reviewer. We documented the inclusion and exclusion status of citations that underwent full-text screening. Throughout the screening process, team members met regularly to discuss training material and issues as they arose to ensure consistent application of inclusion criteria.

We conducted limited additional searching of grey literature (research or other written material produced outside of traditional academic publishing) to identify relevant completed and ongoing studies that met the study design inclusion criteria. Grey literature search results were used to identify studies, outcomes, and analyses not reported in the peer-reviewed published literature to assess publication and reporting bias and inform future research needs. We also tracked published protocols for studies that have not published results in the public domain.

For the guiding question, we conducted forward citation searching of studies with low to moderate strength of evidence for companion articles describing implementation processes.

Lastly, to provide resources for care interventions which may not have been empirically studied using study designs that met inclusion criteria, we searched websites of relevant governmental agencies, professional associations, and AD or ADRD nongovernmental groups for curated lists of known interventions. An example list of organizations is provided in Appendix A.

We will update searches while the draft report is under public/peer review.

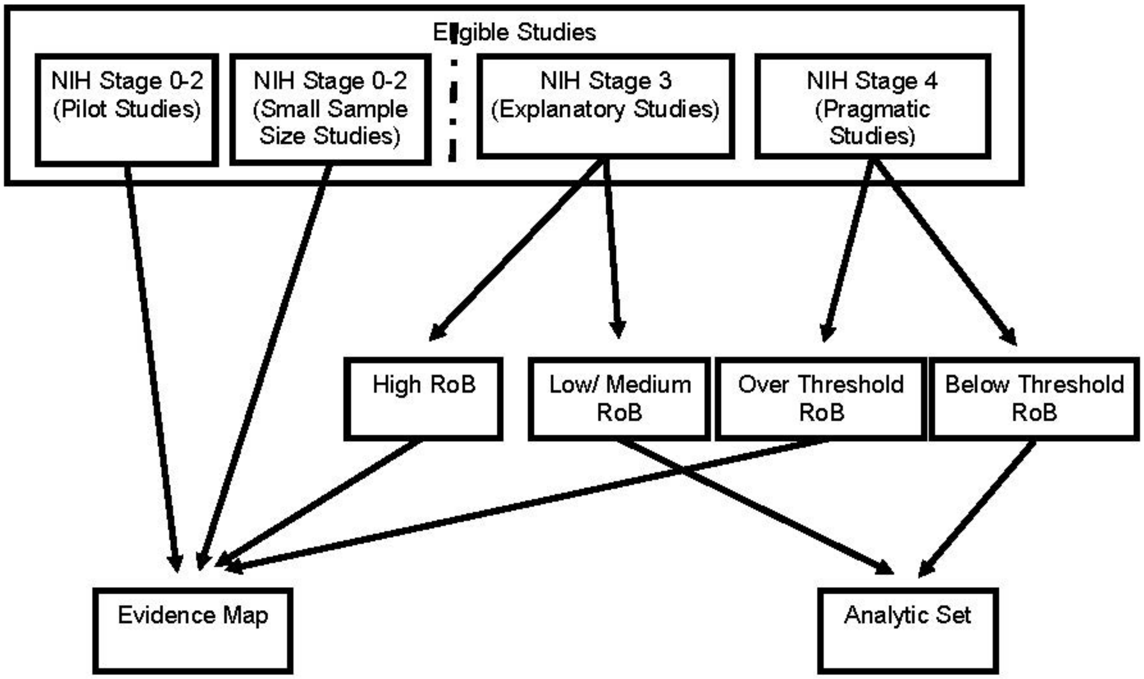
Data Extraction

Studies that met inclusion criteria were distributed to EPC reviewers for data extraction. Data extraction used a two-stage process: (1) we first used an **evidence map** table for basic data extraction, and (2) we then created a series of **analytic set** tables including comprehensive evidence and assessment tables for those studies that went on to further analysis. Figure 2.1 provides a graphic illustration of the flow of studies through the review processes. Data fields for both the evidence map and analytic set included author, year of publication, population of interest (including a granular checklist of PLWD and caregiver characteristics), intervention, comparison, setting, outcomes cited, intervention duration, and study followup.

As mentioned in Chapter 1, we were guided by the NIH Stage Model for Behavioral Interventions.[15] This model provides a conceptual framework of intervention research development, ranging from basic science research (Stage 0) to new intervention creation (Stage 1), research-setting efficacy (Stage 2), "real-world" community-clinic efficacy (Stage 3), broad community-based effectiveness (Stage 4), to eventually dissemination and implementation research (Stage 5). This model not only describes the stages of behavioral intervention development, but also supports eventual implementation. While the stages are not a direct assessment of implementation readiness, the model suggests that interventions at Stage 3 or higher are more likely to be ready for broad dissemination. Interventions at Stage 4 that use pragmatic study designs move research closer to "real world" conditions and population levels.

For studies that appeared to be at NIH Stage 0 to 2 (pilot, feasibility, and small sample size studies), extraction was complete at the evidence map stage; *these studies did not advance to further extraction or outcome assessment*. For NIH Stage 3 (efficacy or explanatory studies) and NIH Stage 4 studies (effectiveness, or pragmatic studies), if a study was assessed as high risk of bias or over threshold risk of bias (see section below on risk of bias assessment for further details), *these studies did not advance to further extraction or outcome assessment*, however, we do present details of the risk of bias assessment.

Figure 2.1. Review assessment and extraction processes



Abbreviations: ROB= Risk of bias

The remaining studies that were assessed as having low to moderate risk of bias and appearing to be NIH Stage 3 to 5 comprise the analytic set. We extracted additional data fields including subject inclusion criteria, more detailed PLWD and caregiver characteristics, intervention and comparison characteristics, descriptions and results of included outcomes and harms, risk of bias elements, elements to distinguish NIH Stage 3 or 4 (where appropriate), and study funding source. Intervention characteristics included theory base, components and activities, timing, frequency, duration, use of technology, training, delivery approach (prescriptive or manualized vs. tailored), other delivery modalities, and use of cultural adaptations or modifications. We noted the point on the disease continuum (i.e. stage of dementia) for which the intervention was intended and methods for targeting the interventions to PLWD and/or caregivers and their identified goals and priorities.

We extracted relevant data into Microsoft Excel. Evidence map tables were verified for accuracy by a second EPC reviewer. For the analytic set, one reviewer extracted data to evidence and outcomes tables, and a second reviewer reviewed and verified the data for accuracy. Given the number of included studies, we did not contact study authors for missing data.

Assessing Methodological Risk of Bias and NIH Stage of Individual Studies

Based on AHRQ guidance,[18] two EPC reviewers independently assessed risk of bias for all eligible studies. Reviewers consulted to reconcile discrepancies in overall risk of bias. Overall risk of bias assessments for each study were classified as low, moderate, or high based on the collective risk of bias inherent in each domain and the level of confidence that the results were believable given the study's limitations. However, the approach differed based on the KQ and study NIH Stage mode; these differences are detailed below. We began with an initial sorting into NIH Stages 0 to 2 versus NIH Stages 3 to 5 by simple examination of the study aims.

For KQ 1-8: For studies of individual care interventions, we used a modified Cochrane risk of bias tool to assess them as high, medium, or low for each of the following domains: (1) selection bias (adequacy of randomization method [RCTs], accounting for imbalance in prognostic variables [observational studies]); (2) attrition bias (differentiated by mortality versus loss to followup); (3) detection bias (outcome measurement quality, outcome assessor masking); (4) performance bias (intention to treat or test analysis, adjustment for potential confounding variables, participant masking to treatment assignment); (5) reporting bias (selective reporting of outcomes). (Appendix A) While we were not expressly looking for studies identified as quality improvement interventions, we recognize that complex care delivery interventions use multicomponent approaches similar to quality improvement interventions. Therefore, for these complex interventions, risk of bias included domains similar to those outlined in a risk of bias tool for quality improvement, e.g., fidelity to the program.[19]

For KQ 9 - 10: We anticipated that care delivery studies would generally fall in the range of NIH Stage 3 to 4 effectiveness trials, with the possibility that a few were carried out as quality improvements and thus Stage 5. Along with categorizing studies by NIH Stage Model, we also broadly labeled study designs as explanatory or pragmatic. **Explanatory** studies test whether an intervention works under optimal conditions, similar to Stage 3, while **pragmatic** studies evaluate effectiveness of interventions in real-life practice conditions, similar to Stage 4.[20] Since study designs exist on a continuum, rather than as discreet categories, we included a "**balanced**" category for study designs that appeared poised between explanatory and pragmatic. Because both the higher NIH stages and pragmatic trials are explicitly designed to balance, or trade off, internal and external validity, we approached risk of bias assessment as a threshold requirement rather than a continuum for suspected pragmatic design studies. We targeted studies self-identifying as pragmatic and studies using advanced study designs such as cluster or stepped wedge designs. We assessed whether such studies were below the threshold of high risk of bias based on selection bias, level of attrition, and fidelity to the intervention. If a study was over threshold risk of bias, we abstracted it into the evidence map with no further action. If a study was determined to be below the threshold, we then assessed it for NIH stage. To assess NIH stage, we used a modified PRECIS-2 tool,[21] initially developed to help interventionists design pragmatic trials. Because explanatory and pragmatic classifications fall along a continuum rather than being discrete categories,[20] and because reporting details for fine distinctions are often lacking in publications, we used the three categories outlined above (explanatory, balanced, and pragmatic) rather than the 5-point scale of the PRECIS-2 tool. Appendix A provides the modified tool. (Advanced study designs such as cluster trials were considerably less prevalent in KQ 1 – 8 and often readily identified as explanatory based on the stated purpose of the study and the reason for using a cluster design. We therefore found it essentially unnecessary to use this staged assessment process for KQ 1 – 8.)

Data Synthesis

We summarized results in evidence maps or analytic set tables and synthesized evidence for each unique population, comparison, and outcome or harm. *Evidence maps* provide a quick synthesis of what the identified literature has studied. *Analytic set tables* gather a more comprehensive set of data, allowing the reviewer to attempt to go further and answer "what did the included studies find." For this review, we organized analytic set tables by intervention targets, interventions, comparators, and PLWD, caregiver, or other system-level outcomes. We reported descriptive information regarding numbers of studies reporting more granular PLWD or caregiver characteristics.

Because we could not identify a consensus taxonomy of interventions to apply to the literature, we categorized interventions empirically by intervention and comparator pairs. Because splitting into very narrow categories can make drawing conclusions impossible (due to few studies of often questionable risk of bias), we sought to balance two competing concerns: (1) a need to group broadly conceptual ideas together as much as possible in order to have sufficient studies informing the synthesis, and (2) avoiding excessive heterogeneity in the studies grouped together because that makes interpretation difficult. We used the explanatory or pragmatic classifications along with the NIH Stage Model to inform our qualitative synthesis of the **intervention's research context** (i.e., a brief representation of the current state of the research and its development over time, including a summary and description of the eligible studies). The intervention research context sections function as the main results reporting for the evidence maps, and as contextual information for outcomes reported for the analytic sets.

For the KQs, we assessed the effects of outcomes using clinically important differences if well-established, but for many outcomes this was not the case. Because of the very wide range of outcomes of interest across the panel of potential interventions, we did not list specific priority outcomes beyond those noted in Table 1.1. For any individual study, we examined no more than five to seven outcomes per PLWD or caregiver population, prioritizing person-centered outcomes, (e.g., quality of life, function, and harms), over intermediate outcomes (e.g., laboratory test values, subscales of outcome measurement tools). Our rationale for this decision is that excessive reporting of outcomes generally happens with the latter type of outcome.

When pooling outcomes across studies was possible, we used random effects models. For continuous outcomes, we calculated weighted mean differences and/or standardized mean differences with the corresponding 95 percent confidence intervals. We assessed the clinical and methodological heterogeneity and variation in effect size to determine appropriateness of pooling data. We assessed statistical heterogeneity with Cochran's Q test and measure magnitude with I2 statistic.

Grading the Strength of Evidence for Major Comparisons and Outcomes

The overall strength of evidence for select outcomes for KQs 1 – 10 were evaluated based on five required domains: (1) study limitations (risk of bias); (2) consistency (similarity of effect direction and size); (3) directness (single, direct link between intervention and outcome); (4) precision (degree of certainty around an estimate); and (5) reporting bias.[22] An outcome with an overall rating of "high strength of evidence" implies that the included contributing studies were randomized controlled trial studies with both a low risk of bias, and with consistent, direct, and precise domains. We assessed strength of evidence for key final health outcomes measured with validated scales.

Based on study design and risk of bias, we rated study limitations as low, medium, or high. Consistency was rated as consistent, inconsistent, or unknown/not applicable (e.g., single study) based on whether intervention effects were similar in direction and magnitude, and statistical significance of all studies. Directness was rated as either direct or indirect based on the need for indirect comparisons when inference requires observations across studies (i.e., more than one step was needed to reach the conclusion). Precision was rated as precise or imprecise based on the degree of certainty surrounding each effect estimate or qualitative finding. An imprecise estimate is one for which the confidence interval is wide enough to include clinically distinct conclusions. If we had found any outcome to have at least moderate or high strength of evidence, we would have evaluated reporting bias by the potential for publication bias, selective outcome reporting bias, and selective analysis reporting bias. We would have done this by comparing reported results with those mentioned in the methods section and an assessment of the grey literature to assess potentially unpublished studies. However, no findings rose to this level. Other factors considered in assessing strength of evidence included weighting by strength of study design to address broad dissemination (thus pragmatic trials hold stronger weight), dose-response relationship, the presence of confounders, and strength of association.

Based on these factors, we rated the overall strength of evidence for each outcome as:

High: Very confident that estimate of effect lies close to true effect. Few or no deficiencies in body of evidence, findings are believed to be stable.

Moderate: Moderately confident that estimate of effect lies close to true effect. Some deficiencies in body of evidence; findings likely to be stable, but some doubt.

Low: Limited confidence that estimate of effect lies close to true effect; major or numerous deficiencies in body of evidence. Additional evidence necessary before concluding that findings are stable or that estimate of effect is close to true effect.

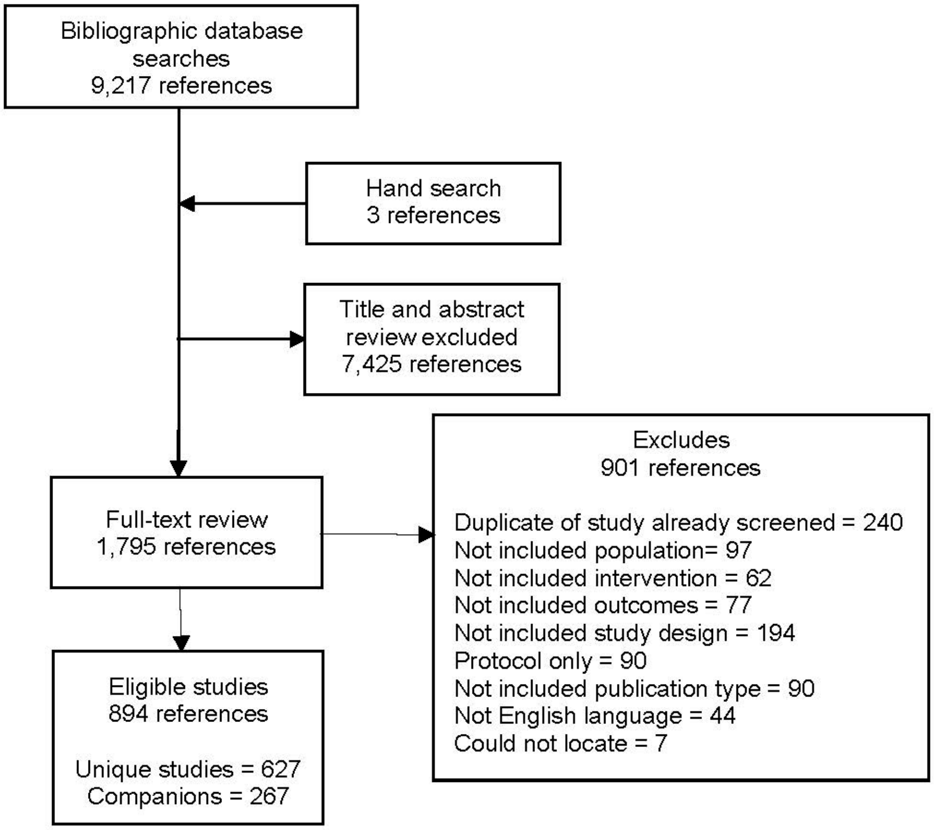
Insufficient: No evidence, unable to estimate an effect, or no confidence in estimate of effect. Available evidence or lack of evidence precludes judgment.

Notably, an assessment of insufficient evidence does not mean that the intervention is ineffective. Rather, it means that due to the uncertainty of the evidence, we could not draw meaningful conclusions about its effectiveness at this time.

Chapter 3. Search Results

Our search identified 9,217 publications for screening. Based on inclusion criteria, we identified 595 unique eligible studies discussed in 850 publications. We list studies excluded at full text screening, by exclusion category, in Appendix B. See Figure 3.1 for details of the screening process.

Figure 3.1. Literature flow diagram



Of the eligible 627 unique studies, we categorized 409 studies as pilot or small sample studies which thus appeared to be NIH Stage 0 – 2 (i.e., for newer interventions that would not be appropriate to address readiness for implementation). A further 218 were assessed as high risk of bias, most commonly due to issues with selection bias, attrition, or intervention fidelity. This left 100 low to moderate risk of bias studies for the analytic set. (Table 3.1) Non-U.S. studies were a large portion of the eligible studies. Overall, approximately 67 percent of the literature emerged from research conducted outside of the United States. This was heavily weighted by care interventions for treating or managing behavioral or psychological symptoms of dementia for people living with dementia (PLWD) (Chapter 4) or PLWD well-being (Chapter 5).

Unfortunately, many important groups warrant further inclusion in research, including people with Down syndrome, who are living longer and who overall experience higher rates of dementia than the general population. Individuals with complex presentations of dementias, e.g., early-onset, amnestic forms, also need further consideration. We also found little information to determine whether interventions are equally appropriate for or have been successfully adapted to other race/ethnic cultures within the United States, with only a handful of studies providing sufficient inclusion of African-American or Hispanic/Latino populations. Interventions for rural communities were found to be even more rare in the literature. Additionally, the many countries in which these care interventions were evaluated were almost exclusively high-resource, with very few low-resource countries represented. Finally, few studies gathered the granular detail necessary for a deeper understanding of the applicability of the interventions. For example, the minority of studies that measured PLWD disability used medical approaches, like the Charlson score, rather than functional approaches that note disability prior to dementia onset.

Based on the structure of the key questions and the eligible studies identified in the search process, we developed categories and assigned each study (or comparison within a multi-arm study) to one of 37 major intervention categories. A few interventions exhibited characteristics that could be ascribed to more than one category. Further, some care interventions are variably defined and described within the literature, making categorization more challenging. We attempted to keep clearly defined interventions together and classified less clearly defined interventions into more general categories such as psychosocial therapies or multicomponent interventions. If an intervention's characteristics were balanced between a care intervention and a care delivery intervention, we tended to classify the intervention into the care intervention category and present it in Chapters 4 – 7.

Table 3.1. Identified unique eligible studies by intervention category, by results chapter

Location	Intervention	Total Unique Studies	# Analytic Set	# Evidence map	# non-U.S.
Chapter 4 Managing PLWD BPSD	Assisted Therapy	16	1	15	15
	Multi-Sensory Stimulation/Snoezelen	9	2	7	6
	Complementary and Alternative Medicine (CAM) Therapies	21	5	16	19
	Bright Light Therapy	9	0	9	4
	Psychosocial Therapies for BPSD	6	0	6	1
	Multicomponent Interventions for BPSD	9	0	9	5
	Chapter 4 TOTAL	**70**	**8**	**62**	**50**
Chapter 5 PLWD Wellbeing	Exercise	53	10	43	48
	Music	35	5	30	26
	Reminiscence Therapy	25	4	21	22
	Cognitive Rehabilitation	23	3	20	19
	Cognitive Training	18	5	13	15
	Cognitive Stimulation Therapy	12	2	10	11
	Recreation Therapy	14	3	11	11
	Psychosocial Interventions for PLWD well-being	7	0	7	4
	Creative Expression Therapy	5	0	5	2
	Multicomponent Interventions	24	3	21	14
	Assistive Technology	4	0	4	2
	Electrostimulation	14	0	11	12
	Other Interventions for PLWD well-being	7	0	7	4
	Chapter 5 TOTAL	**241**	**35**	**207**	**190**
Chapter 6 Informal Caregivers	Psychosocial Interventions for Informal Caregiver Wellbeing	122	29	93	74
	Social Support	13	2	11	10
	Lifestyle Interventions	19	1	18	10
	Respite Care	3	0	3	0
	Multicomponent for Informal Caregivers	22	7	15	13

Location	Intervention	Total Unique Studies	# Analytic Set	# Evidence map	# non-U.S.
	Other Interventions for Informal Caregiver Wellbeing	6	0	6	4
	Chapter 6 TOTAL	**185**	**39**	**146**	**111**
Chapter 7 Formal Caregivers	Formal Caregiver Wellbeing	3	0	3	3
	Chapter 7 TOTAL	**3**	**0**	**3**	**3**
Chapter 8 Care Delivery	**Care Service Provision**	50	6	44	29
	Consultation Services	5	1	4	4
	Case Management	9	3	6	6
	Care Protocols for PLWD	17	0	17	11
	Advance Care Planning	9	1	8	3
	Palliative Care	5	0	5	3
	Other Service Provision Interventions	5	1	4	2
	Care Delivery Models or Programs	31	12	18	18
	Care Delivery Staff Education and Support Needs	46	1	45	27
	Caregiver Staff Training	22	0	22	18
	Informal Caregiver Staff Training	12	0	12	6
	Family Education and Partnering	5	0	5	1
	Mutitier Training	7	1	6	2
	Chapter 8 TOTAL	**127**	**19**	**107**	**74**

Abbreviations: BPSD=behavioral and psychological symptoms of dement12ia; CAM=Complementary and Alternative Medicine; PLWD=persons with dementia

Chapter 4. Care Interventions for Managing BPSD in PLWD

This chapter includes care interventions that aimed to address behavioral or psychological symptoms of dementia (BPSD) in people living with dementia (PLWD). Studies in this chapter enrolled PLWD currently identified as experiencing BPSD, the term most commonly used in this literature set. In contrast, Chapter 5 includes studies of interventions aimed at improving the general well-being of PLWD (e.g., exercise, music) and tested with PLWD regardless of presence of BPSD. Care delivery interventions specifically designed to address BPSD in PLWD are presented in Chapter 8.

For each intervention, we present Key Points followed by results in three general sections: Intervention Description, Eligible Studies, and Intervention Research Context. For interventions with no eligible studies assessed as low to medium risk of bias, we present the studies from the evidence map with a brief discussion of what has been examined and the research context. For interventions for which low- to medium-risk-of-bias studies were available for an analytic set, we present Outcomes sections by PLWD, by caregiver, and by variation in outcomes when available. Because differences in outcome measures and intervention complexity prohibited combining outcomes for a statistical meta-analysis, we present summary findings as brief statements of how many studies reported statistically significant benefit or no difference between the intervention and the comparator. Detailed information on all eligible studies can be found in Appendix C.

Assisted Therapy

Assisted therapy interventions aim to reduce BPSD in PLWD with the assistance of an animal or an object that represents a living being. Eligible studies examined therapy with robots, dogs, and dolls. While the use of such interventions does not depend on the setting, all studies examined the use of assisted therapy in nursing homes or other long-term care settings.

Robot-assisted Therapy

Key Points

- Evidence was insufficient to draw conclusions about the effect of robot-assisted therapy on PLWD and their caregivers.

Intervention Description

Robot-assisted therapy studies primarily focused on the use of PARO, an autonomous, robotic baby harp seal.

Eligible Studies

Table 4.1 summarizes the characteristics of the literature set. We identified eight unique studies from 13 publications that examined robot-assisted therapy for the treatment of dementia.[23-33] Four studies were pilots or small sample studies[30, 31, 33, 34] and another three were assessed as high risk of bias;[27-29, 32] therefore, these six studies were excluded from the analytic set.[27-29, 32] We present information on all pilot studies and high risk of bias studies in the evidence map in Appendix C.

The remaining study (n=415) was a three-arm cluster randomized trial comparing PARO versus usual care and PARO with the robotic features deactivated in PLWD in Australian nursing homes.[23-26] The study was assessed as medium risk of bias and categorized as explanatory, or Stage 3 of the NIH Stage Model. It enrolled individuals living in long-term care facilities with a documented dementia diagnosis (all types and severities). Appendix C provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.

Table 4.1. Basic characteristics of literature set: robot-assisted therapy

Characteristic	Information
Total Studies	8 studies
Non-U.S. studies	7 studies
Evidence map studies	2 pilot studies 2 small sample studies 3 high risk of bias studies
Analytic set studies	1 cluster randomized controlled trial
Risk of bias of analytic set	1 medium
Number of PLWD in analytic set	415
Dementia type/definition	All dementia types and severities
Caregiver type (number)	Not reported

Intervention Research Context

The literature on robot-assisted therapy generally follows the NIH Stage Model, and consists primarily of pilots. With the exception of one U.S. study,[32] the studies were conducted in Australia,[31, 34] New Zealand,[30] the Netherlands,[27] Norway,[28] and Spain.[33] We identified two pilots comparing PARO versus usual care or an attention control.[30, 31, 34] We also identified a pilot comparing PARO versus live animal therapy, a human-like robot, and usual care.[33] The PARO study included in our analytic set appears to be one of the first larger cluster RCTs of sufficient methodological rigor that compares PARO versus usual care.[23-26] The study also appears to be one of the first larger cluster RCTs to compare PARO versus PARO with robotic features deactivated. While the study also included outcomes related to motor activity and sleep patterns, these outcomes were exploratory and data were available for less than half the study population.[25]

PLWD Outcomes

Evidence was insufficient to draw conclusions about either PARO versus usual care (n=257) or PARO versus PARO with robotic features deactivated (n=278).[23-26] Table 4.2 summarizes the primary findings. Results for reduction in agitation were mixed. PLWD showed more visual and verbal engagement with PARO than with PARO with robotic features deactivated. The two groups did not differ for positive behavioral engagement or social engagement. No harms were assessed.[23-26] An assessment of insufficient evidence does not mean that the intervention is determined to be of no value. Rather, it means that due to the uncertainty of the evidence we could not draw meaningful conclusions at this time.

Table 4.2. Summary of findings for PLWD outcomes: robot-assisted therapy

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Agitation measures PARO vs. usual care	1 cluster RCT[26] (n=257) 10 weeks	All dementia severities and types in Australia	1 found benefit 1 found no difference	Insufficient
Agitation measures PARO vs. deactivated PARO	1 cluster RCT[26] (n=278) 10 weeks	All dementia severities and types in Australia	0 found benefit 2 found no difference	Insufficient
Engagement measures PARO vs. deactivated PARO	1 cluster RCT[26] (n=278) 10 weeks	All dementia severities and types in Australia	2 found benefit 2 found no difference	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: n=number; RCT=randomized controlled trials

Caregiver Outcomes

The analytic study set did not report outcomes related to informal or formal caregivers.

Variation in Outcomes

In the PARO group, lower levels of agitation at baseline were associated with greater behavioral positive engagement and visual engagement at 10 weeks.[26] No similar analysis was conducted for the PARO with robotic features deactivated group. The analytic study set did not report variation in outcomes by caregiver or intervention characteristics.

Live Animal- and Doll-assisted Therapy

Key Points

- Studies of live animal- and doll-assisted therapy were described in the evidence map but not considered for analysis due to limitations in study designs.

Intervention Description

Live animal-assisted therapy involves treatment sessions that include animals with a focus on specific goals (e.g., mental, emotional and/or social). Doll-assisted therapy involves offering dolls to PLWD in order to improve their comfort, engagement, and quality of life.

Eligible Studies

We identified five unique studies from five publications that examined animal-assisted therapy (with dogs) in the treatment of dementia. (Table 4.3) Two were pilot or small sample studies and the remaining three studies were assessed as high risk of bias.[35-39] Three unique pilot studies examined doll-assisted therapy.[40-42] We present information on all pilot studies and high risk of bias studies in the evidence map in Appendix C.

Table 4.3. Basic characteristics of literature set: live animal- and doll-assisted therapy

Characteristic	Information
Total Studies	8 studies
Non-U.S. studies	8 studies

Characteristic	Information
Evidence map studies	5 pilot studies 3 high risk of bias
Analytic set studies	0 studies

Intervention Research Context

One study compared the use of doll-therapy versus an active control of hand warmers, which would mimic the sensory characteristics of holding a doll, in PLWD residing in an Italian nursing home.[42] A second compared doll-therapy to teaching PLWD to use gestures to improve communication in Italian nursing homes.[40] An third study compared doll-therapy to usual care in Australian nursing homes.[41] One study compared individual animal therapy versus usual care in PLWD in German nursing homes,[35] while another used group animal therapy in Italian adult daycare centers.[36] Two others compared group animal therapy versus usual care in PLWD in nursing homes in Norway,[37, 38] while the third compared group animal therapy versus group therapy without an animal in Australian nursing homes.[39]

Multi-Sensory Stimulation/Snoezelen

Key Points

- Evidence was insufficient to draw conclusions about the effect of multi-sensory stimulation (MSS) on PLWD and their caregivers.

Intervention Description

MSS is intended to have both relaxing and activating effects that promote calm engagement for PLWD in nursing homes through an experiential process that includes light, sound, scents, and music, usually with the accompaniment of an aide or therapist. The “Snoezelen rooms” often used for this intervention were developed in the Netherlands in the 1970s, and are designed to deliver stimuli to various senses, including through different tactile materials and floors that may be adjusted to stimulate the sense of balance.

Eligible Studies

Table 4.4 summarizes the characteristics of the literature set. We identified nine unique studies from 11 publications.[43-50] Two studies (N = 256) were assessed as medium risk of bias and classified as explanatory, or Stage 3 of the NIH Stage Model.[44, 45] One was a two-arm randomized trial comparing Snoezelen versus activity sessions, which were treated as an active control.[44] The other was a three-arm randomized trial comparing Sonas, a different type of MSS intervention, to reading sessions and to usual care.[45] Appendix C provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.[46-52] Pilot studies, small sample studies, or studies assessed as high risk of bias were excluded from the analytic set. We present information on these studies in the evidence map in Appendix C.

Table 4.4. Basic characteristics of literature set: multisensory stimulation/Snoezelen

Characteristic	Information
Total studies	9 studies
Non-U.S. studies	6 studies

Characteristic	Information
Evidence map studies	2 pilot studies 4 small sample studies 1 high risk of bias studies
Analytic set studies	2 randomized controlled trials
Risk of bias of analytic set	2 medium
Number of PLWD in analytic set	256
Dementia type/definition	Diagnoses of Alzheimer's, vascular, or mixed dementia
Caregiver type (number)	Not reported

Intervention Research Context

This literature set did not clearly follow progression along the NIH Stage Model. Earlier studies were either pilots[50] or full studies that reported a pilot component[43, 44] However, later studies did not appear to progress to pragmatic trials. The studies generally used active controls, such as activity or reminiscence sessions.

PLWD Outcomes

Evidence was insufficient to draw conclusions about the effect of MSS on BPSD compared to an active control.[44] There was no significant mean change on several measures of behavioral problems in the study. Table 4.5 summarizes these findings. Similarly, evidence was insufficient to draw conclusions about the effect of MSS on social function versus both an attention control and usual care.[45] There was a statistically significant benefit for MSS versus both comparators on improvements in PLWD communication.

Table 4.5. Summary of findings for PLWD outcomes: multisensory stimulation/Snoezelen

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Neuropsychiatric symptoms MSS vs. attention control	1 RCT[44] (n=136) 4 weeks, 8 weeks	Persons with Alzheimer's, vascular, or mixed dementia in Norway	0 found benefit 1 found no difference	Insufficient
Social function MSS vs. attention control	1 RCT[45] (n = 120) 24 weeks	Persons with Alzheimer's, vascular, or mixed dementia in Norway	1 found benefit 0 found no difference	Insufficient
Social function MSS vs. usual care	1 RCT[45] (n = 120) 24 weeks	Persons with Alzheimer's, vascular, or mixed dementia in Norway	1 found benefit 0 found no difference	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: n=number; MSS=multisensory stimulation; RCT=randomized controlled trial

Caregiver Outcomes

No studies in the analytic set reported caregiver outcomes.

Variation in Outcomes

In PLWD with severe cognitive impairment (Mini-Mental State Examination (MMSE) scores 0 to 9), MSS appeared slightly more effective than the activity control at improving behavior at 4 weeks (mean difference -1.0 points, $p < 0.05$).[44] For PLWD with moderate cognitive impairment, activity sessions appeared to improve the behavior more than MSS (mean difference 0.8 points, p-value not significant).[44] However, this trend was not seen with other outcomes.

In PLWD with severe cognitive impairment (MMSE scores 0 to 10), MSS was reported more effective than the active control group at improving HCS scores at 12 weeks, but not at 24 weeks. In addition, MSS did not show a significant advantage in improving HCS scores when compared to usual care.[45]

Complementary and Alternative Medicine (CAM) Therapies

Key Points

- Evidence was insufficient to draw conclusions about the effects of aromatherapy or foot massage on PLWD and their caregivers.

Intervention Description

CAM is a set of therapies that are intended to achieve health effects, but are not part of conventional medical practice. While this category has the potential to be very broad, only a few interventions were examined in the eligible literature, mainly aromatherapy, massage, acupressure, and healing touch. Interventions that involve physical movement, such as yoga or tai chi/taiji, are presented with the section on exercise in Chapter 5.

Eligible Studies

Table 4.6 summarizes the characteristics of the literature set. We identified 21 unique studies from 23 publications that examined CAM for the treatment of dementia.[53-71] Five studies were assessed as low to moderate risk of bias and included in the analytic set.[57, 67, 72-74] Four studies (n=278) evaluated the effects of aromatherapy in the form of lavender and lemon-balm oils versus either sunflower oil or usual care in the United Kingdom,[72, 73] Hong Kong,[74] or Taiwan.[67] The fifth study (n=55) assessed the effects of foot massage for PLWD versus attention control.[57] No study in the analytic set was conducted in the United States. Appendix C provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes. The evidence map in Appendix C provides information on all other studies.[53-56, 58-66, 68, 71, 75]

Table 4.6. Basic characteristics of literature set: complementary and alternative medicine

Characteristic	Information
Total studies	21 studies
Non-U.S. studies	19 studies
Evidence map studies	6 pilot studies 8 small samples 2 high risk of bias studies
Analytic set studies	5 randomized controlled trials
Risk of bias of analytic set	4 medium (aromatherapy) 1 low (foot massage)
Number of PLWD in analytic set	278 (aromatherapy) 5 (foot massage)
Dementia type/definition	All dementia types and severity
Caregiver type (number)	Not reported

Intervention Research Context

As evaluated against the NIH Stage Model, this literature is overall preliminary and based on small sample studies that have not developed beyond a basic explanatory stage, or Stage 3. Evidence map studies examined various CAM techniques such as healing touch and body talk cortices,[60] acupressure/acupuncture,[61, 64] mixed aroma exposure,[62] back and leg massage with moisturizing cream,[70] aromatherapy,[53, 54, 58, 66, 67, 71, 76] aromatherapy and hand massage,[55] aromatherapy massage,[56] aromatherapy massage plus acupressure,[59, 67] and therapeutic touch.[65, 68] Evidence map trials are from Hong Kong,[59, 64] China,[61] Japan[53, 62] Taiwan,[67] Canada,[65, 68] Australia,[55, 58] Spain,[70] United States,[54, 58-60]the United Kingdom,[56] and Israel.[66]

PLWD Outcomes

Evidence was insufficient for all outcomes. The most commonly investigated outcomes were agitation and neuropsychiatric symptoms. Table 4.7 summarizes the number of studies investigating each outcome and the number of studies that found a benefit and no difference between PLWD and comparison groups.

Agitation was investigated by three of the four included studies. One found that lavender oil versus sunflower oil resulted in short-term improvements (3 weeks).[74] Another compared lavender plus orange oil versus usual care and found no improvement,[67] while two other studies found mixed results, with lemon balm oil versus sunflower oil reducing agitation at 4 weeks,[72] but not 12 weeks.[73]

Depression was investigated in one study that compared lavender plus orange oil versus usual care, and reported improved depression scores with the intervention at 9 weeks.[67]

Neuropsychiatric symptoms were investigated in two studies comparing lavender oil and lemon balm oil versus sunflower oil. Lavender oil seemed to improve neuropsychiatric symptoms at 3 weeks,[74] but not at 12 weeks.[73]

Quality of life and activities of daily living were examined in one study that evaluated lemon balm oil versus sunflower oil and reported that quality of life seemed to improve over 12 weeks, but activities of daily living did not.[73]

One study examined foot massage versus attention control.[57] Both increased agitation in PLWD, but the increase was greater in the comparator group than in the intervention group (p=0.03).[57]

Table 4.7. Summary of findings for PLWD outcomes: complementary and alternative medicine

Outcome Comparison	# Studies/ Design (n analyzed) Timing	Population	Finding	Strength of Evidence*
Agitation Lavender vs sunflower oil	1 RCT[74] (n=70) 3 weeks	PLWD with significant agitation in Hong Kong	1 found benefit 0 found no difference	Insufficient
NPI Lavender vs sunflower oil	1 RCT[74] (n=70) 3 weeks	PLWD with significant agitation in Hong Kong	1 found benefit 0 found no difference	Insufficient
Agitation Lavender and orange oil vs. Usual care	1 RCT[67] (n=59) 9 weeks	PLWD with mild to severe dementia in Taiwan	0 found benefit 1 found no difference	Insufficient
Depression Lavender and	1 RCT[67] (n=59) 9 weeks	PLWD with mild to severe dementia in Taiwan	1 found benefit 0 found no difference	Insufficient

Outcome Comparison	# Studies/ Design (n analyzed) Timing	Population	Finding	Strength of Evidence*
orange oil vs. usual care				
Agitation Lemon Balm oil vs sunflower oil	2 RCT[72, 73] (n=149) 4 - 12 weeks	PLWD with agitation in the United Kingdom	1 of 2 found benefit 1 of 2 found no difference	Insufficient
NPI Lemon Balm oil vs sunflower oil	1 RCT[73] (n=77) 12 weeks	PLWD with agitation in the United Kingdom	0 found benefit 1 found no difference	Insufficient
QoL Lemon Balm oil vs sunflower oil	1 RCT[73] (n=77) 12 weeks	PLWD with agitation in the United Kingdom	1 found benefit 0 found no difference	Insufficient
Caregiver Burden Lemon Balm oil vs sunflower oil	1 RCT[73] (n=77) 12 weeks	PLWD with agitation in the United Kingdom	0 found benefit 1 found no difference	Insufficient
Agitation Foot massage vs attention control	1 RCT[57] (n=55) 3 weeks	Moderate to late stage PLWD in Australia with history of agitation	1 found benefit for control group	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: n=number; NPI= Neuropsychiatric Inventory; PLWD= Persons with Dementia; QoL= Quality of life; RCT=Randomized controlled trial

Caregiver Outcomes

The analytic study set did not report outcomes related to informal or formal caregivers.

Variation in Outcomes

The analytic set did not report variations in outcomes by PLWD, caregiver, or intervention characteristics.

Bright Light Therapy

Key Points

- Studies on bright light therapy were described in the evidence map but not considered for analysis due to limitations in study designs.

Intervention Description

Bright light therapy interventions focus on technology to influence the circadian rhythm of PLWD in order to improve a range of psychiatric symptoms and behavioral disturbances including sleep disruption, agitation, or depression.

Eligible Studies

We identified nine unique studies from 12 publications that examined the use of bright light therapy interventions for individuals with dementia.[77-85] (Table 4.8) Excluded from the analytic set are five pilot or small sample studies and four studies assessed as high risk of bias. We present information on all studies in the evidence map in Appendix C.

Table 4.8. Basic characteristics of literature set: bright light therapy

Characteristics	Information

Total unique studies	9 studies
Non-U.S. studies	4 studies
Evidence map studies	1 pilot 4 small sample studies 4 high risk of bias studies
Analytic set studies	0

Intervention Research Context

This literature set is preliminary. Studies examined bright light therapy on PLWD[77-79, 81-83, 86] tailored lighting,[85] or dawn-dusk simulation, a “naturalistic” form of light therapy.[80] Publications date from 1998, but U.S.-based studies continued until 2019, while the last non-U.S. study was published in 2009. Non-U.S. settings included Japan,[82] Switzerland,[80] and the Netherlands.[86] Nursing home or long-term care facilities were the most common setting with the exception of one study that took place in the geriatric unit of a psychiatric hospital.[81]

Psychosocial Therapies for BPSD

Key Points

- Studies on psychosocial therapies were described in the evidence map but not considered for analysis due to limitations in study designs.

Intervention Description

Psychosocial therapies for PLWD include a diverse set of interventions, ranging from cognitive behavioral training for anxiety to individualized social activities to improve sleep to validation group therapy.

Eligible Studies

We identified six unique studies from seven publications that examined the use of psychosocial interventions for individuals with dementia.[87-92] (Table 4.9) Excluded from the analytic set are four pilot or small sample studies and two studies assessed as high risk of bias.[87-92] We present information on all studies in the evidence map in Appendix C.

Table 4.9. Basic characteristics of literature set: psychosocial therapies for PLWD

Characteristics	Information
Total unique studies	6 studies
Non-U.S. studies	1 study
Evidence map studies	1 pilot 3 small sample studies 2 high risk of bias studies
Analytic set studies	0

Intervention Research Context

This literature set is preliminary. One study examined problem adaptation therapy for depression and suicidal ideation in U.S. PLWD with early stage dementia.[91] One study examined the effect of individualized social activity on disruptive behaviors,[90] while another examined on sleep patterns in PLWD in U.S. nursing homes.[92] Two studies examined the use of cognitive behavioral training to control anxiety in PLWD living in the community with mild to moderate dementia in the United Kingdom[88] and United States.[89] An early 1997 publication examined validation therapy in PLWD in U.S. nursing homes.[87]

Multicomponent Interventions for BPSD

Key Points

- Studies of various unique multicomponent interventions were described in the evidence map but not considered for analysis due to limitations in study designs.

Intervention Description

This section encompasses a small and diverse set of interventions combining several components targeted at improving behavioral and psychological symptoms of dementia.

Eligible Studies

We identified nine unique studies from 10 publications that examined the use of various multicomponent interventions among PLWD.[90, 93-100] (Table 4.10) All the studies were either small; sample studies or assessed as high risk of bias; we describe them in the evidence map in Appendix C.

Table 4.10. Basic characteristics of literature set: multicomponent interventions for BPSD

Characteristics	Information
Total unique studies	9 studies
Non-U.S. studies	5 studies
Evidence map studies	1 pilot 3 small sample studies 5 high risk of bias
Analytic set studies	0

Intervention Research Context

This research is generally preliminary, consisting of a small set of distinct and mostly unrelated studies. One study used question-asking, reading, reminiscence, and cognitive behavioral techniques, as well as environmental supports and individualized behavioral activity for depression in PLWD in U.S. nursing homes.[94] One small study examined an intervention in U.S. nursing homes to balance periods of high and low arousal in PLWD throughout the day.[96] An earlier 1998 study used a somewhat similar stimulation-retreat model.[97] One study conducted in Taiwan long-term care facilities examined a combined acupressure and Montessori-based activity to address anxiety in PLWD.[98] One community-based study in Hong Kong examined self-management support plus therapeutic exercise for knee osteoarthritis for PLWD.[93] One study in a German nursing home modified a cognitive engagement program for people with autism and combined it with music therapy for PLWD with moderate dementia.[95]

One set of two studies on emotion-oriented care were conducted in the Netherlands.[99, 100] Emotion-oriented care is a combination of validation therapy and sensory stimulation (discussed briefly in the sections above) and reminiscence therapy, which we present in Chapter 5. Although publications did not clarify whether authors of the separate studies collaborated on study development and purpose, the study by Schrijnemaeker and colleagues tested an intervention with more elements aimed at broader intervention implementation.[99] Reported results between the two studies were mixed.

The study by Beck and colleagues examined several groups of PLWD in U.S. nursing homes.[90] It is also included this chapter's section on psychosocial interventions and Chapter 5's section on cognitive rehabilitation. We present it here because one study group used a combination of ADL-focused cognitive rehabilitation plus the psychosocial engagement activity.[90]

Conclusion

We found 63 unique studies from 76 publications that coalesced into six categories of care interventions aimed at managing BPSD in PLWD. Applying the framework for care interventions from the NASEM Families Caring for an Aging America 2016 report (Figure 1.1 in Chapter 1), the vast majority of the care interventions were delivered at the individual level. Almost 90 percent of the studies were pilots or small sample studies, Stage 0 to 2 according to the NIH Stage Model, or assessed as high risk of bias. Of the three care interventions that had low to moderate risk of bias studies—robot-assisted therapy, multisensory stimulation/Snoezelen, and CAM—we found the uncertainty of the evidence was too high to draw conclusions. However, our being unable to draw a conclusion does not mean that the intervention has no effect. Research on interventions to change behavioral and psychological outcomes is challenging, and many factors can influence the outcomes. Future research may reduce uncertainty enough to allow for conclusions about the effect of these interventions to be made with greater confidence.

Chapter 5. Care Interventions for PLWD Well-Being

This chapter includes care interventions intended to improve the quality of life and well-being of people living with dementia (PLWD). Interventions use a wide range of approaches from physical to cognitive to environmental, both alone and in combination. Most studies did not base study enrollment on the absence or presence of behavioral or psychological symptoms of dementia (BPSD).

We organized this chapter by the most commonly studied interventions first, followed by whole person, multisensory stimulation, and various "other" intervention categories, including assistive technology. For each intervention, we present Key Points followed by results in three general sections: Intervention Description, Eligible Studies, and Intervention Research Context. For interventions with no studies assessed as low to medium risk of bias, we present the studies from the evidence map with a brief discussion of what has been examined and the research context. For interventions for which low- to medium-risk-of-bias studies were available for an analytic set, we present Outcomes sections by PLWD, by caregiver, and by variation in outcomes when available. Because we were generally unable to pool outcomes for any given intervention and comparison group, we synthesized the information qualitatively; therefore, we present summary findings as brief statements of how many studies reported statistically significant benefits or no difference between the intervention and the comparator. We present detailed information on all eligible studies in Appendix D.

Exercise

Key Points

- For both community-dwelling PLWD and PLWD living in residential care facilities, evidence was insufficient to draw conclusions about the effects of exercise interventions on PLWD and their informal caregivers or care partners (CG/P).

Intervention Description

Exercise interventions are used to improve daily function, aerobic conditioning, strength, gait and balance. While exercise can be done in a wide range of activities and intensity, most exercise interventions compared moderate- to high-intensity aerobic plus strength training exercise with usual care or seated group activities. The type and duration of exercise varied widely. Aerobic training usually involved walking or stationary cycling. Strength training involved repetitive functional maneuvers that relied on body weight, or standard weight training via gym or therapy equipment. Specific balance training was uncommon and involved functional maneuvers conducted with a therapist.[101] More often, improvements in balance and gait speed were anticipated outcomes from general aerobic and lower extremity strengthening interventions. Exercise programs commonly included a build-up phase. Settings varied from unidentified areas of nursing homes to gyms, adult daycare, outpatient rehabilitation, homes, or church halls. Most exercises were supervised and conducted in small groups. Those supervising the interventions had varied training and experience. Only two studies also involved incorporating CG/P in exercise training activities.[102, 103]

Eligible Studies

Below, we provide a summary of exercise intervention studies for adults with dementia (Table 5.1). We identified 53 unique studies from 69 eligible publications that reported the effects of exercise interventions on quality of life and functional outcomes in PLWD. Of these, eight randomized trials (RCT) with low or medium risk of bias were included in the analytic set.[101, 102, 104-111] (Table 5.1). Information on all pilot, small sample, and high risk of bias studies is provided as part of the evidence map in Appendix D.[75, 103, 112-150] Appendix D provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes of the analytic set.

Table 5.1. Basic characteristics of literature set: exercise

Characteristic	Information
Total studies	53 studies
Non-U.S. studies	48 studies
Evidence map studies**	13 pilot 21 small sample studies 9 high risk of bias
Analytic set studies:	7 randomized controlled trials 3 cluster randomized controlled trials
Risk of bias of analytic set	2 low, 8 medium
Number of PLWD in analytic set	1,706
Dementia type/definition	Mostly mild to moderate Alzheimer's disease, although the range included mild to severe and type included vascular and mixed dementias
Caregiver type (number)	NA

Intervention Research Context

Exercise was the most commonly examined care intervention for PLWD. Most studies assessed the effects of exercise on functional and cognitive outcomes in adults with mild or moderate dementia. Enrolled adults typically had few mobility restrictions, could follow directions, were healthy enough to exercise moderately, and were dependent in at least one activity of daily living (ADL). Few studies included adults with severe dementia, and when included, their outcomes were not separately reported.

Overall, this literature is broad but dominated by pilot and small sample studies, reflecting that preliminary investigations for PLWD are more common. All eligible trials were published within the last two decades, and most (85%) within the past 10 years. The higher quality, analytic set studies were all published within the past decade, yet small sample and pilot studies are scattered throughout the publication dates.

Outcome domains included quality of life, function, neuropsychiatric symptoms, intervention adherence, adverse events, health or social service use, costs, and cognition. Daily functioning, measured with various ADL scales, was the most common outcome reported. The interpretability and clinical utility of reported outcomes varied considerably. Assessed outcomes were highly heterogeneous, even within domains and residential sites. Most outcomes were proxy-reported, except quality of life. Adverse events were proxy reported or chart-identified.

PLWD Outcomes

Evidence was insufficient to address any PLWD outcome. Table 5.2 summarizes the primary findings from 10 exercise intervention studies. We could not pool data for any outcome due to the wide variety of outcome measures, outcomes timing, and idiosyncratic reporting that rendered some outcomes uninterpretable or noncomparable. Given these and other study limitations, the exercise intervention literature was insufficient for all intervention-outcome comparisons. An assessment of insufficient evidence does not mean that the intervention is determined to be of no value. Rather, it means that due to the uncertainty of the evidence we could not draw meaningful conclusions at this time.

Three exercise trials (n=864) assessed quality of life.[104, 105, 107] Two trials (n=694) tested moderate to high intensity aerobic conditioning plus strength training exercises in community settings compared with usual care.[104, 105] One trial compared high-intensity functional exercise with seated group activities in 18 nursing homes (n=170).[107] Intervention duration was 3[107] to 4 months,[104, 105] and final outcomes were reported from 4 to 12 months. Studies used four quality of life measures, and one study reported dual quality of life measures.[104] Self-reported quality of life did not differ significantly between group aerobic with strength training exercises versus usual care in community-dwelling PLWD with mild to moderate dementia. Similarly, no meaningful between-group differences were seen for quality of life with high-intensity functional exercise compared with seated group activities in nursing home residents with mild to moderate dementia.[107]

Eight randomized trials (n=1,518) assessed daily functioning using nine different outcome measures.[101, 102, 104-107, 110, 111] Five of these were conducted in nursing facilities[101, 106, 107, 110, 111] Six studies found no benefit for any outcome from exercise versus an inactive comparator, while two found some benefit on activities of daily living. The use of multiple daily functioning measures over varied followup time frames precluded pooling of data.

Balance was reported in two nursing home-based RCTs that examined high-intensity functional exercise versus seated group activities, and both reported balance outcomes with the Berg Balance Scale[101, 107]in adults with mild to moderate dementia. One RCT (n=186) reported a post-intervention benefit of exercise on balance at 4 months, but improvement was not sustained at 7 months;[101] the other trial found no difference at 3 or 6 months.[107] Other mobility-related outcomes were varied, incompletely reported, or shown only as percent change from baseline.[102, 107, 108] Worse baseline motor function was associated with greater functional gains in one RCT.[108]

Although neuropsychiatric symptoms were not required for study enrollment, half of analytic set RCTs reported at least one neuropsychiatric outcome.[105, 107, 109, 111, 151] Group Tai Chi improved neuropsychiatric symptoms and depression in one RCT (n=80), while all other exercise interventions had no significant impact on the neuropsychiatric symptoms, depression, or anxiety.

Exercise-related adverse events, when reported, were most often musculoskeletal, such as muscle soreness. Serious adverse events were uncommon, variably reported, questionably related to the intervention, and similar between groups.[101, 102, 105, 107, 108, 111, 151]

Other outcomes included exercise intervention adherence, attendance, or compliance, which ranged from 65 percent to 94 percent in studies that reported it.

Estimated costs of healthcare services in adults enrolled in a community-based group exercise intervention were statistically significantly lower than those of the usual care group at 24 months,[102] but home exercise and usual care costs did not differ.

Table 5.2. Summary of findings for PLWD outcomes: exercise

Outcome Comparison	# Studies (# NH) n analyzed Outcome timing	Population	Finding	Strength of Evidence*
Quality of Life Group exercise vs usual care or seated group activity	3 RCTs.[104, 105, 107] (1 NH) n=864 3-12 months	Mild to Moderate	0 of 3 found benefit 3 of 3 found no difference	Insufficient
Daily function Group exercise vs usual care or home exercise	3 RCTs[102, 104, 105] (0 NH) n=904 4-12 months	1 Mild 1 Mild-Moderate 1 Mild-Severe	1 of 3 found benefit for group exercise vs UC, and in-home exercise vs UC; 2 of 3 found no difference	Insufficient
Daily function Group exercise vs seated group activity	3 RCTs[101, 106, 107] (3 NH) n=474 3-7 months	2 Mild-Moderate 1 Mild-Severe	1of 3 found benefit for combined group exercise vs social activity, and walking vs social activity; 2 of 3 found no difference	Insufficient
Daily function Group Tai Chi vs usual care	1 RCT[111] (1 NH) n=80 10 months	Mild	0 found benefit 1 found no difference	Insufficient
Daily function: Eating help needed. Hand exercise program vs usual care	1 RCT[110] (1 NH) n=60 6 months	Mild to Moderate	1 found benefit 0 found no difference	Insufficient
Daily function: Autonomous eating time. Hand exercise program vs usual care	1 RCT[110] (1 NH) n=60 6 months	Mild to Moderate	1 found benefit 0 found no difference	Insufficient
Balance HIFE (strength + balance) vs. seated group activity	2 RCT[101, 107] (2 NH) n=356 3-7 months	Mild to moderate	1 of 2 found early benefit 1 of 2 found no difference	Insufficient
Neuropsychiatric symptoms Group exercise vs usual care (2) or seated group activity (1)	3 RCTs.[104, 105, 107] (1 NH) n=864 3-12 months	Mild to Moderate	1 of 3 found benefit (non-NH) 2 of 3 found no difference (1 NH)	Insufficient
Neuropsychiatric symptoms: Group Tai Chi vs usual care	1 RCT[111] (1 NH) n=80 10 months	Mild	1 found benefit	Insufficient
Depression Group exercise vs usual care (1) or seated group activity (2)	3 RCTs.[101, 104, 107] (2 NH) n=436 3-6 months	Mild to Moderate	0 of 3 found benefit 3 of 3 found no difference	Insufficient
Anxiety Group hand movement program vs. attention control	1 RCT[107] (NH) n=66 3 months	Moderate	0 found benefit 1 found no difference	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: HIFE= High-intensity functional exercise (repetitive strength, balance, and mobility moves that mimic daily activities, such as rising from a chair); NH= nursing home; RCT=randomized controlled trial

Caregiver Outcomes

Caregiver quality of life and burden did not differ over 6 and 12 months in the one RCT that measured it.[151]

Variation in Outcomes

Two of eight RCTs reported subgroup outcomes for adults with Alzheimer's disease (AD) versus other dementias.[101, 102] Adults with AD showed higher healthcare costs in all groups (group exercise in adult daycare versus home exercise versus usual care), but a similar cost pattern per intervention group to those with other dementias.[102] Compared with adults with AD, adults with non-AD dementia showed greater balance improvements with high-intensity functional exercise versus seated group activity.[101] Men were more likely to enroll in[101] and adhere to[151] exercise interventions than women. Session attendance was higher for exercise than for control group activities.

Music

Key Points

- Evidence was insufficient to draw conclusions about the effects of music interventions for PLWD or CG/P.

Intervention Description

Music interventions are intended to be calming or to provide pleasure or cognitive and sensory stimulation. They can be delivered as individual or group activities, often with music choices based on familiarity or preferences of PLWD. PLWD may be encouraged to move with the music (ranging from small hand movements to dancing) or listen passively (e.g., background music at mealtimes).

Eligible Studies

Table 5.3 summarizes the effect of music interventions for PLWD and caregivers. We identified 35 unique studies from 38 publications of music interventions for PLWD and caregivers. Five studies, all RCTs, were assessed as medium risk of bias and included in the analytic set.[152-159] Four used group music as an intervention compared with usual care.[153-156] One compared music-with-movement with music listening combined with social activity.[152] The analytic set studies were conducted in either Hong Kong or Taiwan. We describe the 10 pilot, 13 small sample, and seven high risk of bias studies in the evidence map in Appendix D.[153, 155, 160-184] Appendix D also includes an evidence table, summary of risk of bias assessments, and strength of evidence.

Table 5.3. Basic characteristics of literature set: music

Characteristic	Information
Total unique studies	35 studies
Non-U.S. studies	26 studies
Total Evidence map studies	10 pilot studies 13 small sample studies 7 high risk of bias studies
Analytic set studies	5 randomized controlled trials
Risk of bias of analytic set	Medium
Number of PLWD in analytic set	404

Characteristic	Information
Dementia type/definition	All types of dementia with all stages of severity
Caregiver type (number)	1 randomized controlled trial with 59 family, 30 nurses

Intervention Research Context

Using the NIH Stage Model, about 65 percent of the studies were categorized as preliminary pilot or small sample studies and the rest were categorized as explanatory, or Stage 3. The analytic set consisted of basic explanatory designs; the largest study enrolled 165 PLWD. We did not see the evolution of research on any particular intervention over time; instead, each study tested a different music intervention approach. Interventions in the evidence map were similar to those in the analytic set. Interventions were administered in groups[115, 162, 168, 170, 172, 174, 176, 178, 180-182, 185-188] or individually[160, 165-167, 175, 177, 183, 189] and included watching live music[164, 169, 190] or listening to familiar songs from recordings,[182, 183] playing with musical instruments,[95, 173] and singing along or dancing to music.[171, 174] Only one study used background music as an intervention.[161] Non-US settings include: Australia,[164, 165, 172] France,[167, 182] Germany,[183] Hong Kong,[184] Iceland,[178] Italy,[160, 174, 191, 192] Japan,[173] the Netherlands,[187] Norway,[175] Singapore,[168] South Korea,[162] Taiwan,[161, 176, 188] Turkey,[177]and the United Kingdom.[169]

PLWD Outcomes

Evidence was insufficient to draw conclusions about music therapy for agitation, anxiety, depression, mood, and quality of life. Table 5.4 provides a summary of findings.

One study (n=84) found the intervention improved quality of life in PLWD.[155]

Three studies examined agitation in PLWD; two compared (n=155) group music versus usual care over a period of 6 weeks,[154, 156] and one (n=165) compared music-with-movement versus music listening combined with social activity for 6 weeks.[152] Results were inconsistent. While one study reported a significant effect of group music on agitation,[154] the other two reported no statistical difference between intervention and control groups.

One study (n=55) found a group music intervention decreased anxiety compared with usual care.[156] One study reported that a group music intervention significantly decreased depression after 6 weeks.[158] A three-armed study (n=84) found music improved mood.[155]

Table 5.4: Summary of findings for PLWD outcomes: music

Outcome Comparison	# Studies/ Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Quality of Life Group music vs. usual care	1 RCT[155] (n=84) 10 weeks	Dementia (all types) with mild-moderate	1 found benefit 0 found no difference	Insufficient
Agitation Group music vs. Standard/usual care	3 RCT[152, 154, 156] (n=320) 6 weeks	All dementia types with mild to severe severity	1 of 3 found benefit 2 of 3 found no difference	Insufficient
Agitation Music with movement vs. music listening & social activity	1 RCT[152] (n=165) 6 weeks	Any type of dementia with moderate severity	0 found benefit 1 found no difference	Insufficient
Anxiety Group music vs. usual care	1 RCT[156] (n=55) 6 weeks	Any type of dementia with moderate severity	0 found benefit 1 found no difference	Insufficient

Outcome Comparison	# Studies/ Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Depression Group music vs. usual care	1 RCT[156] (n=55) 6 weeks	Any type of dementia with moderate severity	0 found benefit 1 found no difference	Insufficient
Mood Group music vs. usual care	1 RCT[155] (n=84) 10 weeks	Dementia (all types) with mild-moderate	1 found benefit 0 found no difference	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: N=number; RCT=randomized controlled trial

Caregiver Outcomes

Evidence was insufficient for the effect of music on stress and caregiver burden for family caregivers. One study reported psychological well-being outcomes (stress and burden) for family caregivers and found benefit at 9 months.[155] Table 5.5 summarizes the primary findings. No significant reduction in stress was reported.

Table 5.5. Summary of findings for caregiver outcomes: music

Outcome comparison	Studies/ Design (n=analyzed) Timing	Population	Findings	Strength of Evidence*
Stress & burden Group music vs. usual care	1 RCT[155] (n=84) 9 months	Informal caregivers	One benefit	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: RCT=randomized controlled trial

Variation in Outcomes

A single study reported that both singing and listening were more effective in improving mood in PLWD with mild dementia and AD, while listening-only interventions were more beneficial for PLWD with moderate non-AD dementia (e.g., vascular and mixed dementias, frontotemporal dementia).[155]

Reminiscence Therapy

Key Points

- Evidence was insufficient to draw conclusions about the effect of reminiscence therapy versus usual care for PLWD and CG/P.

Intervention Description

Reminiscence therapy for PLWD involves a discussion of past life events and experiences with the goal of improving memory and well-being. These discussions can be held in groups, individually, or as a combination of both. Sessions may incorporate sentimental objects or photographs and include family members/caregivers.

Eligible Studies

We identified 25 unique studies from 27 publications examining reminiscence therapy for PLWD.[47, 193-217] Table 5.6 summarizes the characteristics of the literature set. Four studies were included in the analytic set.[193-198] All studies in the analytic set were RCTs comparing group reminiscence therapy to usual care for PLWD. One study enrolled PLWD-CG/P dyads.[197, 198] Three studies examined the use of reminiscence therapy for PLWD with mild to moderate dementia.[193, 194, 197, 198]. One study examined the use of reminiscence therapy for PLWD with mild to severe dementia.[195, 196] Appendix D provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.

Eleven studies were pilots or had fewer than 50 participants and were not included as part of the analytic study set.[47, 199-207, 218] Ten additional studies were assessed as high risk of bias.[208-217, 219] We present information on all pilot studies and high risk of bias in the evidence map in Appendix D.

Table 5.6. Basic characteristics of literature set: reminiscence therapy

Characteristic	Information
Total Studies	25 studies
Non-U.S. studies	22 studies
Evidence map studies	7 pilot studies 4 small sample size 10 high risk of bias
Analytic set studies	4 randomized controlled trials
Risk of bias of analytic set	Medium
Number of PLWD in analytic set	904
Dementia type/definition	Predominantly mild to moderate dementia
Caregiver type (number)	Informal caregivers (n=904)

Intervention Research Context

This literature set comprises mostly pilot studies and small RCTs. Included studies were published between 1999 and 2019. Only three studies were conducted in the United States. and none of these were in the analytic set.[203, 205, 208] Eleven studies, including the four in the analytic set, examined group reminiscence therapy.[193-199, 209, 210, 212, 213, 217, 218] Ten studies examined individual reminiscence therapy, including life-story approaches.[47, 201, 205-207, 211, 214-216] Four studies examined reminiscence therapy using technology such as audio recordings and web-based videos.[200, 202, 203, 208] We observed no clear trend in the publication of pilot studies or larger RCTs. Most of the studies that examined technology in reminiscence therapy were pilots, and we identified a mix of both pilots and small to large RCTs for group and individual reminiscence published across a two-decade span. The continuation of pilot studies might be partially attributed to study quality, as we found that a large proportion of non-pilot studies had high risk of bias. Potential detection and performance bias were significant concerns in non-pilot studies rated as high risk of bias.

PLWD Outcomes

Evidence was insufficient to draw conclusions about the effects of reminiscence therapy for PLWD. Four studies in the analytic study set reported outcomes for PLWD.[193-198] Two studies enrolled PLWD with mild to moderate AD,[193, 194] one study enrolled PLWD with mild to moderate dementia of any type,[197, 198] and one study enrolled PLWD with dementia of any type or severity.[195, 196] Studies measured a range of outcomes for PLWD. We were able to quantitatively analyze and pool PLWD outcomes in four domains: activities of daily living, BPSD, depression, and quality of life. However, we assessed the evidence as insufficient due to the variety of measures used within domains, lack of minimally important differences for measures, and variation in analytic methods across studies.

Table 5.7 summarizes the primary outcomes for PLWD. Three studies with a total of 802 PLWD reported measures of activities of daily living.[193, 194, 197, 198] At 3 months, groups did not differ significantly across all three studies. One study also reported outcomes at 6 months, finding no difference between groups.[194] Two studies with a total of 416 PLWD reported measures of BPSD.[193, 194] Reminiscence therapy and usual care groups did not differ at 3 months.[193, 194] Four studies with a total of 1,006 PLWD reported measures of depression.[193-198] Individual study findings were mixed; however the pooled effect size showed no difference between groups at 2 to 3 months. Two studies with a total of 814 PLWD reported measures quality of life. Both found no difference between groups at 3 months.[193, 197, 198]

Two studies reported additional PLWD outcomes. One (n=488) reported a measure of anxiety and a PLWD assessment of the PLWD-caregiver relationship.[197, 198] The second (n=326) reported a measure of apathy and a measure of dependency.[193] Groups did not differ at 3 months for either measure.

Table 5.7. Summary of findings for PLWD outcomes: reminiscence therapy

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Activities of Daily Living Reminiscence vs usual care	3 RCTs [193, 194, 197, 198] (n=802) 3 months	Mild to moderate dementia	0 of 3 found benefit 3 of 3 found no difference	Insufficient
BPSD Reminiscence vs usual care	2 RCTs [193, 194] (n=416) 3 months	Mild to moderate AD	0 of 2 found benefit 2 of 2 found no difference	Insufficient
Depression Reminiscence vs usual care	4 RCTs [193-198] (n=1,006) 2 to 3 months	All dementia types and severities	0 of 4 found benefit 4 of 4 found no difference	Insufficient
Quality of Life Reminiscence vs usual care	2 RCTs [193, 197, 198] (n=814) 3 months	Mild to moderate dementia	0 of 2 found benefit 2 of 2 found no difference	Insufficient
Anxiety Reminiscence vs usual care	1 RCT [197, 198] (n=488) 3 months	Mild to moderate dementia	0 found benefit 1 found no difference	Insufficient
PLWD-Caregiver Reminiscence vs usual care Relationship	1 RCT [197, 198] (n=488) 3 months	Mild to moderate dementia	0 found benefit 1 found no difference	Insufficient
Apathy Reminiscence vs usual care	1 RCT [193] (n=326) 3 months	Mild to moderate AD	0 found benefit 1 found no difference	Insufficient
Dependency Reminiscence vs usual care	1 RCT [193] (n=326) 3 months	Mild to moderate AD	0 found benefit 1 found no difference	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: AD=Alzheimer's disease; BPSD=behavioral and psychological symptoms of dementia; PLWD=People Living with Dementia; RCT=Randomized Controlled Trial; n=Number

Caregiver Outcomes

Evidence was insufficient to draw conclusions about the effects of PLWD reminiscence therapy for CG/P. Three studies in the analytic set reported a range of outcomes for CG/P of

PLWD.[193, 194, 197, 198] Overlap between outcome measures was insufficient to assess the potential benefit of PLWD reminiscence therapy for CG/P. Table 5.8 summarizes the primary outcomes for CG/P.

Two studies enrolled PLWD with mild to moderate AD.[193, 194] One study (n=326) measured caregiver burden, finding no difference between the reminiscence therapy group and the usual care group at 3 months.[193] Another study (n=90) measured CG/P distress, with no difference between groups at 3 months or 6 months.[194]

One study (n=488) enrolled PLWD with mild to moderate dementia of any type. The study reported measures of mental health, quality of life, stress, anxiety, and depression in CG/Ps.[197, 198] The study also measured CG/Ps' ratings of their relationship with the PLWD. At 3 months, groups did not differ in any of these measures.[197, 198]

Table 5.8. Summary of findings for caregiver outcomes: reminiscence therapy

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Caregiver Burden Reminiscence vs usual care	1 RCT [193] (n=326) 3 months	Informal caregivers	1 found no benefit.	Insufficient
Caregiver Distress Reminiscence vs usual care	1 RCT [194] (n=90) 3 months, 6 months	Informal caregivers	1 found no benefit.	Insufficient
Mental Health Reminiscence vs usual care	1 RCT [197, 198] (n=488) 3 months	Informal caregivers	1 found no benefit.	Insufficient
Quality of Life Reminiscence vs usual care	1 RCT [197, 198] (n=488) 3 months	Informal caregivers	1 found no benefit.	Insufficient
Stress Reminiscence vs usual care	1 RCT [197, 198] (n=488) 3 months	Informal caregivers	1 found no benefit.	Insufficient
Anxiety Reminiscence vs usual care	1 RCT [197, 198] (n=488) 3 months	Informal caregivers	1 found no benefit.	Insufficient
Depression Reminiscence vs usual care	1 RCT [197, 198] (n=488) 3 months	Informal caregivers	1 found no benefit.	Insufficient
PLWD-Caregiver Relationship Reminiscence vs usual care	1 RCT [197, 198] (n=488) 3 months	Informal caregivers	1 found no benefit.	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: PLWD=People Living with Dementia; RCT=Randomized Controlled Trial; n=Number

Variation in Outcomes

The analytic study set did not report variation in outcomes by PLWD, caregiver, or intervention characteristics.

Cognitive Rehabilitation

Key Points

- Evidence was insufficient to draw conclusions about the effects of cognitive rehabilitation for PLWD and their CG/P.

Intervention Description

Cognitive rehabilitation, originally developed for people experiencing cognitive impairment from brain injury, was later adapted for use among PLWD with the goal of enabling them to maintain as much independent function as possible in areas they care most about. [220, 221] We classified studies as cognitive rehabilitation when interventions focused on cognitive activities required for daily living (such as memory and executive function), and/or were aimed at recovery[222] or "reactivation of retained daily skills."[223] Therefore, studies in this section range from cognitive process activities in PLWD with mild dementia, to specific, task-based guidance to complete single or multiple ADLs in adults with more advanced dementia.

Eligible Studies

We identified 23 unique studies from 28 publications that examined various cognitive rehabilitation interventions for adults with dementia (Table 5.9).[90, 193, 221, 222, 224-243] Three randomized trials were assessed as low or medium risk of bias and are included in the analytic set.[193, 224, 244] The remaining 23 studies were pilot, small sample trials, or assessed as high risk of bias.[90, 154, 221, 222, 225-230, 232-234, 239-245] We present information on all eligible studies in the evidence map in Appendix D.

Table 5.9. Basic characteristics of literature set: cognitive rehabilitation

Characteristics	Information
Total unique studies	23 studies
Non-U.S. studies	19 studies
Evidence map studies	2 pilot studies 15 small samples studies 3 high risk of bias studies
Analytic set studies	3 studies
Risk of bias of analytic set	Low/medium
Number of PLWD in analytic set	890
Dementia type/definition	Mild to moderate dementia
Caregiver type (number)	Informal caregivers (n=474)

Intervention Research Context

The cognitive rehabilitation literature largely comprises unique interventions that have been tested only in small sample studies, thus the literature is largely preliminary. Trials included small group or individually tailored activities that engaged a variety of cognitive functions to improve the completion of daily activities in PLWD. Interventions were diverse, and details about both cognitive exercises and task guidance were often lacking, especially for individual rehabilitation of basic functional tasks.

Most included studies compared cognitive rehabilitation to other active cognitive approaches or usual care. The longest study lasted 2 years,[193] although most ranged from 3 to 6 months. Some studies reported both task-based outcomes and measures of positive affect surrounding task accomplishment, such as satisfaction, quality of life, or reduction in neuropsychiatric symptoms. Studies were community,[193, 220, 221, 224, 225, 228, 230, 232] hospital,[239] or nursing home-based[90, 229, 231, 235, 240 227, 233, 241] interventions, and two studies included a mix of nursing home and community residents.[222, 228] Most studies (83%) took place outside of the United States.

PLWD Outcomes

Evidence was insufficient to draw conclusions about the effects of cognitive rehabilitation to improve quality of life, function, neuropsychiatric symptoms, mood, health service use, institutionalization, and harms for adults with dementia. We could not combine studies because the three trials tested very different interventions and assessed different outcomes at varying time points. The three analytic set trials (n=890) were conducted in noninstitutionalized adults with mild to moderate dementia.[193, 224, 244] Table 5.10 summarizes the primary findings.

The largest, medium risk of bias RCT of 653 community-dwelling adults found no benefit of individual cognitive rehabilitation versus group usual care (n=311 for these study arms) on function, ADLs, behavioral issues, quality of life, depression, or caregiver burden over 24 months.[193] However, authors reported greater 24-month clinical benefits, including slower functional declines, improved survival, and marginal benefits on behavior, caregiver burden and resource use.[193]

A medium risk of bias RCT of 475 community-dwelling adults found a statistically but not clinically significant benefit of individual cognitive rehabilitation compared with usual care on function assessed as self-rated goal attainment, at three and nine months.[244] The mean Mini Mental State Exam scores of enrolled adults was 24 (range 18 to 30), which marginally met criteria for mild dementia. There was no benefit of cognitive rehabilitation on quality of life, depression, or anxiety, compared with usual care.[244]

One RCT found no benefit of errorless learning with feed-forward (continuous verbal) training over trial and error learning on ADLs in adults with AD and mixed dementia who were living at home.[224]

Table 5.10: Summary of findings for PLWD outcomes: cognitive rehabilitation

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Quality of Life Individual cognitive rehabilitation vs usual care	1 RCT[193] (n=311) 24 months	Mild to moderate dementia	0 foun benefit 1 found no difference	Insufficient
Quality of Life Individual cognitive rehabilitation vs usual care	1 RCT[244] (n=475) 9 months	Mild dementia	0 found benefit 1 found no difference	Insufficient
Daily function Individual cognitive rehabilitation vs usual care	1 RCT[193] (n=311) 24 months	Mild to moderate dementia	0 found benefit 1 found no difference	Insufficient
Daily function Errorless Learning (feed-forward instructions) vs Trial & Error Learning	1 RCT[224] (n=161) 6 months	Mild to moderate dementia	0 found benefit 1 found no difference	Insufficient
Self-rated goal attainment Individual cognitive rehabilitation vs usual care	1 RCT[244] (n=475) 9 months	Mild dementia	1 found benefit 0 found no difference	Insufficient
Dependency Individual cognitive rehabilitation vs usual care	1 RCT[193] (n=311) 24 months	Mild to moderate dementia	1 found benefit 0 found no difference	Insufficient
Neuropsychiatric symptoms Individual cognitive rehabilitation vs usual care	1 RCT[193] (n=311) 24 months	Mild to moderate dementia	0 found benefit 1 found no difference	Insufficient
Neuropsychiatric symptoms Errorless Learning (feed-forward instructions) vs Trial & Error Learning	1 RCT[224] (n=161) 6 months	Mild to moderate dementia	0 found benefit 1 found no difference	Insufficient
Depression Individual cognitive rehabilitation vs usual care	1 RCT[244] (n=475) 9 months	Mild dementia	0 found benefit 1 found no difference	Insufficient
Anxiety Individual cognitive rehabilitation vs usual care	1 RCT[244] (n=475) 9 months	Mild dementia	0 found benefit 1 found no difference	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: n-number; RCT=randomized controlled trial

Caregiver Outcomes

Cognitive rehabilitation offered no significant benefit over reminiscence on CG/P burden or apathy in the one trial that measured it.[193] Cognitive rehabilitation offered no significant benefit over usual care on CG/P stress, quality of life, or health-related quality of life over 9 months.[244]

Variation in Outcomes

No analytic set studies reported variations in outcomes by PLWD, caregiver, or intervention characteristics.

Cognitive Training

Key Points

- Evidence was insufficient to draw conclusions about the effect of cognitive training interventions for PLWD and their CG/P.

Intervention Description

Cognitive Training interventions involve repetitive or progressive drill-type exercises aimed at improving various domains of cognitive function (e.g., memory or executive functions).[193] The cognitive training interventions included in eligible studies incorporated some form of cognitive drills, whether paper-pencil tests or computer-based.

Eligible Studies

We identified 18 unique studies from 18 publications that examined cognitive training interventions among PLWD (Table 5.11).[189, 191, 193, 246-260] Five studies were assessed as medium risk of bias and were included in the analytic set.[189, 193, 246-249] Appendix D provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes. Ten studies had small sample sizes,[191, 250-252, 254-257, 259-261] and two were assessed as high risk of bias.[253, 258] We present information on all pilot studies and high risk of bias studies as part of the evidence map in Appendix D.

Table 5.11. Basic characteristics of literature set: cognitive training

Characteristics	Information
Total unique studies	18 studies
Non-U.S. studies	15 studies
Evidence map studies	3 pilot 9 small sample studies 1 high risk of bias
Analytic set studies	5 randomized controlled trials
Risk of bias of analytic set	Medium
Number of PLWD in analytic set	748
Dementia type/definition	All types and severities
Caregiver type (number)	Informal (n=324), Formal (n=NR)

Intervention Research Context

The majority of eligible studies were small sample size trials involving fewer than 50 total participants each. Studies were published between 2001 and 2019, and were mostly conducted outside the United States. Intervention mode ranged from paper-and-pencil tasks to software or web-based cognitive training. Cognitive training tasks targeted a range of functions that included memory, language, and executive function. Interventions were delivered in community-based (e.g., adult day care centers) or institutional settings (e.g., nursing homes, veterans homes). Three of the studies included in the analytic set took place at nursing homes, dementia special care units, or assisted-living residences,[189, 246, 249] while two took place at adult day care or memory clinics.[193, 247, 248]

PLWD Outcomes

Evidence was insufficient to draw conclusions about the effects of cognitive therapy for PLWD. Five studies reported outcomes for PLWD. Four studies compared cognitive training interventions to usual care.[189, 193, 247-249] One study compared cognitive training with an attention control.[246] Table 5.12 summarizes the primary outcomes for PLWD. Two studies enrolling a total of 471 PLWD reported measures of quality of life and found no difference between groups at 3 months.[193, 247, 248] Two studies enrolling a total of 404 PLWD reported measures of depression found no difference between groups from 3 to 6 months.[193, 246]

Two studies enrolling a total of 197 PLWD with excessive eating, or hyperphagia, reported outcome measures of hyperphagic behavior.[189, 249] Both studies found that hyperphagia behaviors improved in the cognitive training group versus usual care at 6 weeks.[189, 249] One study measured hyperphagia behavior up to 6 months post-intervention (30 weeks total), finding that this benefit was sustained in the cognitive training group.[249] Both studies reported a variety of additional measures related to excessive eating. One study (n=97) reported food intake, finding a reduction in average food intake for the cognitive training group versus usual care at 6 weeks.[189] The other study (n=100) reported measures of short meal frequency, pica behavior, and change in eating habits from post-intervention (6 weeks) to 6-months post-intervention (30 weeks).[249] Short-meal frequency improved in the cognitive training group versus the usual care group at all measured time points.[249] Pica behavior improved in the cognitive training group immediately post-intervention as well as at 1 and 3 months post-intervention, but the benefit was not sustained 6 months post-intervention.[249] Groups did not differ for change in eating habits.[249]

One study (n=324) also reported measures of BPSD, function/ADLs, apathy, and dependence, and found no difference between groups at 3 months.[193] Another study (n=80) reported a measure of anxiety and found no difference between groups at 3 and 6 months.[246] Appendix D provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.

Table 5.12. Summary of findings for PLWD outcomes: cognitive training

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Quality of Life Cognitive training vs usual care	2 RCTs [193, 247, 248] (n=471) 3 months	Mild to moderate AD or other dementia	0 of 2 found benefit 2 of 2 found no difference	Insufficient
Depression Cognitive training vs usual care	2 RCTs [193, 246] (n=404) 3 to 6 months	Early-stage to Moderate AD	0 of 2 found benefit 2 of 2 found no difference	Insufficient
Hyperphagia Behavior Cognitive training vs usual care	2 RCTs [189, 249] (n=197) 6 to 30 weeks	Dementia with hyperphagia	2 of 2 found benefit 0 of 2 found no difference	Insufficient

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Food Intake Cognitive training vs usual care	1 RCT [189] (n=97) 6 weeks	Dementia with hyperphagia	1 found benefit 0 found no difference	Insufficient
Short meal frequency Cognitive training vs usual care	1 RCT [249] (n=100) 6 to 30 weeks	Dementia with hyperphagia	1 found benefit at all time points 0 found no difference	Insufficient
Pica behavior Cognitive training vs usual care	1 RCT [249] (n=100) 6 to 30 weeks	Dementia with hyperphagia	1 found benefit favoring intervention post-intervention, but not sustained 6-months post-intervention 0 found no difference	Insufficient
Change in eating habits Cognitive training vs usual care	1 RCT [249] (n=100) 6 to 30 weeks	Dementia with hyperphagia	0 found benefit 0 found no difference	Insufficient
BPSD Cognitive training vs attention control	1 RCT (n=324) 3 months	Mild to moderate AD	0 found benefit 1 found no difference	Insufficient
Function/ADLs Cognitive training vs attention control	1 RCT [193] (n=324) 3 months	Mild to moderate AD	0 found benefit 1 found no difference	Insufficient
Apathy Cognitive training vs attention control	1 RCT [193] (n=324) 3 months	Mild to moderate AD	0 found benefit 1 found no difference	Insufficient
Dependence Cognitive training vs attention control	1 RCT [193] (n=324) 3 months	Mild to moderate AD	0 found benefit 1 found no difference	Insufficient
Anxiety Cognitive training vs attention control	1 RCT [246] (n=80) 3 and 6 months	Early-stage AD	0 found benefit 1 found no difference	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: AD=Alzheimer's disease; n=Number; PLWD=People with Dementia; RCT=Randomized Controlled Trial

Caregiver Outcomes

Evidence was insufficient to draw conclusions about the effects of cognitive therapy for informal and formal caregivers of PLWD. Two studies reported outcomes for caregivers and compared cognitive training interventions compared with usual care.[193, 249] Table 5.13 summarizes primary outcomes for caregivers. One study (n=324) reported a measure of caregiver distress for CG/P, and found no difference between groups at 3 months.[193] The second study reported a measure of formal caregiver distress specific to PLWD hyperphagic behavior, and found benefit for formal caregivers of the cognitive training group versus the usual care group post-intervention (6 weeks).[249] However, the benefit was not sustained at 6 months.[249]

Table 5.13. Summary of findings for caregiver outcomes: cognitive training

Outcome Comparator	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Caregiver Distress Cognitive training vs usual care	1 RCT [193] (n=324) 3 months	Informal caregivers	0 found benefit 1 found no difference	Insufficient
Caregiver Distress, PLWD hyperphagic behavior Cognitive training vs usual care	1 RCT [249] (n=NR) 6 to 30 weeks	Formal caregivers	1 found benefit favoring intervention group immediately post-intervention (6 weeks); however, difference was not sustained over the 6-month period post-intervention.	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: NR=not reported; PLWD=People Living with Dementia; RCT=Randomized Controlled Trial; n=Number

Variation in Outcomes

Studies in the analytic set did not examine variation in outcomes by PLWD, caregiver, or intervention characteristics.

Cognitive Stimulation Therapy

Key Points

- Evidence was insufficient to draw conclusions about the effect of cognitive stimulation therapy (CST) for PLWD and their CG/P.

Intervention Description

Cognitive stimulation is an intervention for people with mild to moderate dementia that offers engagement in various activities and discussions (usually in a group) aimed at general enhancement of cognitive and social functioning. Activities and material are presented in a game-like manner rather than as schooling.

Eligible Studies

Table 5.14 summarizes the characteristics of the literature set. We identified 12 unique studies from 15 publications.[44, 212, 262-272] One of these was a pilot study, four had small samples, and two were assessed as high risk of bias; these seven studies were not part of the analytic set but information about them is provided as part of the evidence map in Appendix D. One study (n=201) was assessed as low risk of bias,[262, 264] and the other (n=236) was assessed as medium risk of bias.[263] The first compared CST versus usual care.[262, 264] The second compared CST maintenance therapy versus withdrawal of CST (in both cases after an initial period of CST).[263] Neither study reported caregiver outcomes. Appendix D provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.

Table 5.14. Basic characteristics of literature set: cognitive stimulation therapy

Characteristic	Information
Total studies	12 studies
Non-U.S. studies	11 studies

Characteristic	Information
Evidence map studies	1 pilot study 5 small sample studies 4 high risk of bias studies
Analytic set studies	2 randomized controlled trials
Risk of bias of analytic set	1 low, 1 medium
Number of PLWD in analytic set	437
Dementia type/definition	Mild to moderate severity
Caregiver type (number)	Not reported

Intervention Research Context

The literature set remains mostly preliminary, using the NIH Stage Model, with pilot or small sample studies. One study reported a pilot component,[264] but the other did not. One study in the literature set described itself as a pilot study to adapt CST to the Hong Kong context.[273] Three studies had an active control,[265, 268, 272] and another had both an active control and a usual care arm.[212] The remaining studies used usual care or some variation thereof as the control.

PLWD Outcomes

Evidence was insufficient to determine the effect of CST on quality of life, function, neuropsychiatric symptoms, and mood. Table 5.15 summarizes the primary outcomes for PLWD. Only one study addressed the effect of CST versus usual care on quality of life, cognition, neuropsychiatric symptoms, anxiety, and depression (n = 201 subjects analyzed).[44] The other study took place after an initial session of CST, and examined the effect of CST maintenance therapy versus withdrawal of CST on quality of life, cognition, and neuropsychiatric symptoms.[263]

Table 5.15. Summary of findings for PLWD outcomes: cognitive stimulation therapy

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Quality of life CST vs. usual care	1 RCT [44] (n=201) 8 weeks	PLWD	1 found benefit 0 found no difference	Insufficient
Function CST vs. usual care	1 RCT [44] (n=201) 8 weeks	PLWD	0 found benefit 1 found no difference	Insufficient
Neuropsychiatric symptoms CST vs. usual care	1 RCT [44] (n=201) 8 weeks	PLWD	0 found benefit 1 found no difference	Insufficient
Anxiety CST vs. usual care	1 RCT [44] (n=201) 8 weeks	PLWD	0 found benefit 1 found no difference	Insufficient
Depression CST vs. usual care	1 RCT [44] (n=201) 8 weeks	PLWD	0 found benefit 1 found no difference	Insufficient
Quality of life CST maintenance therapy after initial CST vs. withdrawal of CST after initial CST	1 RCT [263] (n=236) 12 weeks 24 weeks	PLWD	1 found benefit 0 found no difference	Insufficient
Function CST maintenance therapy after initial CST vs. withdrawal of CST after initial CST	1 RCT [263] (n=236) 12 weeks 24 weeks	PLWD	1 found benefit 0 found no difference	Insufficient

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Neuropsychiatric symptoms CST maintenance therapy after initial CST vs. withdrawal of CST after initial CST	1 RCT [263] (n=236) 12 weeks 24 weeks	PLWD	1 found benefit 0 found no difference	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: CST=Cognitive Stimulation Therapy; n=Number; PLWD=People Living with Dementia: RCT=Randomized Controlled Trial

Caregiver Outcomes

No studies reported caregiver outcomes.

Variation in Outcomes

One study reported that women appeared to benefit more than men for quality of life, neuropsychiatric symptoms, and function. The study did not report the magnitude of the differences, nor did it report p-values.[264] Neither study reported variation in outcomes by caregiver or intervention characteristics.

Recreation Therapy

Key Points

- Evidence was insufficient to draw conclusions about recreation therapy interventions for PLWD or their CG/Ps.

Intervention Description

Recreation therapy interventions may involve art, games, music, or exercise. They are usually structured and facilitated, and may be conducted in groups or individually. Most of these interventions aim to involve participants actively in the chosen activity, rather than letting them participate passively (e.g. listen to music or read).

Eligible Studies

Table 5.16 summarizes the effect of recreation therapy for PLWD. We identified 14 unique studies from 14 publications that examined the effect of recreation therapy for PLWD. Three studies were assessed as low or medium risk of bias and included in the analytic set. All studies were randomized controlled trials (RCTs; n = 552),[274-276] and all used usual care as the comparator. The studies were conducted in the United States, Australia, and Italy.. All pilot, small sample, and high-risk-or-bias studies are described as part of the evidence map in Appendix D.[276-287] An evidence table, summary of risk of bias assessments, and strength of evidence is provided in Appendix D.

Table 5.16. Basic characteristics of literature set: recreational therapy

Characteristic	Information
Total unique studies	14 studies
Non-U.S. studies	11 studies

Total Evidence map studies	1 pilot study 5 small sample studies 5 high risk of bias studies
Analytic set studies	3 randomized controlled trial
Risk of bias of analytic set	Medium
Number of PLWD in analytic set	552
Dementia type/definition	Type of dementia not reported, severity not reported
Caregiver type (number)	Not reported

Intervention Research Context

The literature for recreational therapy interventions is still quite preliminary. Using the NIH Stage Model, large majority of studies were assessed as pilot and small sample studies. The largest study enrolled 389 PLWD. All but two studies were conducted outside of the United States. We did not see evolution of a particular intervention over time; instead, each study tested a different recreational therapy approach. Two studies involved activity sessions conducted one—on-one with an aide, a wheelchair tandem bicycle ride,[277] and individualized activities such as singing or working with clay.[288] The remainder involved larger group activities. The studies involved a diverse set of activities, and some studies involved more than one type of activity. One involved some form of group sporting activity.[277, 279] Four involved different types of games: GO,[281] chess,[286] dhakonan, [287] or party games.[285] One based activities on Chinese folk art, music, and games.[280] Three involved art in some form, such as singing in a choir or visits to art museum plus art-making.[278, 280, 283] Of the evidence map studies, only four used usual care as a comparator.[277, 279-281]

PLWD Outcomes

Evidence was insufficient to draw conclusions about PLWD outcomes, including neuropsychological symptoms, depression, agitation, social function, physical function, quality of life, and antipsychotic medication use. Table 5.17 provides a summary of findings. For the most part, each outcome was only covered in one study.

Two studies (n=552) compared neuropsychiatric symptoms using the NPI, with one finding a benefit and the other showing no difference. The studies also reported markedly different baseline levels of neuropsychiatric symptoms.[274, 275] Two other studies (n=517) [274, 276] compared agitation; neither found a difference.

At both 13 and 26 weeks, the humor therapy study (n=389) reported quality of life, depression and agitation symptoms, and social function, and found no difference between groups at either time point.[274]

The indoor garden study (n=163) reported a small but statistically insignificant benefit for physical function. However, the study reported a statistically significant reduction in antipsychotic use at 24 weeks.[275]

Table 5.17: Summary of findings for PLWD outcomes: recreational therapy

Outcome comparison	# Studies/Design (n=analyzed) Timing	Population	Findings	Strength of Evidence*
Neuropsychiatric symptoms Recreational therapy vs. usual care	2 RCTs [274, 275] (n=552) 24-26 weeks	Dementia type and severity not reported	1 of 2 found benefit 1 of 2 found no difference	Insufficient

Outcome comparison	# Studies/Design (n=analyzed) Timing	Population	Findings	Strength of Evidence*
Depression Recreational therapy vs. usual care	1 RCT [274] (n = 389) 13 and 26 weeks	Dementia type and severity not reported	1 found benefit 1 found no difference	Insufficient
Agitation Recreational therapy vs. usual care	2 RCTs [274, 276] (n = 517) Up to 13 weeks	Dementia type and severity not reported	0 found benefit 2 no difference	Insufficient
Function, social Recreational therapy vs. usual care	1 RCT [274] (n = 389) 13 and 26 weeks	Dementia type and severity not reported	0 found benefit 1 found no difference	Insufficient
Function, physical Recreational therapy vs. usual care	1 RCT [275] (n = 163) 24 weeks	Dementia type and severity not reported	1 found benefit 0 found no difference	Insufficient
Quality of life Recreational therapy vs. usual care	1 RCT [274] (n = 389) 13 and 26 weeks	Dementia type and severity not reported	0 found benefit 1 found no difference	Insufficient
Antipsychotic use Recreational therapy vs. usual care	1 RCT [275] (n = 163) 24 weeks	Dementia type and severity not reported	1 found benefit 0 found no difference	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: RCT=randomized controlled trial

Caregiver Outcomes

No studies in the analytic set reported caregiver outcomes.

Variation in Outcomes

No studies in the analytic set reported any variation in outcomes.

Psychosocial Interventions for PLWD Well-being

Key Points

- Studies of psychosocial interventions to improve PLWD well-being were described in the evidence map but not considered for analysis due to limitations in study designs.

Intervention Description

Psychosocial interventions include components such as group counseling, use of an assigned nursing home resident buddy, or approaches to improve effective communication in order to help psychosocial and behavioral aspects by improving communication, memory, and interpersonal skills among PLWD.

Eligible Studies

We identified seven unique studies from eight publications that examined various psychosocial session interventions among PLWD.[289-296] (Table 5.18) All studies were either pilots or small sample studies, and we provide information about them in the evidence map in Appendix D.

Table 5.18. Basic characteristics of literature set: psychosocial interventions for PLWD

Characteristics	Information

Total unique studies	7 studies
Non-U.S. studies	4 studies
Evidence map studies	1 pilot study 4 small sample studies 2 high risk of bias studies
Analytic set studies	0

Intervention Research Context

The research is largely preliminary with small sample or pilot trials. Psychosocial session topics included psychodynamic interpersonal therapy for community-dwelling PLWD in the United Kingdom,[289] using non-cognitively impaired nursing home residents as “buddies” for PLWD in the United States,[290] a self-management group intervention for PLWD in the early stages of dementia in the United Kingdom,[291, 292] therapeutic conversation counseling sessions for community-dwelling PLWD in the United States,[293] and peer support group sessions for community-dwelling PLWD in Hong Kong.[294] Lastly, two studies examined the use of reality orientation therapy among PLWD in the United States in 1997[295] and Italy in 2005.[296]

Creative Expression Therapy

Key Points

- Studies to assess the effect of creative expression therapy were described in the evidence map but not considered for analysis due to limitations in study designs.

Intervention Description

Creative expression programs are emerging interventions targeted at improving quality of care and life for PLWD in long-term care facilities. Creative expression interventions, such as storytelling or theatrical improvisation, do not require PLWD to access or use memories. They instead focus on creativity in the moment.

Eligible Studies

We identified five unique studies from five publications that examined creative expression interventions for PLWD and formal caregivers. (Table 5.19) Three studies were assessed as high risk of bias and two were pilot studies; all five were therefore excluded from the analytic set. We present information on all studies as part of the evidence map in Appendix D.

Table 5.19. Basic characteristics of literature set: creative expression therapy

Characteristics	Information
Total unique studies	5 studies
Non-U.S. studies	2 studies
Evidence map studies	2 pilot studies 3 high risk of bias studies
Analytic set studies	0

Intervention Research Context

Four interventions examined “TimeSlips (TS),” a group storytelling method,[297-300] while one study investigated the “Veder Method” which integrates theater improvisation techniques with elements from other communication methods.[301] These interventions are relatively new, and the research is emerging (published between 2009 and 2019). Three studies were conducted in the U.S.,[297, 298, 300] and the other two were conducted in China[299] and the Netherlands.[301] All five studies focused mainly on the outcomes of behavior, mood, and quality of life for PLWD, although one study examined the caregiver outcomes of job satisfaction, attitude towards residents, and burnout.[297]

Multicomponent Interventions for PLWD Well-being

Key Points

- Evidence is insufficient to draw conclusion about the effects of multicomponent care interventions in PLWD or their caregivers.

About the Interventions

The multicomponent studies in this set are largely unrelated. Earlier in this chapter we reported on another multicomponent intervention, CST. Since CST had a relatively distinct literature set, we chose to report it in a separate section.

Multicomponent interventions aimed at improving PLWD include a combination of components used simultaneously to support cognitive function, quality of life, and other health outcomes for PLWD. Intervention components may include cognitive and/or motor stimulation, physical activity using daily living activities, strategies adapted from cognitive training and neurorehabilitation, reminiscence therapy, and reality orientation, and exposure to bright light. Multicomponent interventions are intended to improve PLWD outcomes such as functional ability (to engage in activities of daily living) and depression. Multicomponent may or may not use special personnel such as nurses, aides, and therapists, and are delivered in varied settings including the PLWD's home, day care centers, and nursing homes.

Eligible Studies

Table 5.20 summarizes the characteristics of the literature set. We identified 24 unique studies from 39 publications. Three studies were assessed as low to medium risk of bias and were included in the analytic set. Multicomponent interventions targeting quality of life, function, and/or non-BPSD symptoms in PLWD included three unique studies across four publications. One study examined an intervention in Germany including motor stimulation, activities of daily living, and cognitive stimulation components, delivered by two therapists, one aide, and nurses when necessary.[302, 303] One study examined walking, light therapy, and combination exercise, light therapy, and education in the U.S.[304] One Japanese study examined reminiscence and reality orientation therapy care methods, in addition to a routine day-care service.[305] Excluded from the analytic set are 21 pilot, small sample, and high risk of bias studies and are described as part of the evidence map in Appendix D.[44, 94, 114, 116, 303, 306-324] Appendix D provides an evidence table, summary of risk of bias assessments, and strength of evidence for the analytic set.

Table 5.20. Basic characteristics of literature set: multicomponent for PLWD well-being

Characteristics	Information
Total unique studies	24 studies
Non-U.S. studies	14 studies
Evidence map studies	3 pilot studies 7 small sample studies 11 high risk of bias
Analytic set studies	3 randomized controlled trials
Risk of bias of analytic set	Medium

Number of PLWD in analytic set	333
Dementia type/definition	Varied across studies
Caregiver type (number)	NA

Intervention Research Context

Evidence map studies published between 2004 and 2020 tended to be largely preliminary or early Stage 3 of the NIH Stage Model. Studies in the analytic set were likewise explanatory in nature and as a whole, they did not exhibit much progression along the NIH Stage Model. Study duration ranged from 6 weeks to 18 months, targeted highly varied PLWD populations, and focused primarily on PLWD with mild and moderate dementia residing in various community-based residences and nursing homes. Two of the trials targeting PLWD with mild to moderate dementia focused on an intervention for motor stimulation, activities of daily living, and cognitive stimulation.[302, 325] These trials represented the most pragmatic approach to multicomponent interventions for PLWD health outcomes.

PLWD Outcomes

Evidence was insufficient for drawing conclusions about the effects of multicomponent interventions for PLWD well-being. The findings are summarized in Table 5.21. One study reported small benefit for PLWD quality of life (social behavior), cognitive function, and instrumental activity of daily living for PLWD with mild to moderate dementia living in nursing homes.[302, 303] One study reported a small reduction of sleep disturbances.[304] and the other reported small improvements in overall cognitive and social function.[305]

Table 5.21 Summary of findings for PLWD outcomes: multicomponent for PLWD well-being

Outcome Comparison	# Studies/Design (n=analyzed) Timing	Population	Findings	Strength of Evidence
Instrumental Activities of Daily Living Multicomponent: motor stimulation, activities of daily living, and cognitive stimulation components contact control	1 RCT 302, 303 n=98 6 months	ADRD	1 found benefit 0 found no difference	Insufficient
Sleep Walking, light, combination treatment versus contact control	1 RCT 304 n=66 6 months	People with AD and their in-home caregivers.	0 found benefit 1 found no difference.	Insufficient
Cognitive and Social Function Reminiscence and reality orientation care methods, routine day-care service versus usual care	1 RCT 305 n=60 10 weeks	Community-dwelling older PLWD.	1 found benefit 0 found no difference	Insufficient

*Insufficient ratings due to few studies and imprecision in the findings.

Abbreviations: AD=Alzheimer's disease; ADRD=Alzheimer's disease and related dementia; PLWD=People living with dementia; RCT=randomized controlled trial

Caregiver Outcomes

Where studies may have included caregiver outcomes, these lacked sufficient or clear reporting for caregiver outcomes.

Variation in Outcomes

Studies did not report variation in PLWD outcomes by PLWD characteristics, caregiver characteristics, or setting.

Assistive Technology

We classified as assistive technology interventions include technology that controls house functions such as lights and/or systems that alert caregivers when a PLWD is at risk. Additionally, these interventions evaluated caregiver outcomes such as job satisfaction, relieving worry, and sleep quality.

Key Points

- Studies of assistive technology interventions were described in the evidence map but not considered for analysis due to limitations in study designs.

Eligible Studies

We identified four unique studies from four publications that examined the use of assistive technology for PLWD and informal/formal caregivers. (Table 5.22) All included studies were pilot studies. Information on all studies is provided as part of the evidence map in Appendix D.[320, 326-329]

Table 5.22. Basic characteristics of literature set: assistive home technology

Characteristics	Information
Total unique studies	4 studies
Non-U.S. studies	2 studies
Evidence map studies	4 pilot studies
Analytic set studies	0

Intervention Research Context

Assistive technology interventions identified are relatively novel and thus these studies were preliminary in design, spanning nine years from 2010 to 2019. Intervention topics include the effectiveness of implementation of assistive technology in group homes in Amsterdam on the quality of life of PLWD and on the job satisfaction of caregivers.[326] The effectiveness of home-based technologies coupled with teleassistance service was also assessed in order to prevent indoor falls of individuals with dementia in France.[328] Additionally, a home monitoring system designed to track the movements of PLWD was assessed to see if it would relieve worry and improve sleep in caregivers in the United States.[330] A second U.S. study examined wearable technology to alert caregivers of activities, generating reports of activity patterns over time.[329]

Electrostimulation

Key Points

- Studies of electrostimulation were described in the evidence map but not considered for analysis due to limitations in study designs.

Intervention Description

Electrostimulation interventions encompass a variety of techniques using either electric current or electromagnetic pulses of different intensity in various of parts of brain to improve cognitive and behavioral functioning for PLWD.

Eligible Studies

We identified 14 unique studies from 15 publications that examined electrostimulation among PLWD. (Table 5.23) All studies were either pilots or had small sample sizes.[50, 320, 326-328, 331-343] We present information on all studies as part of the evidence map in Appendix D.

Table 5.23. Basic characteristics of literature set: electrostimulation

Characteristics	Information
Total unique studies	14 studies
Non-U.S. studies	12 studies
Evidence map studies	5 pilot 9 small sample studies
Analytic set studies	0

Intervention Research Context

The research is early in development and based on small sample sizes, thus preliminary. Nursing home or other long-term care facilities were the most common settings. Non-U.S. locations included Brazil, Canada, China, Egypt, Japan, Italy, The Netherlands, and Spain. Electrostimulation topics are highly technical neuroscience research. Please refer to the evidence map for more details.[331-345]

Other Interventions for PLWD Well-being

Key Points

- No studies of other care interventions for PLWD well-being advanced from the evidence map to further analysis.

Intervention Description

This section encompasses a wide range of interventions. These included passive exercise (movement therapy or finger movement performed by a formal caregiver on PLWD), suicide prevention programs to pain assessments to verbal cues, and handfeeding techniques to help improve various (physical, mental, cognitive and behavioral) aspects of functioning.

Eligible Studies

We identified seven unique studies from eight publications that examined the various interventions among PLWD.[133, 302, 325, 346-352] (Table 5.24) All the studies were either pilot or small sample studies. We present information on all studies in the evidence map in Appendix D.

Table 5.24. Basic characteristics of literature set: other interventions for BPSD

Characteristics	Information
Total unique studies	7 studies
Non-U.S. studies	4 studies
Evidence map studies	4 pilot 1 small sample studies 1 high risk of bias

Characteristics	Information
Analytic set studies	0

Intervention Research Context

This research is preliminary. Publications included a suicide prevention program tested in South Korea for older adults with early-stage dementia,[351] pain assessment in Norwegian nursing homes,[352] passive finger movement exercise to improve grip strength in Chinese PLWD in residential facilities,[133] various handfeeding techniques in PLWD with advanced dementia in the United States,[346] and passive movement therapy for severe paratonia, or muscle stiffness, in late-stage dementia.[349] One study from 1997 examined directed verbal prompts and positive reinforcements for eating independence in PLWD in U.S. nursing homes.[347]

Conclusion

We found 223 unique studies that we grouped into 13 categories of care interventions aimed at improving PLWD quality of life and well-being. The large majority of studies, 85 percent, were conducted in non-U.S. settings. Eighty-five percent of the studies were pilots or small sample studies, Stage 0 to 2 according to the NIH Stage Model, or assessed as high risk of bias. Of those interventions with an analytic set of low to moderate risk of bias studies, we found the uncertainty of the evidence was too high to draw conclusions. Challenges with clear definitions of classes of interventions, and variability both in outcomes and how they were measured, hampered our ability to combine studies. Loss of PLWD participants after study enrollment was a frequent cause of increased risk of bias. However, evidence that is insufficient does not mean that none of the individual interventions described are potentially useful for individual PLWD or their caregivers. It simply means the uncertainty of the evidence is too high for us to draw conclusions, at present.

Chapter 6. Care Interventions for Informal Caregivers

This chapter includes care interventions for informal caregivers, with the goal of improving their quality of life and well-being. While the large majority of studies use the term "informal caregiver," the term care partner is also occasionally present; we use the term caregiver/partner, or CG/P. The interventions include psychosocial interventions, social support, lifestyle interventions, respite care, multicomponent interventions, and other interventions that did not fall into these previous categories. We also present in this chapter interventions that target dyads of people living with dementia (PLWD) and their CG/P.

For each intervention, we present Key Points followed by results in three general sections: Intervention Description, Eligible Studies, and Intervention Research Context. For interventions with no studies assessed as low to medium risk of bias, we present the studies from the evidence map with a brief discussion of what has been examined and research context. For interventions for which low- to medium-risk-of-bias studies were available for an analytic set, we present Outcomes sections by PLWD, by caregiver, and by variation in outcomes when available.

We present a qualitative synthesis of the findings, because differences in outcome measures and intervention complexity prohibited the pooling of outcomes for a statistical analysis, such as a meta-analysis. We present summary findings as brief statements of how many studies reported statistically significant benefits or no difference between the intervention and comparator. Effect sizes and the data to calculate them were rarely reported in this literature. In studies where an effect size was reported, we present the study's originally reported effect size where it may be helpful for interpreting the study's findings. We present detailed information on eligible studies in Appendix E.

Psychosocial Interventions to Support Informal Caregiver Well-being

Key Points

- For both PLWD and CG/Ps, evidence is insufficient to draw conclusions about the effects of psychosocial interventions targeting CG/P.
- For CG/P, we found no studies that assessed harms for psychosocial interventions targeting CG/P well-being.

Intervention Descriptions

As an umbrella term, we use "psychosocial interventions" to capture a wide range of psychoeducational and psychotherapeutic interventions that seek to improve the well-being of caregivers. Newly formulated conceptual definitions for psychoeducational and psychotherapeutic caregiver interventions do exist. However, overlap in intervention components made it impossible for us to use these newer definitions to categorize our eligible interventions.[353] Figure 6.1 provides a visual representation of the overlap of intervention components drawn from the analytic set (for which results are provided below). No clear pattern distinguished interventions as either psychoeducational or psychotherapeutic.

Figure 6.1. Collaboration network visualization of CG/P psychosocial intervention components

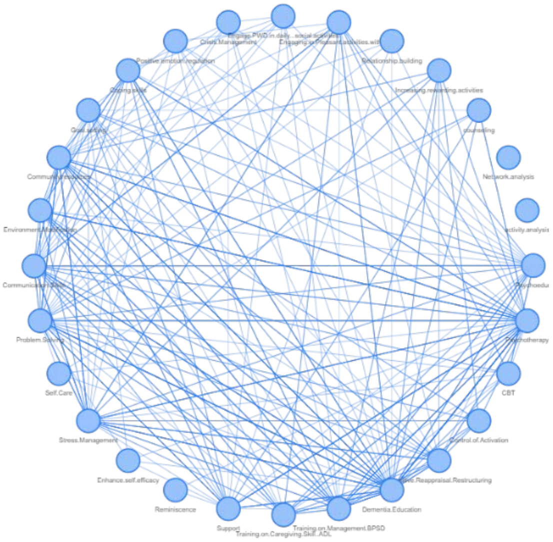


Figure 6.1 Legend for network, starting at the top and moving clockwise
Engage PLWD in Daily/Social Activities
Relationship Building
Increasing Rewarding Activities
Counseling
Network Analysis
Activity Analysis
CBT
Control of Activation
Cognitive Reappraisal/ restructuring
Dementia Education
Training - Managing BPSD
Training – Caregiving Skill
Support
Reminiscence
Enhance Self-efficacy
Stress Management
Self-Care
Problem Solving
Communication Skills
Environmental Modification
Community Resources
Goal Setting
Coping Skills
Positive Emotion Regulation
Crisis Management

We also could not categorize interventions based on duration, dose, delivery elements, or the interventionists. In almost all of the studies, interventionists were highly trained health care professionals or graduate level trainees, such as psychologists, social workers, registered nurses, occupational therapists, and licensed therapists. Interventions lasted anywhere from 6 weeks to 10 months, and participants spent anywhere from 5.5 to 32 hours receiving education, skills training, or counseling. Interventions were delivered to groups, individuals, and caregiver/ PLWD dyads. Most sessions occurred in person, a few by phone, and one online. We summarize intervention components, interventionists, duration, dose, and delivery format in Appendix E.

Eligible Studies

Table 6.1 summarizes the characteristics of the literature set on psychosocial interventions for CG/P. We identified 122 unique studies from 161 publications. Excluded from the analytic set are 46 pilot and small sample studies and 47 studies assessed as high risk of bias. The analytic data set includes 29 studies with medium to low risk of bias, and represents 5054 caregiver/ PLWD dyads.[354-381] The majority of PLWD had mild to moderate dementia; however, studies infrequently reported dementia severity. We provide information on all pilot studies and high risk of bias studies as part of the evidence map in Appendix E.[382-476] Appendix E also provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.

Table 6.1. Basic characteristics of literature set: psychosocial interventions for CG/P

Characteristic	Information
Total unique studies	122 studies
Non-U.S. studies	74 studies (17 analytic set non-U.S.)

Characteristic	Information
Evidence map studies	28 pilot studies 18 small sample studies 47 high risk of bias studies
Analytic set studies	27 randomized controlled trials 1 cluster randomized controlled trial
Risk of bias of analytic set	29 medium/low
Number of PLWD in analytic set	5054
Dementia type	Predominantly mild to moderate dementia, commonly not defined
Caregiver type (number)	Informal caregivers (4952)

Intervention Research Context

Using the NIH Stage Model, about 40 percent of the studies were categorized as pilot studies and the rest were categorized as explanatory, or Stage 3. Most of the randomized controlled trials had high risk of bias. All of the 28 medium to low risk of bias studies in the analytic data set were categorized as explanatory studies using the NIH Stage Model. None were categorized as a pragmatic trial, or Stage 4. All but two of the studies occurred in high-resource countries including the United States, the United Kingdom, France, Hong Kong, Finland, Spain, Germany, Denmark, Norway, and the Netherlands. These interventions tended to be costly and resource intensive. Two smaller studies occurred in Peru and Iran, low-resource countries. The Peruvian intervention was a modification of the 10/66 Helping Carer's to Care program from India that was designed for diverse low to middle income countries with limited health and social care resources. The Iranian intervention promoted resilience training. Few studies investigated diverse caregivers (three investigated Latino caregivers, and one investigated African American caregivers). About half of the studies used attention control groups of generic psychoeducational programs, reminiscence, or support. A single comparative effectiveness study compared two cognitive behavioral therapy programs, one conducted by phone and one in person.

Modifications of the REACH Palo Alto Coping with Caregiving program were investigated in several countries including the United States,[371, 372] the United Kingdom,[363] Spain,[375 364]and Hong Kong.[354] Over time, the Coping with Caregiving group program[371] was adapted for individual sessions occurring in the caregiver's home or by phone and for shorter sessions.

A research program of occupational therapy interventions were also investigated in the United States,[359, 373] Germany,[224] and the Netherlands.[374] The occupational therapy interventions added components of environmental adaptations and compensatory actions for the PLWD's daily activities to common psychoeducational activities.

PLWD Outcomes

Only 16 of the 29 medium to low risk of bias studies reported outcomes related to PLWD. We synthesized results qualitatively because differences in outcome reporting, outcome measures, time to outcomes, and comparison groups prohibited quantitative pooling. The most commonly investigated outcomes were function, neuropsychiatric symptoms, and quality of life, and the least commonly investigated were depression, healthcare use, social support, harms, and institutionalization. Table 6.2 summarizes the number of studies investigating each outcome and the number of studies that found a statistically significant benefit or no difference in outcomes between PLWD and controls.

Evidence was insufficient to draw conclusions about the effects of psychosocial interventions for any PLWD outcome. The inability to combine outcomes from multiple studies made it impossible to show precision in any outcome. Several outcomes were only investigated by a single study, making the consistency of findings unknown. Many PLWD outcomes were deemed indirect because the researchers relied on proxy respondents. Although a few comparisons had reasonably large numbers of participants (500 to 900+) and several studies contributing, the studies often failed to report effect sizes or the data needed to calculate them. The uncertainty regarding a true "no difference between groups" finding versus an "inability to show a difference" finding remained too high.

Depression was investigated by four studies using usual care and one study using attention control groups, with only one study reporting benefit for the psychosocial intervention in the short term and one study reporting benefit in the long term. One RCT reported improvements in PLWD depression at 6 weeks for the psychosocial treatment group.[374] Three RCTs reported no group differences in depression scores over 12 to 52 weeks between psychosocial groups and usual care,[224, 355, 367] with one study reporting a Cohen's d effect size of 0.[367] One RCT reported improved depression scores over 1 year for their psychosocial treatment group versus attention control.[369]

Function was investigated by three studies using usual care and five using attention control groups, with mixed benefit for the psychosocial interventions. Two[373, 374] found short-term improvements in function for the psychosocial treatment group versus usual care, but one did not.[355] Three studies found no differences in long-term function between psychosocial intervention groups and usual care comparisons.[224, 356, 367] Outcomes were mixed for psychosocial groups versus attention control groups; one study found improved functioning for the treatment group,[359] but a second found no difference.[369]

Neuropsychiatric symptoms were investigated by three studies using usual care and five studies with attention control groups. For studies using usual care comparisons, only one found improved neuropsychiatric symptoms for the psychosocial group,[377] while three found no difference over 3 to 6 months.[355, 361, 373] For studies using an attention control group, two found short-term benefits in neuropsychiatric symptoms for their psychosocial treatment groups,[359, 360] but three found no long-term differences in neuropsychiatric symptoms.[356, 369, 370]

Quality of life was investigated by six studies using usual care and two using attention control groups. For studies using usual care comparisons, only one found improved PLWD quality of life at 6 weeks,[377] while five found no difference in quality of life over 6 to 24 months.[224, 356, 362, 363, 367] For studies using an attention control group, one study found benefits in quality of life for their psychosocial treatment group,[369] but another[359] found no difference.

Social support was investigated by one study using usual care and another using an attention control. Both found no difference in PLWD social support over 6 months.[367, 368]

Unmet needs was investigated by one study using education and information support over 6 months. No difference was found between groups.[477]

Health care use was investigated by four studies using usual care and one using an attention control group. One English study found that participants in the psychosocial group spent 436 fewer pounds sterling over 2 years (p=0.035) on healthcare services than their usual care group.[362] However, four other studies found no difference in healthcare use over 4 to 24 months.[363, 375, 378]

Harms were investigated by one study using a usual care control group. It found zero adverse events for participants in both the psychosocial treatment and control groups.[378]

Nursing home placement was investigated by two studies using usual care and two using attention control groups. One of the two studies using a usual care control group found a benefit for the psychosocial intervention,[376] and the other found no difference.[355] The studies using an attention control group found no difference between groups.[368, 370]

Table 6.2. Summary of findings for PLWD outcomes: psychosocial interventions for CG/P

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Depression sychosocial vs Usual care	4 RCTs [224, 355, 367, 374] (n=592) 6-52 weeks	CG/P	1 of 4 found benefit 3 of 4 found no difference	Insufficient
Depression Psychosocial vs Attention control	1 RCT [369] n=330 52 weeks	CG/P	1 found benefit 0 found no difference	Insufficient
Function Psychosocial vs Usual care	3 RCTs [355, 373, 374] (n=545) 6-12 weeks	CG/P	2 of 3 found benefit 1 of 3 found no difference	Insufficient
Function Psychosocial vs Usual care	3 RCTs [224, 356, 367] (n=540) 6-12 months	CG/P	0 of 3 found benefit 3 of 3 found no difference	Insufficient
Function Psychosocial vs Attention control	2 RCTs [359, 369] (n=490) 4-12 months	CG/P	1 of 2 found benefit 1 of 2 found no difference	Insufficient
Neuropsychiatric symptoms Psychosocial vs Usual care	4 RCTs[355, 361, 373, 457] (n=740) 3-6 months	CG/P	1 of 4 found benefit 3 of 4 found no difference	Insufficient
Neuropsychiatric symptoms Psychosocial vs Attention control	2 RCTs [359, 360] (n=227) 4-6 months	CG/P	2 of 2 found benefit 0 of 2 found no difference	Insufficient
Neuropsychiatric symptoms Psychosocial vs Attention control	3 RCTs [356, 369, 370] (n=916) 12-18 months	CG/P	0 of 3 found benefit 3 of 3 found no difference	Insufficient
Quality of life Psychosocial vs Usual care	1 RCT[457] (n=135) 6 weeks	CG/P	1 found benefit 0 found no difference	Insufficient
Quality of life Psychosocial vs Usual care	5 RCTs [224, 356, 362, 363, 367] (n=936) 6-24 months	CG/P	0 of 5 found benefit 5 of 5 found no difference	Insufficient
Quality of life Psychosocial vs Attention control	2 RCTs [359, 369] (n=490) 4-12 months	CG/P	1 of 2 found benefit 1 of 2 found no difference	Insufficient
Social support Psychosocial vs Usual care	1 RCT [367] (n=108) 6 months	CG/P	0 found benefit 1 found no difference	Insufficient
Social support Psychosocial vs Attention control	1 RCT [368] (n=250) 6 months	CG/P	0 found benefit 1 found no difference	Insufficient
Health care usage Psychosocial vs Usual care	4 RCTs [224, 362, 363, 375] (n=652) 4-24 months	CG/P	1 of 4 found benefit 3 of 4 found no difference	Insufficient
Health care usage Psychosocial vs Attention control	1 RCT [368] (n=250) 6 months	CG/P	0 found benefit 1 found no difference	Insufficient

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Harms – adverse events Psychosocial vs Usual care	1 RCT [224] (n=141) 52 weeks	CG/P	0 found benefit 1 found no difference	Insufficient
Institutionalization Psychosocial vs Usual care	2 RCTs [355, 376] (n=288) 6-12 months	CG/P	1 of 2 found benefit 1 of 2 found no difference	Insufficient
Institutionalization Psychosocial vs Attention control	2 RCT [368, 370] (n=545) 6-18 months	CG/P	0 of 2 found benefit 2 of 2 found no difference	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; RCT=randomized controlled trial

Caregiver Outcomes

All 29 medium to low risk of bias studies reported caregiver outcomes related to the caregivers' psychological health, quality of life, social support, healthcare use, and their perception of caregiving burden, bother or distress, confidence, knowledge, and skills. We synthesized results qualitatively because differences in outcome measures, time to outcomes, and comparison groups prohibited quantitative pooling. The most commonly investigated outcomes were depression, quality of life, caregiver burden, and caregiver bother or distress, and the least common were coping, caregiving knowledge, social support, healthcare use, and relationship with PLWD. No studies looked for caregiver harms associated with the psychosocial intervention. Table 6.3 summarizes the number of studies investigating each outcome and the number of studies that found a statistically significant benefit or no difference in outcomes for caregivers enrolled in the psychosocial intervention group and those enrolled in the comparison group.

Evidence was insufficient for all caregiver outcomes. The insufficient ratings were attributed to several limitations across the bodies of evidence. The inability to quantitatively combine outcomes from multiple studies made it impossible to show precision for any outcome. Several outcomes were only investigated by a single study, making the consistency of findings unknown. Even though a few comparisons had reasonably large numbers of PLWD (500 to 900+) combined from several studies, those studies rarely reported effect sizes or the data to calculate them. The uncertainty regarding a true no difference between groups versus an inability to show a difference remained too high.

Anxiety was investigated by two studies using usual care and two using attention control groups, and only one study reported benefit for the psychosocial intervention. For studies using usual care comparisons, just one reported short-term improvements at 6 weeks for the psychosocial group with a Cohen's d effect size of -0.32 (-.63, -.02).[366] However, another study found no group difference in anxiety over the long term.[363] Both of the two studies using attention control comparisons found no group differences in anxiety over 6 to 12 months.[356, 360]

Depression was investigated by 10 studies using usual care and 10 others using attention control groups; most found no statistically significant difference between the psychosocial and comparison groups. For studies using usual care comparisons, two found short-term benefits for the psychosocial groups,[366, 377] while three found no short-term group differences in depression.[358, 366, 367] Two studies found long-term benefits for the psychosocial group,[355, 379] while three found no group differences in depression over 1 to 2 years.[224, 356, 363] For studies using attention control groups, six found short-term benefits for the psychosocial groups,[354, 357, 360, 368, 372, 380] with one reporting a moderate Cohen's d effect size of -0.66 (-1.04, -0.74).[354] However, one study reported no short-term group differences in depression.[359] We calculated the standardized mean difference (SMD) and 95 percent confidence intervals for each of these studies and found a nonsignificant overall SMD of 0.207 (-0.117, 0.531) (p=0.15). See forest plots in Appendix E. Depression in the long-term studies was investigated by three studies that all reported no group differences in depression at 12 or 18 months.[356, 369, 370]

Stress was investigated by three studies using usual care and one using attention control groups, with only one study reporting benefit for the psychosocial intervention. Three studies using usual care comparisons found no group differences in caregiver stress in the short or long term,[355, 366, 367] with one study reporting a non-significant Cohen's d effect size of -0.20 (-0.50, 0.11).[366] A single study using an attention control comparison found improvements in stress for the psychosocial group.[372]

Caregiving burden was investigated by six studies using usual care and four using attention control groups with no apparent pattern of benefit for the psychosocial interventions. For studies using usual care comparisons, three found no short-term group differences,[364, 366, 377] with one reporting a non-significant Cohen's d effect size of -0.16 (-0.46, 0.14).[366] Results for long-term caregiver burden were mixed, with two studies finding benefit for the psychosocial intervention[361, 376] and three finding no group differences.[224, 358, 375] For studies using attention control groups, results were mixed, with three studies finding benefit for the psychosocial group,[354, 357, 380] and two finding no group differences in caregiving burden.[359, 368]

Caregiving bother/distress was investigated by four studies using usual care and five using attention control groups, with most studies finding no group differences. For studies using usual care comparisons, only one study found benefit for the psychosocial group, [377] while three studies found no group differences in caregiver bother.[361, 366, 373] For studies using attention control comparisons, results were mixed, with three studies finding benefit for the psychosocial interventions,[359, 360, 372] but two finding no group differences for caregiving burden.[356, 368]

Caregiving knowledge was investigated by a single study using a usual care comparison. It found that the psychosocial group had greater improvements in their caregiving knowledge than the usual care comparison group at 6 months.[358]

Caregiving confidence was investigated by three studies using usual care and three using attention control groups, and more studies found no group differences than benefit for the psychosocial intervention. For studies using a usual care comparison, only one study found a benefit for the psychosocial group, [377] while two found no group differences at 12 to 24 weeks.[367, 373] For studies using attention controls, two studies found a benefit for the psychosocial interventions [354, 360] one of which reported moderate Cohen's d effect size of 0.86 (1.24, 0.46),[354] while another study found no group differences.[368]

Caregiving skill was investigated by five studies using usual care and two using attention control groups, with six of the seven reporting no long-term group differences, and a single study reporting short-term benefit for the psychosocial intervention. For studies using usual care comparisons, one found short-term benefit at 6 weeks for the psychosocial group,[374] one found no short-term benefit,[457] and three found no difference in caregiving skill long term.[224, 358, 362] An additional two studies using attention control comparisons also found no long-term group differences in caregiving skill.[368, 370]

Coping was investigated by a single study using a usual care comparison. This study reported higher coping skills in the psychosocial group at 6 months.[358]

Quality of life was investigated by 11 studies using usual care and three using attention control groups. Eight studies found no group differences while six found benefit for the psychosocial group. For studies using usual comparison groups, four found short-term benefits for the psychosocial groups,[366, 374, 376, 381] and three found no group differences.[361, 364, 367] In the long term, only one study found a benefit for the psychosocial group,[375] while three did not.[224, 362, 363] For studies using attention control comparisons, a single study found short-term benefits for the psychosocial group;[357] however, two found no group differences long term.[356, 368]

The caregiver/PLWD relationship was investigated by three studies using attention control groups. One found a benefit for the psychosocial group and reported a moderate Cohen’s d effect size of 0.44 (0.82, 0.07),[354]while two found no group differences.[356, 368]

Social support was investigated by two studies using usual care comparisons and one using attention control groups. The two studies using usual care comparisons found no group differences in social support.[367, 376] A single study using an attention control group found a benefit for the psychosocial group at 6 months. [368]

Healthcare use was investigated by two studies using usual care and two using attention control groups. Only one study using an attention control group found a benefit for the psychosocial group, [368] while all the others found no group differences.[362, 365, 375]

No studies reported outcomes on caregiver harms for psychosocial interventions.

Table 6.3. Summary of findings for caregiver outcomes: psychosocial interventions for CG/P

Outcome Comparison	# Studies/ Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Anxiety Psychosocial vs Attention control	2 RCT [356, 360] n=358 24-52 weeks	CG/P	0 of 2 found benefit 2 of 2 found no difference	Insufficient
Anxiety Psychosocial vs Usual care	1 RCT [366] n=170 6 weeks	CG/P	1 found benefit 0 found no difference	Insufficient
Anxiety Psychosocial vs Usual care	1 RCT [363] n=260 2 years	CG/P	0 found benefit 1 found no difference	Insufficient
Burden of care Psychosocial vs Attention control	5 RCT [354, 357, 359, 368, 380] n=725 8-24 weeks	CG/P	3 of 5 found benefit 2 of 5 found no difference	Insufficient
Burden of care Psychosocial vs Usual care	3 RCT [364, 366, 457] n=680 6-16 weeks	CG/P	0 of 3 found benefit 3 of 3 found no difference	Insufficient
Burden of care Psychosocial vs Usual care	5 RCT [224, 358, 361, 375, 376] n=561 24-52 weeks	CG/P	2 of 5 found benefit 3 of 5 found no difference	Insufficient
Depressive symptoms Psychosocial vs Attention control	7 RCT [354, 357, 359, 360, 368, 372, 380] n=976 8-24 weeks	CG/P	6 of 7 found benefit 1 of 7 found no difference	Insufficient
Depressive symptoms Psychosocial vs Attention control	3 RCT [356, 369, 370] n=916 52-72 weeks	CG/P	0 of 3 found benefit 3 of 3 found no difference	Insufficient

Outcome Comparison	# Studies/ Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Depressive symptoms Psychosocial vs Usual care	5 RCT [358, 366, 367, 374, 457] n=852 6-24 weeks	CG/P	2 of 5 found benefit 3 of 5 found no difference	Insufficient
Depressive symptoms Psychosocial vs Usual care	5 RCT [224, 355, 356, 363] n=1073 52-104 weeks	CG/P	2 of 5 found benefit 3 of 5 found no difference	Insufficient
Caregiving bother/distress/affect Psychosocial vs Attention control	5 RCT [356, 359, 360, 368, 372] n=952 4-12 months	CG/P	3 of 5 found benefit 2 of 5 found no difference	Insufficient
Caregiving bother/distress/affect Psychosocial vs Usual care	4 RCT[361, 366, 373, 457] n=702 6-24 weeks	CG/P	1 of 4 found benefit 3 of 4 found no difference	Insufficient
Health care usage Psychosocial vs Attention control	2 RCT [365, 368] n=359 3-6 months	CG/P	1 of 2 found benefit 1 of 2 found no difference	Insufficient
Health care usage Psychosocial vs Usual care	2 RCT [362, 375] n=251 4-24 months	CG/P	0 of 2 found benefit 2 of 2 found no difference	Insufficient
Caregiving knowledge Psychosocial vs Usual care	1 RCT [358] n=167 24 weeks	CG/P	1 found benefit 0 found no difference	Insufficient
Quality of life Psychosocial vs Attention control	1 RCT [357] n=132 8 weeks	CG/P	1 found benefit 0 found no difference	Insufficient
Quality of life Psychosocial vs Attention control	2 RCT [356, 368] n=541 24-52 weeks	CG/P	0 of 2 found benefit 2 of 2 found no difference	Insufficient
Quality of life Psychosocial vs Usual care	7 RCT [361, 364, 366, 367, 374, 376, 381] n=843 6-24 weeks	CG/P	4 of 7 found benefit 3 of 7 found no difference	Insufficient
Quality of life Psychosocial vs Usual care	4 RCT [224, 362, 363, 375] n=652 9 months to 2 years	CG/P	1 of 4 found benefit 3 of 4 found no difference	Insufficient
Relationship with person with dementia Psychosocial vs Attention control	4 RCT [354, 356, 368, 477] n=652 20-52 weeks	CG/P	1 of 4 found benefit 3 of 4 found no difference	Insufficient
Caregiving confidence Psychosocial vs Attention control	3 RCT [354, 360, 368] n=428 20-24 weeks	CG/P	2 of 3 found benefit 1 of 3 found no difference	Insufficient
Caregiving confidence Psychosocial vs Usual care	3 RCT[367, 373, 457] n=582 12-24 weeks	CG/P	1 of 3 found benefit 2 of 3 found no difference	Insufficient
Caregiving skill Psychosocial vs Attention control	2 RCT [368, 370] n=545 6-18 months	CG/P	0 of 2 found benefit 2 of 2 found no difference	Insufficient
Caregiving skill Psychosocial vs Usual care	2 RCT [374, 457] n=407 6-16 weeks	CG/P	1 of 2 found benefit 1 of 2 found no difference	Insufficient

Outcome Comparison	# Studies/ Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Caregiving skill Psychosocial vs Usual care	3 RCT [224, 358, 362] n=444 24-52 weeks	CG/P	0 of 3 found benefit 3 of 3 found no difference	Insufficient
Stress Psychosocial vs Attention	1 RCT [372] n=184 6 months	CG/P	1 found benefit 0 found no difference	Insufficient
Stress Psychosocial vs Usual care	3 RCT [355, 366, 367] n=486 6-52 weeks	CG/P	0 of 3 found benefit 3 of 3 found no difference	Insufficient
Social support Psychosocial vs Attention control	1 RCT [368] n=250 6 months	CG/P	1 found benefit 0 found no difference	Insufficient
Social support Psychosocial vs Usual care	2 RCT [367, 376] n=188 12-24 weeks	CG/P	0 of 2 found benefit 2 of 2 found no difference	Insufficient
Caregiving coping Psychosocial vs Usual care	1 RCT [358] n=167 24 weeks	CG/P	1 found benefit 0 found no difference	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; RCT=randomized controlled trial

Variation in Outcomes

By PLWD Characteristics

Only one study identified how PLWD characteristics may influence outcomes. A subgroup analysis for the Farran study (2004) found that data from 143 caregivers of family members with baseline agitated behaviors indicated more reduction of emotional distress with the skill-building intervention than with an information- and support-oriented comparison over an 18-month period. These researchers suggested their findings indicate that dementia caregivers exposed to agitated behaviors can benefit from psychosocial interventions, particularly those aimed at building behavioral management skills.[370]

By Caregiver Characteristics

Only a few studies identified how caregiver characteristics may influence outcomes. Gallagher-Thompson and colleagues (2003) found no differences between Hispanic and non-Hispanic white female caregivers (n=213) in caregiver coping, depression, social support, and caregiver burden 3 months after completing the Coping with Caregiving intervention.[371]

Gallagher-Thompson and colleagues in 2008 investigated differences in caregiver coping, depression, stress, support, burden, and bother between Hispanic and non-Hispanic white female caregivers (n=184).[372] The only differences they found were that non-Hispanic white female caregivers reported higher bother managing neuropsychiatric symptoms at baseline (p=0.03) and post intervention (p=0.010) than Hispanic female caregivers. The two groups did not differ in depressive symptoms or perceived stress before or 6 months after completing a psychosocial intervention.

Gitlin and colleagues (2001) reported that intervention spouses reported reduced upset (p=.049), women reported enhanced self-efficacy in managing PLWD behaviors (p=.038), and women (p=.049) and racial/ethnic minorities (p=.037) reported enhanced self-efficacy in managing PLWD functional dependency.[373]

A moderator analysis of the Gallagher-Thompson (2003) intervention[371] found that caregiver self-efficacy predicted differential outcomes in a randomized trial comparing a cognitive behavior psychoeducational intervention versus an enhanced support group. The four key outcomes were depression, anxiety, social support, and coping. The findings showed that low baseline self-efficacy scores better predicted positive response to treatment in the psychosocial intervention than in the enhanced support group intervention. This study supports the use of self-efficacy as a screening tool for appropriate caregiver intervention assignment.[478]

Otero and colleagues (2015) reported that caregivers younger than 65 years and with higher emotional distress at baseline were more likely than those receiving usual care to improve their depressive symptoms after completing five weeks of a group-based cognitive behavioral program focused on problem solving.[379]

By Intervention Characteristics

No studies investigated whether intervention characteristics modified the intervention effects.

Social Support

Key Points

- Evidence was insufficient to draw conclusions about the effect of in-person social support on PLWD and their CG/P.
- Phone-based social support for CG/P were described in the evidence map but not considered for analysis due to limitations in study designs.

Intervention Description

We defined social support interventions as those targeted to provide information, resources, and a form of social interaction to caregivers of PLWD. Intervention delivery modes could involve talking to peers or other supports in-person or over the phone, or automated support programs that were phone or web-based. Phone and web-based platforms provided some form of social interaction either through automated conversations, voicemail, or chat groups.

Eligible Studies

We identified 13 unique studies from 16 publications (Table 6.4).[479-493] Two studies were assessed as medium risk of bias for the analytic set.[479-481] We provide information on all pilot studies and high risk of bias studies as part of the evidence map in Appendix E.

The two studies in the analytic set were categorized as being in the explanatory stage, or Stage 3 of the NIH Stage Model. One (n=78) was a randomized trial comparing in-person, peer-led mutual support groups for CG/P with usual care.[481] Support groups met bi-weekly over 24 months. The other (n=100) was a randomized trial comparing an automated phone support system for CG/P with usual care.[479, 480] The phone support system included an activity-respite module that engaged PLWD in an 18-minute automated conversation, weekly automated conversations to check stress levels, a personal voice mailbox, and a phone support group "bulletin board" (which functioned like an internet chat group). The support system was available for 22 hours a day over 12 months.[479, 480] Appendix E provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.

Table 6.4. Basic characteristics of literature set: in-person social support

Characteristic	Information
Total Studies	13 studies
Non-U.S. studies	10 studies
Evidence map studies	4 pilot studies 7 high risk of bias studies
Analytic set studies	2 randomized controlled trials
Risk of bias of analytic set	2 medium
Number of PLWD in analytic set	178
Dementia type/definition	All dementia types and severities (primarily AD and cerebrovascular) Probable AD with functional impairments and AD-related disturbing behavior
Caregiver type (number)	Informal caregivers (n=178)

Abbreviations: AD=Alzheimer's disease

Intervention Research Context

The eligible literature on social support services for caregivers generally comprises pilot or explanatory research. Studies were published between 1990 and 2019 and tended to be pilot, small sample, or high risk of bias studies. One intervention did show studies progressing along the NIH Stage Model.[489, 490]

In-person social support approaches included a befriending intervention where volunteers were recruited and trained to befriend CG/Ps.[481, 482, 485, 487] One study examined social support groups that engaged CG/P and PLWD dyads separately and together.[485] The automated social support for CG/P comprised phone-based automated support and web-based automated support. We identified only one study that examined the use of phone-based automated support, which was included in our analytic study set.[479, 480] The lack of additional studies on phone-based automated support may be due to a shift towards web-based platforms as technology has evolved. Four web-based approaches were piloted in Europe.[486, 488, 489] One piloted a tool allowing caregivers to assess their needs for care and support and providing tailored advice as well as links to local support organizations. Two piloted platforms providing information, relaxation exercises, a social networking platform, and allowing caregivers to assess their health and reach out to clinical sites. An additional pilot examining the use of a website to provide stress reduction, support, and information for caregivers was conducted in the United States.[494] The pilots suggested some benefit to web-based social support tools. However, a later small study was assessed as high risk of bias.[490] One study examined email contacts with a specialist dementia nurse with on-line videos and e-bulletins.[493]

PLWD Outcomes

No reportable PLWD outcomes were available from the analytic set.

Caregiver Outcomes

Evidence was insufficient to draw conclusions about in-person social support versus usual care for CG/P. Table 6.5 summarizes the primary outcomes for CG/P. At 28 weeks, findings showed statistically significant differences in Neuropsychiatric Inventory-Caregiver Distress Scale scores between the peer support and usual care groups, with the peer support group reporting lower levels of distress.[481] The peer support group also had statistically significant improvements in quality of life at 28 weeks compared with the usual care group. Groups did not differ in the use of mental health services. No harms were reported.

Evidence was also insufficient to draw conclusions about automated social support versus usual care for CG/P. At 6 months, findings showed no difference between the automated phone-based support group and usual care in depressive symptoms.[479, 480] Additionally, no difference was found between groups in anxiety.[479, 480] No study assessed harms.

Table 6.5. Summary of findings for caregiver outcomes: social support

Outcome Comparison	# Studies/ Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Quality of Life In person social support vs. Usual care	1 RCT[481] (n=78) 28 weeks	CG/P, respite centers in China	1 found benefit 0 found no difference	Insufficient
Caregiver Distress In person social support vs. Usual care	1 RCT[481] (n=78) 28 weeks	CG/P, respite centers in China	1 found benefit 0 found no difference	Insufficient
Depression Automated social support vs. Usual care	1 RCT[479] (n=100) 6 months	CG/P	0 found benefit 1 found no difference	Insufficient
Anxiety Automated social support vs. Usual care	1 RCT[479] (n=100) 6 months	CG/P	0 found benefit 1 found no difference	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; RCT=randomized controlled trial

Variation in Outcomes

No studies reported variation in outcomes by PLWD, caregiver, or intervention characteristics.

Lifestyle Interventions

Lifestyle interventions include a range of interventions targeted at improving the health and well-being of participants, including physical activity, leisure activities, visual arts, and mindfulness, meditation, or spiritually focused activities.

Mindfulness, Meditation, or Spiritually-Focused Activities

Key Points

- Evidence was insufficient to draw conclusions about the effect of mindfulness-based stress reduction on PLWD and their CG/P.

Eligible Studies

We identified 10 unique studies from 10 publications examining mindfulness, meditation, or spiritually focused activities. Table 6.6 summarizes the characteristics of the literature set. Only one study was included in the analytic study set.[495] The study was assessed as medium risk of bias and categorized as explanatory, or Stage 3 of the NIH stage model. Three studies were pilot studies and four studies had fewer than 50 participants.[496-502] Two studies were assessed as high risk of bias due to potential performance bias.[503, 504] We provide information on all pilot studies and high risk of bias studies in the evidence map in Appendix E. Appendix E also provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.

Table 6.6. Basic characteristics of literature set: mindfulness, meditation, and spiritually-focused activities

Characteristic	Information
Total Studies	10 studies
Non-U.S. studies	5 studies
Evidence map studies	3 pilot studies 4 small sample size studies 2 high risk of bias studies
Analytic set studies	1 randomized controlled trial
Risk of bias of analytic set	Medium
Number of PLWD in analytic set	31
Dementia type/definition	Progressive dementia diagnosis
Caregiver type (number)	Informal caregivers (31)

Intervention Research Context

The literature set follows the NIH Stage Model, with most research consisting of pilots and small RCTs. Studies were published between 2010 and 2019, reflecting the relatively recent interest in these types of interventions for CG/P of PLWD. These studies generally used group sessions as the intervention delivery mode, and they focused on therapy or education using mindfulness, religion, or meditation as a main feature of the intervention. Interventions lasted from 5 to 12 weeks. Five studies specifically examined the effect of mindfulness therapy or mindfulness-based stress reduction for CG/P.[495, 496, 498, 501, 502] Two studies examined spiritually based therapy or education.[503, 504] Three studies examined meditation.[497, 499, 500]

PLWD Outcomes

The analytic study set did not report outcomes related to PLWD.

Caregiver Outcomes

One study was included in the analytic set and reported outcomes for CG/P.[495] The study (n=78) randomized CG/P to either mindfulness-based stress reduction or education and support. Evidence was insufficient to draw conclusions about the impact of mindfulness-based stress reduction versus education and support. In both arms, participants attended in-person group sessions over 8 weeks. The education and support group also received support calls by phone. The study reported outcomes for caregiver stress, burden, depression, anxiety, mental health, physical health, and social support at 2 months (immediately post-intervention) and 6 months.[495]

Table 6.7 summarizes the outcomes for CG/P. Groups did not differ significantly at either time point for measures of caregiver burden, social support, or physical health.[495] Participants in the mindfulness group showed statistically significant improvements in mental health versus the education and support group at 2 and 6 months.[495] Participants in the mindfulness group also showed a reduction in anxiety at 2 and 6 months versus the education and support group. At 2 months, participants in the mindfulness group showed a statistically significant reduction in stress versus those in the education and support group. This difference was not sustained at 6 months.[495] However, this was also true for depression, where the mindfulness group showed a statistically significant improvement in depressive symptoms versus the education and support group at 2 months, but not 6 months.[495]

Table 6.7. Summary of findings for caregiver outcomes: mindfulness, meditation, and spiritually-focused activities

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Caregiver Stress Mindfulness vs Active Control	1 RCT (n=78)[495] 2 months, 6 months	CG/P	1 found benefit 0 found no difference	Insufficient
Caregiver Burden Mindfulness vs Active Control	1 RCT (n=78)[495] 2 months, 6 months	CG/P	0 found benefit 1 found no difference	Insufficient
Depression Mindfulness vs Active Control	1 RCT (n=78)[495] 2 months, 6 months	CG/P	1 found benefit at 2 months but no difference at 6	Insufficient
Anxiety Mindfulness vs Active Control	1 RCT (n=78)[495] 2 months, 6 months	CG/P	1 found benefit at 2 months but no difference at 6	Insufficient
Mental Health Mindfulness vs Active Control	1 RCT (n=78)[495] 2 months, 6 months	CG/P	1 found benefit 0 found no difference	Insufficient
Physical Health Mindfulness vs Active Control	1 RCT (n=78)[495] 2 months, 6 months	CG/P	0 found benefit 1 found no difference	Insufficient
Social Support Mindfulness vs Active Control	1 RCT (n=78)[495] 2 months, 6 months	CG/P	0 found benefit 1 found no difference	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; RCT=randomized controlled trial

Variation in Outcomes

The analytic study set did not report variation in outcomes by PLWD, caregiver, or intervention characteristics.

Physical Activity and Other Lifestyle Interventions

Key Points

- No physical activity or other lifestyle interventions advanced from the evidence map for further analysis.

Intervention Description

Physical activity interventions may involve caregivers alone or caregiver/PLWD dyads, and often involve an interventionist encouraging (in person or via phone or through written materials) physical activity, helping with goal setting, and/or supervising the implementation of assigned physical activity.

Eligible Studies

We identified five unique studies from six publications on physical activity interventions[505-509] and four unique studies from four publications focused on other various lifestyle interventions for CG/P.[510-513] Table 6.8 summarizes the characteristics of the literature set. No studies were eligible for the analytic set. Four studies were assessed as high risk of bias due to potential performance bias.[505-507, 509] The remaining study was a pilot.[508] Appendix E presents information on all studies as part of the evidence map.

Table 6.8. Basic characteristics of literature set: physical activity and other lifestyle interventions

Characteristic	Information
Total Studies	9 studies
Non-U.S. studies	5 studies
Evidence map studies	2 pilot study 7 high risk of bias studies
Analytic set studies	0 studies

Intervention Research Context

Studies were published between 2002 and 2018. Generally, this literature did not progress along the NIH Stage Model, as we identified only two pilot studies. One study enrolled CG/P and PLWD dyads to jointly participate in physical activity.[509] Of the five studies that examined physical activity, three focused on phone-based physical activity interventions.[505-507] Phone contact was used to encourage physical activity, set goals, and/or supervise the implementation of assigned physical activity. The remaining two physical activity studies assigned CG/P a physical activity regimen without the use of phone support.[508, 509] Of four studies that examined leisure interventions, two focused on leisure activities or leisure education for CG/P,[510, 513] while two others enrolled CG/P and PLWD dyads.[511, 512] Of the dyad studies, one study compared a structured visual arts education program (with visual arts projects of increasing difficulty) for CG/P and PLWD versus painting and discussion about art.[511] The second study compared providing assistance to female spouse caregivers and PLWD while on vacation versus a waitlist control.[512]

Respite Care

Key Points

- No respite care interventions advanced from the evidence map for further analysis.

Intervention Description

Respite care interventions provide temporary breaks to caregivers of PLWD. Interventions include in-home care for PLWD, adult day care programs, and institutional respite services. These interventions provide breaks for a few hours a day or allow individuals to take a full break from caregiving for a short-term period of time.

Eligible Studies

We identified three unique studies from four publications (Table 6.9).[514-517] All three were assessed as high risk of bias due to potential attrition bias, and were not included in the analytic set. Two studies used a quasi-experimental study design.[515-517] The remaining study was an RCT.[514] We present information on all high risk of bias studies as part of the evidence map in Appendix E.

Table 6.9. Basic characteristics of literature set: respite care

Characteristic	Information
Total Studies	3 studies
Non-U.S. studies	1 study
Evidence map studies	3 high risk of bias
Analytic set studies	0 studies

Intervention Research Context

The studies were published between 1989 and 2019 and compared a range of respite care activities for CG/P versus usual care. One study examined in-home 24-hour respite care for 5 to 14 days,[515, 516] one study examined adult day care for PLWD (twice or more per week),[517] and one study examined a program offering in-home day care versus institutional respite services used at the discretion of CG/P.[514]

Multicomponent Interventions

Key Points

- Intensive multicomponent intervention with education, group discussion, in-home and phone support sessions, and caregiver feedback for CG/P support (i.e. discrete adaptations of REACH II), improved CG/P depression and quality of life at 6 months. (low-strength evidence)
- Evidence was insufficient to draw conclusions about the effect of other forms of multicomponent interventions on PLWD and their CG/P.

Intervention Description

Multicomponent interventions include more than one care technique or delivery method to foster support, expertise, information, or skills for caregivers in order to improve caregiver quality of life and health outcomes. Care techniques and delivery methods found in multicomponent interventions include therapy and support such as counseling (in groups and/or one-on-one, phone-based and/or in person), training (in person with key personnel, one-on-one and/or paired, group, or classroom style, and/or via written materials), supportive feedback, goal-setting, and planning (in any setting, with family members, in groups, and in person or remote/via phone), as well as relaxation and physical exercises. Offered as structured, programmatic approaches to strengthen communication, develop resources and skills, and/or create or maintain relationships for caregivers and PLWD, multicomponent interventions may benefit informal (family) caregivers.

Eligible Studies

Multicomponent interventions targeting quality of life and other outcomes for informal and formal caregivers included seven studies of three different multicomponent interventions across 22 publications on multicomponent interventions.[383, 518-540] All seven multicomponent interventions in the analytic set targeted outcomes for caregivers by offering multiple intervention components within a structured, programmatic approach for community-dwelling caregivers living with PLWD. We provide information on all pilot studies and high risk of bias studies as part of the evidence map in Appendix E. Appendix E also provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.

Table 6.10. Basic characteristics of literature set: multicomponent for CG/P

Characteristic	Information
Total unique studies	22 studies
Non-U.S. studies	13 studies
Total Evidence map studies	4 pilot studies 2 small sample studies 9 high risk of bias studies

Characteristic	Information
Analytic set studies	6 randomized controlled trials 1 pragmatic trial
Risk of bias of analytic set	7 medium/low
Number of PLWD in analytic set	1688
Dementia type/definition	All types of dementia with all stages of severity
Caregiver type (number)	Informal caregivers (1688)

Intervention Research Context

Studies published from 1993 to 2017 tended to be small or high risk of bias, and largely based on pilot or explanatory research. More trials of structured multicomponent interventions, focusing on how treatments correspond to improvement in outcomes for caregivers (via intervention for caregiver and PLWD dyads) appeared in six of the studies.

The literature in the evidence map and the analytic set contains a considerable amount of preliminary work. However, we observed more development along the NIH Stage Model in this set than in most other intervention categories. This literature set demonstrates growth over time toward the development of both pragmatic trials as well as dissemination/implementation research. Specific examples include the REACH II intervention[519, 520] and the RDAD dual-component intervention.[535, 537]

PLWD Outcomes

One study reported benefits for PLWD physical role functioning and depression.[541] Evidence was insufficient to draw conclusions about PLWD outcomes.

Caregiver Outcomes

Table 6.11 provides a summary of findings. Structured multicomponent interventions presented low-strength evidence for improving caregiver depression[519, 520, 528] and quality of life.[535, 541]

Three studies tested an intensive multicomponent intervention aimed at improving outcomes for community-dwelling informal (family) caregivers. The intervention incorporated education, group discussion, in-home and phone support sessions, and caregiver feedback, four components, for CG/P support across a range of characteristics.[519, 520, 528] This intervention was developed to manage behavioral problems, reduce functional dependence, and prevent functional impairment. Low-strength evidence showed reduced depression for CG/P. One U.S.-based study found moderate effect size for depression at 6 months.[482] This result was consistent with a second study that found no difference between groups but improvement over baseline in both intervention and control groups. For outcomes including caregiver quality of life, stress, burden, caregiver support, and nursing home placement, we found too much variation in outcomes definition, measurement, and reporting within [482] and across studies[482, 483, 491] to draw conclusions. An assessment of insufficient evidence does not mean that the intervention is determined to be of no value. Rather, it means that due to the uncertainty of the evidence we could not draw meaningful conclusions at this time.

Evidence was insufficient from three studies to assess one intervention that used a structured, three-component approach comprising in-person counseling sessions, family counseling sessions involving family members whom caregivers invited, and phone counseling sessions for caregivers on-demand across three countries. Evidence was also insufficient from two studies for one intervention examining combined exercise and CG/P support.

Table 6.11. Summary of findings for caregiver outcomes: multicomponent for CG/P

Outcome Comparison	# Studies/ Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Health Combined exercise & support vs. monthly phone calls & mailed bulletins	1 RCT [535, 541] (n=153) 12 weeks	Community-dwelling PLWD and Informal (family) caregivers	1 found benefit 0 found no difference	Insufficient
Depression Counseling sessions (in-person, family, and phone) for caregivers vs. usual care	1 RCT [528, 531, 533] (n=371) 4-6 months	Spouse caregivers living at home with PLWD	1 found benefit 0 found no difference	Insufficient
Caregiver stress perception Counseling sessions (in-person, family, and phone) for caregivers vs. usual care	1 RCT [528, 531, 533] (n=158) 4-6 months	Spouse caregivers living at home with PLWD	1 found benefit 0 found no difference	Insufficient
Depression Education, group discussion, in-home and phone support sessions, and caregiver feedback vs usual care**	3 RCT [519, 520, 528] (n=895) 6 months	Family caregivers (living with or sharing cooking) with PLWD	2 of 3 found benefit 1 of 3 found no difference	Low discrete adaptations of REACH II
Caregiver stress, burden Education, group discussion, in-home and phone support sessions, and caregiver feedback vs usual care**	3 RCT [519, 520, 528] (n=895) 6 months	Family caregivers (living with or sharing cooking) with PLWD	1 of 3 found benefit 2 of 3 found no difference	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings. **Luchsinger et al. compares REACH II to NYUCS interventions and finds no difference between groups but improvement over baseline in both groups.

Abbreviations: n=number; RCT=randomized controlled trial

Variation in Outcome

Studies reported variation in benefit across racial and ethnic groups studied.[519, 528] In one study, spouse caregivers in the intervention experienced significantly greater improvement in quality of life than those in the control group for all included racial and ethnic groups (Hispanic or Latino, white, and black or African-American).[519] Another study reported benefits for both a four-component intervention and a three-component intervention[533] for Hispanic caregivers.[528]

Other Interventions for Caregiver Well-being

Key Points

- Studies of several other types of interventions were described in the evidence map but not considered for analysis due to limitations in study designs.

Intervention Description

This set of diverse interventions included approaches such as support meetings, decision aids, virtual reality experience to increase empathy, and cranial electrical stimulation of the CG/P.

Eligible Studies

We identified six unique studies from seven publications, each examining a unique intervention.[542-547] We provide characteristics of the literature set in Table 6.12, and information on all studies in the evidence map in Appendix E.

Table 6.12. Basic characteristics of literature set: other interventions for CG/P

Characteristic	Information
Total Studies	6 studies
Non-U.S. studies	4 studies
Evidence map studies	3 pilot studies 3 high risk of bias studies
Analytic set studies	0 studies

Intervention Research Context

The literature set was highly varied, comprising unrelated studies that represented earlier stages of the NIH Stage Model. Two studies were conducted in the United States. One study examined support meetings for CG/P to assist in conversations with PLWD about driving cessation.[546] The other study examined cranial electrical stimulation for CG/P to improve sleep.[544] Four studies were conducted in non-U.S. settings. One study examined an aid for CG/P in Australia to make decisions about community services including respite care.[547] Another study examined an aid for CG/P in the United Kingdom to make decisions about place of residence for PLWD.[543] One study in the Netherlands examined virtual reality devices to give CG/P a simulated experience of having dementia.[542] The last study, conducted in the United Kingdom, examined the use of a caregiver-held record folder that included sections for caregiver/family and professional feedback as well as a caregiver diary.[545]

Conclusion

We identified many studies with a large number of participants that investigated the efficacy of care interventions to improve the well-being of CG/P. Applying the framework for care interventions from the NASEM Families Caring for an Aging America 2016 report (Figure 1.1 in Chapter 1), this category included interventions delivered at two levels: the individual level (i.e., psychosocial programs, lifestyle interventions, and multicomponent interventions) and the social or community level (i.e., social support and respite care). The vast majority of studies investigated psychosocial interventions delivered at the individual level. Fewer investigated multicomponent and lifestyle interventions delivered at the individual level. Very few investigated social support and respite care delivered at the social or community level.

Using the NIH Stage Model as a guide, about one-third of studies were pilot studies, and almost all of the others were explanatory, or Stage 3. Only a few multicomponent interventions were Stage 4 pragmatic trials. Of the explanatory studies, two thirds were rated as high risk of bias and excluded from the analytic set. Ultimately, just over 20 percent of the literature was eligible for the analytic set.

Included studies investigated many types of PLWD and caregiver outcomes. Only psychosocial studies examined PLWD outcomes; the most common were function, neuropsychiatric symptoms, and proxy-rated quality of life. Several important PLWD outcomes, such as depression, healthcare use, social support, and nursing home admission, were infrequently investigated. All of the studies investigated outcomes for the CG/P; the most common were depression, quality of life, caregiving burden, and caregiving bother and distress. Several important CG/P outcomes, such as coping, caregiving knowledge, social support, and healthcare use, were infrequently investigated. Other important outcomes, such as those related to resilience and the positive aspects of caregiving, and social health outcomes, such as social isolation, were also missing from the literature.

While the literature set was large, the overwhelming majority of the evidence was insufficient to draw conclusions about whether or not these interventions work. We found, however, that one intensive multicomponent intervention (i.e. discrete adaptations of REACH II) did have low-strength evidence for improving both depression and quality of life among CG/P. Of all included interventions to improve caregiver well-being, multicomponent interventions used the most targeted components. Possibly, these comprehensive interventions addressed at least one critical need (across a wide range of individual caregiver needs), thus improving outcomes. Multicomponent interventions were structured to provide the same components to all participants. Very few studies were delivered at the social and community level. Only 12 studies investigated social support, and just two of these had low to medium risk of bias. The three studies that examined respite care were all assessed as high risk of bias.

About half of the studies were conducted outside of the United States, and all but one of these occurred in high-resource countries. The vast majority of studies conducted in the United States enrolled white urban or suburban dwelling caregivers. Only a few studies investigated Hispanic and African American caregivers and caregivers living in rural and underserved urban areas.

Our assessment of the evidence as insufficient should not be interpreted to mean that we concluded these interventions do not work. Rather, it means that the findings were too uncertain to draw conclusions about their combined effect. Research on interventions to change behavioral and psychological outcomes is challenging, and many factors can influence the outcomes. The insufficient ratings were driven mainly by the inconsistency and imprecision of study findings. For almost every outcome investigated, findings from several trials were inconsistent; some studies found improvement for the intervention group, and some found no difference in outcomes between the intervention and comparison groups. For studies that found no difference, often the comparison groups scores improved more than the intervention group (although not enough to be statistically significant). The findings were also generally imprecise. Our ability to combine results from several studies was hampered by the heterogeneity of the intervention components, duration and intensity of treatment, and comparison groups. Our ability to combine results from several studies statistically was generally not possible, because studies rarely reported the data necessary to calculate effect sizes.

Chapter 7. Care Interventions for Formal Caregivers

This chapter includes care interventions with elements designed to address the well-being of formal caregivers in the workplace. We present Key Points followed by results in three general sections: Intervention Description, Eligible Studies, and Intervention Research Context. Since no studies were assessed as low to medium risk of bias, we present the studies from the evidence map with a brief discussion of what has been examined, and research context. We present detailed information on all eligible studies in Appendix E.

Formal Caregiver Well-being

Key Points

- Studies of interventions to improve formal caregiver well-being were described in the evidence map but not considered for analysis due to limitations in study designs.

About the Intervention

Interventions categorized as targeting formal caregiver well-being include components such as peer support, stress management, and relaxation techniques.

Eligible Studies

We identified three unique studies from five publications that examined interventions to improve the well-being of formal caregiving staff in long-term care facilities.[548-552] (Table 7.1) All were pilot studies. We provide information on all studies in the evidence map in Appendix E.

Table 7.1. Basic characteristics of literature set: formal caregiver well-being

Characteristics	Information
Total unique studies	3 studies
Non-U.S. studies	3 studies
Evidence map studies	3 pilot studies
Analytic set studies	0

Intervention Research Context

The research is very preliminary, with small pilot studies conducted in non-U.S. settings from 2003 to 2015. Similarly to research conducted to support informal caregivers, the Canadian 2003 study tested the premise that education and training to improve skills will reduce formal caregiver stress (in this case as measured by burnout).[551] Later studies examined more direct interventions such as peer support in Australia[550, 552] and stress management and relaxation techniques to reduce job-related stress and burnout in Portugal.[548, 549]

Conclusion

The literature for formal caregivers is preliminary. Possibly, our search algorithm (designed to maximize the ability to find therapies for PLWD) limited our ability to locate related literature. We chose not to include the workforce literature, since this review is focused on the well-being of both PLWD and caregiver. We anticipated that this association would be more prominent in the informal caregiver literature, but not well-studied in the workforce literature.

Chapter 8. Care Delivery Interventions

This chapter includes care delivery interventions intended to improve how care is delivered. These interventions target the organization of care, including the scheduling of staff and tasks as well as the ways in which staff and tasks are interdependent. While care delivery interventions may be implemented through education and training, they differ from most education and training in that they do not aim to improve already established roles and tasks. Instead, they aim to *change* the tasks that are performed, the set of staff who perform the tasks, or the way the staff work together. This chapter is organized into three categories: care service provision, care delivery models or programs, and care staff education and support needs.

For each intervention, we present Key Points followed by results in three general sections: Intervention Description, Eligible Studies, and Intervention Research Context. For interventions with no studies assessed as low to medium risk of bias, we present the studies from the evidence map with a brief discussion of what has been examined as well as the research context. For interventions for which low to medium risk of bias studies were available for an analytic set, we present Outcomes sections by people living with dementia (PLWD), by caregiver, and by variation in outcomes when available. We use the term caregiver/partner, or CG/P, for informal caregiver outcomes. Because we generally could not pool outcomes for any given intervention and comparison group, we synthesized the information qualitatively; therefore, we present summary findings as brief statements of how many studies reported statistically significant benefits or no statistically significant difference between the intervention and the comparator. We present detailed information on all eligible studies in Appendix F.

Care Service Provision

Care service provision refers to the act of providing care for the PLWD. In general business terms, specialized service provision usually requires qualified staff members to be regularly available to perform the services offered. The qualifications needed for staff will depend on the care being provided or supported.

Consultation Services

Intervention Description

Consultation services include individualized and multidisciplinary approaches targeting PLWD as well as their caregivers. Most of the consultants interacted with CG/P not only to improve well-being among PLWD, but also to improve the health of CG/P by improving their overall knowledge for managing dementia and reducing their burden and depression. While this category of interventions has the potential to be very broad, we identified only a few forms examined in the eligible literature, namely a dementia outreach service, individualized consultations, multidisciplinary care consultations, and a needs assessment for older adults.

Key Points

- Evidence was insufficient to draw conclusions about the effect of consultation services on PLWD and their caregivers.

Eligible Studies

Table 8.1 summarizes the characteristics of the literature set. We identified five unique studies that examined the use of consultation interventions for improving quality of life and reducing hospitalizations and depression among PLWD, and improving efficiency of response among CG/P.[553-557] Four studies were assessed as high risk of bias.[553, 555-557] Only one study was included in the analytic set.[554] We present information on the high risk of bias studies in the evidence map in Appendix E.

The included study (n=84) was a randomized controlled trial targeted at family (informal) caregivers. It compared consultation services versus an attention control.[554] The study was assessed as medium risk of bias and categorized as explanatory, or Stage 3 of the NIH Stage Model. Appendix C Tables provide evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.

Table 8.1. Basic characteristics of literature set: consultation services

Characteristics	Information
Total unique studies	5 studies
Non-U.S. studies	4 studies
Evidence map studies	4 high risk of bias studies
Analytic set studies	1 randomized controlled trial
Risk of bias of analytic set	1 medium
Number of PLWD in analytic set	84
Dementia type/definition	All dementia types and severities
Caregiver type (number)	Informal caregivers (84)

Intervention Research Context

The literature on consultation services comprises mostly high risk of bias studies in non-U.S. locations. We identified a dementia outreach study led by nurse practitioners in Australia; the intervention aimed to assist staff at residential care facilities to better manage behavioral and psychological symptoms of dementia (BPSD).[553] We also identified two other Australian studies that used multidisciplinary consultation approaches to help nursing home staff improve care in order to reduce PLWD depression[555] and BPSD.[556] An additional study conducted in the United Kingdom examined a liaison-mediated intervention to reduce unmet needs and improve quality of life among community-dwelling PLWD.[557]

PLWD Outcomes

Evidence was insufficient to draw conclusions about nursing home admission among PLWD who received individualized consultation versus attention control interventions (n=84) [554] Table 8.2 summarizes the findings.

Table 8.2. Summary of findings for PLWD outcomes: consultation services

Outcomes Comparison	# Studies/ Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Nursing home admission Consultation vs Usual Care	1 RCT[554] (n=84) 12 months	PLWD	0 found benefit 1 found no difference	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; PLWD= Persons with Dementia; RCT=randomized controlled trial

Caregiver Outcomes

Evidence was insufficient to draw conclusions about individualized consultation versus attention control (n=84).[554] Table 8.3 summarizes the findings. The study reported no statistically significant improvement among caregivers in physical health symptoms or self-efficacy for managing dementia, and no reduction in caregiver depression or care burden.

Table 8.3. Summary of findings for PLWD outcomes: consultation services

Outcome Comparison	# Studies/ Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Physical health Consultation vs Usual Care	1 RCT[554] (n=84) 12 months	Primary family caregivers	0 found benefit 1 found no difference	Insufficient
Self-efficacy score Consultation vs Usual Care	1 RCT[554] (n=84) 12 months	Primary family caregivers	0 found benefit 1 found no difference	Insufficient
Depression Consultation vs Usual Care	1 RCT[554] (n=84) 12 months	Primary family caregivers	0 found benefit 1 found no difference	Insufficient
Burden Consultation vs Usual Care	1 RCT[554] (n=84) 12 months	Primary family caregivers	0 found benefit 1 found no difference	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; RCT=randomized controlled trial

Variation in Outcomes

Studies in the analytic set did not examine variation in outcomes by PLWD, caregiver, or intervention characteristics.

Case Management

Intervention Description

Case management is a service to support CG/P and their PLWD care recipient. Case managers help coordinate health and social services to support PLWD and their caregivers. Case managers commonly work with CG/P while the PLWD is still living in the community, although case management can also be engaged in nursing homes or other long-term care facilities. We categorized an intervention as case management if the study did not report the case or care manager as being embedded in a team-based care approach.

Key Points

- Evidence was insufficient to draw conclusions about the effect of case management for PLWD and their caregivers.

Eligible Studies

Table 8.4 summarizes the characteristics of the literature set. We identified nine unique studies from 12 publications that examined the use of case management for improving health outcomes for PLWD and their caregivers. Three studies, all non-U.S. settings, were assessed as low to medium risk of bias and included in the analytic set.[558-561] Excluded from the analytic set were high risk of bias studies,[562-567] which we describe in the evidence map in Appendix F. Evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes for the analytic set are also in Appendix F.

Table 8.4. Basic characteristics of literature set: case management

Characteristics	Information
Total unique studies	9 studies
Non-U.S. studies	6 studies
Evidence map studies	1 pilot/demonstration study 5 high risk of bias studies
Analytic set studies	3 (non-U.S.) studies
Risk of bias of analytic set	Medium
Number of PLWD in analytic set	294
Dementia type/definition	Alzheimer's disease or dementia unspecified
Caregiver type (number)	Informal caregivers (294)

Intervention Research Context

Eligible studies on case management were published between 1993 and 2016, although the analytic set was published between 2001 and 2011. The majority were non-U.S. settings, including Australia,[562] Hong Kong,[558, 559, 561] Finland,[560] and the Netherlands.[564] One study compared case management versus consultation services in a nursing home.[562] The remaining studies were community-based. No particular research program in this literature set showed evolution over time, although the majority of studies were explanatory, or Stage 3 of the NIH Stage Model.

PLWD Outcomes

Evidence was insufficient to assess the effect of case management on PLWD outcomes. Table 8.5 provides the summary findings. All studies reported outcomes for PLWD.[558-561] Studies reported mixed results for rate of institutionalization[558-560] and change in dementia symptoms.[558, 559, 561] Groups showed no statistically significant difference for quality of life or depression.[561]

Table 8.5. Summary of findings for PLWD outcomes: case management

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Institutionalization Case management vs usual care	2 RCTs[558, 560] (n=192) 18-24 months	PLWD dementia unspecified	1 of 2 found benefit 1 of 2 found no difference	Insufficient
NPI Case management vs usual care	2 RCT[558, 561] (n=194) 12-18 months	PLWD dementia unspecified	1 of 2 found benefit 1 of 2 found no difference	Insufficient
Quality of Life Case management vs usual care	1 RCT[561] (n=102) 12 months	PLWD dementia unspecified	0 found benefit 1 found no difference	Insufficient
Depression Case management vs usual care	1 RCT[561] (n=102) 12 months	PLWD dementia unspecified	0 found benefit 1 found no benefit	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; RCT=randomized controlled trial

Caregiver Outcomes

Evidence was insufficient to assess the effect of case management on CG/P outcomes. Table 8.6 summarizes the primary outcomes for CG/P. Two studies reported outcomes for CG/P.[558, 559, 561] The studies found mixed results for quality of life and caregiving burden. One study reported no statistically significant difference between groups for caregiver health status.[561]

Table 8.6. Summary of findings for caregiver outcomes: case management

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Quality of Life Case management vs usual care	2 RCT[558, 561] (n=194) 12-18 months	CG/P	1 found benefit 1 found no difference	Insufficient
Caregiver Burden Case management vs usual care	2 RCT[558, 561] (n=194) 12-18 months	CG/P	1 found benefit 1 found no difference	Insufficient
Caregiver health status Case management vs usual care	1 RCT (n=102) 12 months	CG/P	0 found benefit 1 found no difference	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; RCT=randomized controlled trial

Variation in Outcomes

Studies in the analytic set did not examine variation in outcomes by PLWD, caregiver, or intervention characteristics.

Care Protocols for PLWD

Intervention Description

Interventions in this section targeted the health system level and aimed to improve quality of care through the implementation of protocols. Generally speaking, protocols are rules and procedures for providing care in a health system or in units within an organization. They also specify the tools and tasks to be carried out, and can therefore help formal caregiving staff, regardless of their length of service or experience, understand the processes. Protocols can be based on published guidelines or other sources for what are considered best practices. Staff training is an essential process for implementing protocols. Care protocols can be wide ranging, from decision trees to help formal caregivers systematize care decisions to protocols to improve nutrition care. Many protocols addressed agitation in nursing home settings.

Key Points

- Studies of care protocols for PLWD were described in the evidence map but not considered for analysis due to limitations in study designs.

Eligible Studies

We identified 17 unique studies from 25 publications that examined the impact of training and delivery of evidence-based guidelines/protocols targeted toward PLWD. (Table 8.7) We provide information on all studies in the evidence map in Appendix Tables F.[568-583]

Table 8.7. Basic characteristics of literature set: care protocols for PLWD

Characteristics	Information
Total unique studies	17 studies
Non-U.S. studies	11 studies
Evidence map studies	6 pilot or feasibility studies 11 high risk of bias
Analytic set studies	0

Intervention Research Context

Eligible studies on case management were published between 2006 and 2019. The majority were non-U.S. settings, including Australia,[575] Spain,[580] Germany,[579] Norway,[584] Taiwan,[261] and the Netherlands.[568, 581, 582] Using the NIH Stage Model as a framework for assessment, this literature set comprised Stage 3 explanatory studies. A few studies built directly upon a prior publication, showing some evolution of the research over time. With the exception of the one nutrition protocol,[580] the non-U.S. studies were published in the last 6 years and focused on preventing or addressing BPSD in nursing home settings. While also focused on nursing home settings, U.S.-based studies tended to be older publications, published between 2006 and 2012. However, one U.S.-based study tested a decision algorithm to help care managers create care plans to reduce burden and depression among CG/P in the community.[576]

Advance Care Planning

Key Points

- Evidence was insufficient to draw conclusions about the effect of decision support tools for advance care planning on PLWD and their caregivers.

Intervention Description

Advance care planning is a process that broadly involves individuals making healthcare decisions for themselves or for others about future healthcare needs. Within this section, studies focused on family members/caregivers participating in advance care planning as decisionmakers for PLWD unable to make their own decisions. Advance care planning interventions can include a range of tools such as decision support tools or treatment plans, and they usually include some form of discussion with healthcare professionals. Studies in our analytic set focused on the use of decision support tools for advance care planning.

Eligible Studies

We identified nine unique studies from 12 publications.[585-594] Table 8.8 summarizes the characteristics of the literature set. Three studies were pilots [587, 589, 593, 595] and an additional three were assessed as high risk of bias, therefore these six studies are not part of the analytic set.[588, 590-592] We provide information about them in the evidence map in Appendix F.

One study examining the use of decision support tools in advance care planning was assessed as medium risk of bias and is the analytic set.[585, 586, 596-598] This study enrolled PLWD with advanced dementia and their surrogates, and it examined a brief video decision support tool focused on advance directives, goals of care, and burdensome treatments.[585, 586] Appendix F provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.

Table 8.8. Basic characteristics of literature set: advance care planning

Characteristic	Information
Total Studies	9 studies
Non-U.S. studies	3 studies
Evidence map studies	5 pilot studies 3 high risk of bias studies
Analytic set studies	1 cluster randomized controlled trial
Risk of bias of analytic set	Medium
Number of PLWD in analytic set	402
Dementia type/definition	Advanced dementia (type not specified)
Caregiver type (number)	Informal caregivers (402)

Intervention Research Context

Eligible studies on advance care planning were published between 2011 and 2019 and were primarily conducted in the United States. One study took place in an adult-day care setting among African American family caregivers.[587] The remaining studies took place in nursing homes. The fairly recent publication dates of this literature set and the prevalence of pilot studies may reflect increased interest over the last decade in person-centered care and decision support tools. Four of eight eligible studies examined the use of decision support tools.[585, 586, 589-591] The other four studies examined advance care planning conversations between health professionals and CG/P or decision-makers incorporating education, treatment plans, and other tools.[587, 588, 592, 593, 595]

PLWD Outcomes

Evidence was insufficient to assess the effect of advance care planning decision support tools on PLWD outcomes. Table 8.9 summarizes the primary outcomes for PLWD. One study (n=402) reported hospitalization rates at 12 months, finding them similar between the decision support and usual care groups.[586]

Table 8.9. Summary of findings for PLWD outcomes: advance care planning

Outcome Comparator	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Hospitalizations Advance care planning decision support tool vs usual care	1 cluster RCT[586] (n=402) 12 months	Advanced dementia	0 found benefit 1 found no difference	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; RCT=randomized controlled trial

Caregiver Outcomes

Evidence was insufficient to assess the effect of advance care planning decision support tools on CG/P outcomes. Table 8.10 summarizes the primary outcomes for CG/P. One study (n=402) reported outcomes for whether CG/P completed an advance directive for no hospitalization on behalf of PLWD, participated in a goals of care discussion, or stated a preference for comfort care (over basic or intensive care). Groups did not differ for any outcome at 6 or 12 months.[586]

Table 8.10. Summary of findings for caregiver outcomes: advance care planning

Outcome	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Documented Do Not Hospitalize Directive ACP decision support tool vs usual care	1 cluster RCT[586] (n=402) 6 months, 12 months	Advanced dementia	1 found no benefit.	Insufficient
Goal of care discussions ACP decision support tool vs usual care	1 cluster RCT[586] (n=402) 6 months, 12 months	Advanced dementia	1 found no benefit.	Insufficient
Proxies Preferring Comfort Care ACP decision support tool vs usual care	1 cluster RCT[586] (n=402) 6 months, 12 months	Advanced dementia	1 found no benefit.	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: ACP=advance care planning; n=number; RCT=randomized controlled trial

Variation in Outcomes

The analytic set study did not examine variation in outcomes by PLWD, caregiver, or intervention characteristics.

Palliative Care

Key Points

- Studies of palliative care for PLWD were described in the evidence map but not considered for analysis due to limitations in study designs.

Intervention Description

Palliative care interventions aim improve symptom relief, distress, hospitalization burden, and comfort with death among PLWD and their caregivers.

Eligible Studies

We identified five unique studies from six publications that examined the use of palliative care interventions among PLWD.[599-604] (Table 8.11) All studies were either pilots or assessed as high risk of bias. We present information on all studies in the evidence map in Appendix F.

Table 8.11. Basic characteristics of literature set: palliative care

Characteristics	Information
Total unique studies	5 studies
Non-U.S. studies	3 studies
Evidence map studies	1 pilot study 4 high risk of bias studies
Analytic set studies	0

Intervention Research Context

Eligible studies on palliative care were published between 2000 and 2019. The three non-U.S. studies were set in nursing homes.[599, 600, 602, 604] One examined case conferencing in Australia,[599, 600] one examined a multicomponent intervention that included training, communication, routine palliative care tasks, and a nurse facilitator in Canada,[604] and one compared general versus personalized feedback for end-of-life care in the Netherlands.[602] The U.S.-based studies examined palliative care triggered by acute hospital stays for PLWD.[601, 603]

Other Service Provision Interventions

Key Points

- Evidence was insufficient to draw conclusions about the effect of other service provision interventions on PLWD or their caregivers.

Intervention Description

This set of diverse interventions included approaches such as decision aids, technology to assist CG/P, and a tool-kit to assist CG/P in improving the safety of the home for PLWD.

Eligible Studies

We identified five unique studies from seven publications.[596-598, 605-608] Table 8.12 summarizes the characteristics of the literature set. Two studies were a pilot[605, 608] and two were assessed as high risk of bias;[606, 607] these studies were therefore excluded from the analytic set. We provide information about them in the evidence map in Appendix F.

One study was assessed as medium risk of bias and was classified as an NIH Stage 3 explanatory study. This study enrolled PLWD with advanced dementia and feeding issues, along with their surrogates, to compare a print decision aid for feeding options versus usual care.[596-598] Appendix F provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.

Table 8.12. Basic characteristics of literature set: other service provision interventions

Characteristic	Information
Total Studies	5 studies
Non-U.S. studies	2 studies
Evidence map studies	2 pilot studies 2 high risk of bias studies
Analytic set studies	1 cluster randomized controlled trial
Risk of bias of analytic set	Medium
Number of PLWD in analytic set	256
Dementia type/definition	Advanced dementia (type not specified)
Caregiver type (number)	Informal caregivers (n=256)

Intervention Research Context

All studies were unrelated to each other and U.S.-based. Two studies examined video-based telehealth technology to support community-based CG/P.[605, 607] Another study examined a self-directed educational program and home safety tool-kit to improve home safety for PLWD.[606] Another examined a decision aid to help CG/P make decisions about feeding care for their PLWD with advanced dementia and swallowing difficulties.[596] A fourth study examined including PLWD living in nursing homes in care planning meetings.[608]

PLWD Outcomes

Evidence was insufficient to address PLWD outcomes for a decision aid for PLWD feeding. Table 8.13 provides a summary of the findings. At 3 months, the decision aid study (n=256) found a statistically significant benefit with the intervention in the number of PLWD receiving a specialized dysphagia diet.[596] However, groups did not differ for other types of feeding interventions (e.g., specialized utensils, specialized staff assistance, high-calorie diet).[596]

Table 8.13. Summary of findings for PLWD outcomes: other service provision interventions

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Assisted Feeding Intervention-Specialized Dysphagia Diet Decision aid vs usual care	1 cluster RCT[596] (n=256) 3 months	Advance dementia with feeding issues	1 found benefit 0 found no difference	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; RCT=randomized controlled trial

Caregiver Outcomes

Evidence was insufficient to address CG/P outcomes for a decision aid for PLWD feeding. Table 8.14 provides a summary of the findings. One study (n=256) reported outcomes for CG/P decisional conflict, satisfaction with decisions, decisional regret, and feeding discussions with nursing home staff. At 3 months, CG/P who reviewed the decision support tool reported less decisional conflict than the usual care group.[596] Informal caregivers who reviewed the decision support tool also reported more conversations about feeding issues with doctors, nurse practitioners, and physician’s assistants than usual care.[596] However, the groups did not differ in number of conversations with other nursing home staff.[596] Nor did groups differ in measures of decision satisfaction and regret.[596]

Table 8.14. Summary of findings for caregiver outcomes: other service provision interventions

Outcome Comparison	# Studies/Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
Decisional conflict Decision aid vs usual care	1 cluster RCT[596] (n=256) 3 months	Advance dementia with feeding issues	1 found benefit 0 found no difference	Insufficient
Satisfaction with Decisions Decision aid vs usual care	1 cluster RCT[596] (n=256) 3 months	Advance dementia with feeding issues	0 found benefit 1 found no difference	Insufficient
Decisional Regret Decision aid vs usual care	1 cluster RCT[596] (n=256) 3 months	Advance dementia with feeding issues	0 found benefit 1 found no difference	Insufficient
Feeding Discussions Decision aid vs usual care	1 cluster RCT[596] (n=256) 3 months	Advance dementia with feeding issues	1 found benefit for discussions with doctors, PA, or NP. No benefit for other nursing home staff	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; NP=Nurse practitioner; RCT=randomized controlled trial

Care Delivery Models and Programs

We use the term “model” in a generic manner to refer to developed conceptual approaches. We use the term “program” for more clearly identified sets of components and/or protocols. To further distinguish between interventions presented in Chapters 4 – 7 and the care delivery interventions in this chapter, we use the term intervention in a slightly different manner than in previous chapters. Here, we reserve the term intervention only for discretely identified interventions that, if supported by research, could be incorporated into an evidence-based program or model. Person-centered or individualized programs are interventions that are evidence-based, manualized or algorithmic, and ideally built from studies of individual components that may be incorporated into an individualized plan or approach. This differs from the many tailored interventions presented in Chapters 4 – 7, which rely on care staff to use their knowledge and experience to adapt the intervention to the individual receiving care.

Collaborative Care and Care Coordination Models

Key Points

- Collaborative care models (i.e. Care Ecosystems or discrete adaptations of the ACCESS models) may improve PLWD quality of life. (low-strength evidence) This improvement may be very small to small, or it may be larger but concentrated in some not yet identified subgroup of people.
- Collaborative care models (i.e. discrete adaptations of the ACCESS model) may improve system-level markers, including guideline-based quality indicators and reduction in emergency department visits. (low-strength evidence)
- Evidence was insufficient to draw conclusions about all other outcomes for both PLWD and CG/P.

Intervention Description

Collaborative care models use multidisciplinary teams to integrate medical and psychosocial approaches to healthcare for PLWD. Care coordination functions are usually assigned to specific care coordinators. Team members may be co-located or spread across locations with a designated hub. Since care coordination is central to collaborative care models, we include care coordination studies in this section. Collaborative care is organized at the healthcare system level and may be provided through services either in the community or in residential facilities. As such, these approaches try to leverage local care and support resources. Most are aimed at providing CG/P support, along with coordinating care for PLWD. Often, studies required care coordinators or navigators to have a minimum of one contact per month with CG/P, or with PLWD directly. However, contact could be more frequent if necessary for caregivers to accomplish the care plans. Contact took place by phone or internet except in one German study that used in-home visits. Studies ran from 6 months to almost 2 years, but most outcomes were measured at 12 months.

Eligible Studies

We identified 13 unique studies from 32 publications that examined collaborative care. (Table 8.15) We provide information on all pilot and high risk of bias studies as part of the evidence map in Appendix F.[609-614] The analytic set includes seven low to medium bias of bias studies and represents care for 2,597 PLWD.[615-640] Given the pragmatic nature of most of the studies, information on dementia type and severity is less available. Appendix F provides evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.

Table 8.15. Basic characteristics of literature set: collaborative care models

Characteristics	Information
Total unique studies	13 studies
Non-U.S. studies	4 studies
Evidence map studies	4 pilot studies 2 high risk of bias studies
Analytic set studies	5 pragmatic, 2 explanatory studies
Risk of bias of analytic set	6 medium
Number of PLWD in analytic set	2,641
Dementia type/definition	Generally dementia unspecified, usually more mild to moderate
Caregiver type (number)	Informal caregivers (2,405)

Intervention Research Context

This literature falls mainly into Stage 4 of the NIH Stage Model, or mostly pragmatic trial designs, although we did identify a few pilot studies. The pragmatic studies either cited previous evidence-based research or related pilot studies, but we identified no literature showing any collaborative care approach as progressing through all stages of the model. The pragmatic trials appeared along a spectrum of balanced explanatory/pragmatic to fully pragmatic. Most studies were conducted in high-resource locations, including the United States, Germany, Singapore, and the Netherlands. Few studies investigated diverse caregivers. However, one study enrolled 50 percent urban African-American caregivers,[616] and one study used the ACCESS protocol for Latino/immigrant populations in an underserved urban setting.[617] Two high risk of bias studies of multidisciplinary teams, reported in the evidence map, were conducted in nursing homes. One was a relatively large pragmatic trial of 793 PLWD, but only 40 percent of participants received the intervention, leaving it difficult to understand what drove the lack of difference between the intervention and the control groups.[613]

PLWD Outcomes

Six of the seven medium to low risk of bias studies reported outcomes related to PLWD. We synthesized results qualitatively because differences in outcome measures, time to outcomes, and analytic methods prohibited quantitative pooling. The most commonly investigated outcome was quality of life. We also include quality indicators derived from guideline recommendations as PLWD-related outcomes. Table 8.16 summarizes the number of studies investigating each outcome and the number of studies that found a statistically significant benefit or no difference in outcomes for PLWD in the intervention group versus the comparison group.

Quality of life improvement was supported by low-strength evidence from four studies using usual care controls. One large pragmatic study found statistically significant but very small to small benefit using the QoL-AD.[618] Another large pragmatic trial found benefit greater than the established minimally important difference for the health utility index, which indicates the improvement may have been large enough for the study participants to notice the change.[620] Two other trials found no difference for QoL-AD[619] and the health utility index.[617] However, when assessing the strength of evidence, we gave less weight to the findings from these studies due to the smaller sample sizes and other concerns with the statistical analyses they used.

Quality indicators were supported by low-strength evidence drawn from two studies. These indicators were based on adherence to 19 to 23 dementia guideline recommendations in four domains: assessment, treatment, education and support, and safety. Both studies found benefit of about the same magnitude across the quality indicators.[617, 620]

Low-strength evidence also showed a decrease in rate of emergency department visits over a 12-month period.[618] Five PLWD needed to participate in collaborative care to achieve a decrease of one emergency room visit.

Evidence was insufficient for the remaining outcomes. Some outcomes were only investigated by a singlesmall study, making the consistency in findings unknown. Also, the uncertainty regarding a true "no difference between groups" finding versus an "inability to show a difference" finding remained too high. Two studies investigated neuropsychiatric symptoms, but the outcome was assessed as high risk of bias in one, which was therefore not included. One explanatory study found benefit for the neuropsychiatric symptom inventory.[616] Groups did not differ significantly for daily activities of living,[616, 619], depression as measured by the CSDD,[616] or hospitalization or ambulance.[618] Nursing home placement had mixed results.[616, 619]

Table 8.16. Summary of findings for PLWD outcomes: collaborative care models

Outcome Comparison	# Studies/ Design (n analyzed) Timing	Findings	Strength of Evidence*
Quality of Life Collaborative care vs usual care	4 Pragmatic trials[617-620] (n=1,746) 6-18 months	2 of 4 found benefit 2 of 4 found no difference	Low for benefit (Weighted to larger pragmatic trials)
Neuropsychiatric symptoms Collaborative care vs usual care	1 Explanatory cluster trial[641] (n=152) 12 months	1 found benefit 0 found no difference	Insufficient
Function Collaborative care vs usual care	1 Pragmatic trial[619] 1 Explanatory cluster trial[616] (n=560) 6-12 months	0 found benefit 2 found no difference	Insufficient
Depression Collaborative care vs usual care	1 Explanatory cluster trial[616] (n=152) 12 months	0 found benefit 1 found no difference	Insufficient
Quality indicators Collaborative care vs usual care	2 Pragmatic trials[617, 620] (n=559) 6-18 months	2 of 2 found benefit 0 of 2 found no difference	Low for benefit (Weighted to larger pragmatic trials)
Emergency room visits Collaborative care vs usual care	1 Pragmatic trial[618] (n=780) 12 months	1 found benefit 0 found no difference (no difference for hospitalization or ambulance use)	Low for benefit (Weighted to larger pragmatic trials)
Nursing home placement Collaborative care vs usual care	1 Pragmatic trial[619] 1 Explanatory cluster trial[616] 1 RCT[640] (n=794) 6-18 months	0 found benefit 2 found no difference 1 found benefit at 1.6 years but not at 2 years	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; RCT=randomized controlled trial

Caregiver Outcomes

Six of the seven medium- to low-risk-of-bias studies reported CG/P outcomes. Again, we synthesized results qualitatively because differences in outcome measures, time to outcomes, and analytic methods prohibited quantitative pooling. The most commonly investigated outcomes were caregiver burden and depression. Table 8.17 summarizes the number of studies investigating each outcome and the number of studies that found a statistically significant benefit or no difference in outcomes for CG/P.

Evidence was insufficient to draw conclusions about collaborative care versus usual care for CG/P. The inability to combine outcomes from multiple studies made it impossible to show precision in any outcome. Several outcomes were only investigated by a single study, making the consistency of findings unknown. The uncertainty regarding a true “no difference between groups” finding versus an “inability to show a difference” finding remained too high. One study found no statistical difference between groups for quality of life as measured by the EuroQual-5D.[620] Caregiver burden was variably measured with mixed findings. One large pragmatic trial found very small benefit,[618] while the other study reported mixed findings.[617, 619, 620] Caregiver depression was slightly reduced in one large study,[618] but two other studies found no difference.[615-617] One trial reported no difference between groups for caregiver self-efficacy.[618] Another trial found mixed results in quality measures.[615]

Table 8.17. Summary of findings for caregiver outcomes: collaborative care models

Outcome Comparison	# Studies/Design (n analyzed) Timing	Findings	Strength of Evidence*
Quality of Life Collaborative care vs usual care	1 Pragmatic trial[620] (n=408) 18 months	0 found benefit 1 found no difference	Insufficient
Caregiver burden Collaborative care vs usual care	4 Pragmatic trials[615, 617-620] (n=1,719) 6-18 months	2 of 4 found benefit 2 of 4 found no difference (also no difference in several related measures such as role captivity or physical health strain)	Insufficient
Depression Collaborative care vs usual care	3 Pragmatic trials[615, 617, 618] 1 Explanatory cluster trial[616] (n=1,570) 6-18 months	1 of 4 found benefit 3 of 4 found no difference	Insufficient
Self-efficacy Collaborative care vs usual care	1 Pragmatic trial[618] (n=780) 12 months	0 found benefit 1 found no difference	Insufficient
Quality measures Collaborative care vs usual care	1 Pragmatic trial[615] (n=486) 12 months	1 found benefit inunmet needs but no no difference in use of support services or informal helpers	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; RCT=randomized controlled trial

Variation in Outcomes

By PLWD Characteristics

One pragmatic study, the ACCESS study, enrolled primarily white urban caregivers and found variation in outcomes by caregiver education. Those who had not graduated from high school showed greater improvement than college graduates in the quality indicators (44.4 vs 29.5 for the assessment dimension, 36.9 vs. 15.7 for the treatment dimension, and 52.7 vs. 40.9 for the safety dimension [P < .001 for all three]).[632]

The ACCESS protocol was also later tested with a more intensive in-person protocol in an urban Latino population with a large immigrant population. This study also found improvement in quality indicators, further supporting the ACCESS trial. However, they were unable to confirm that more intensive in-person delivery further improved scores. Since the adapted model was also tested with a different population, we could not separate the potential effects of the new model from those of the new population.

By Caregiver Characteristics

The VA Partners in Dementia Care program reported that benefits were larger among CG/P of PLWD with higher baseline cognitive impairment (unmet needs: B=-0.97, p<0.001), caregivers with higher baseline conflict with caregiving (role captivity: B=-0.23, p=0.02), and caregivers of PLWD with higher baseline behavior problems (physical health strain: B=-0.09, p=0.06; number informal helpers: B=0.61, p=0.005).[615]

By Intervention Characteristics

The ACCESS study also reported increased benefit with increased contact between CG/P and providers. For every additional monthly encounter between a health organization care manager and a caregiver, the mean percentage of quality care indicators rose between 10 and 16 percentage points across four quality domains.[631]

Nursing Home-Based Interdisciplinary Individualized Care/Person Centered Care and Dementia Care Mapping

Intervention Description

Similar to Collaborative Care models for community-dwelling PLWD and their CG/P, models and programs to improve care have also been used in nursing home settings. Collaborative Care models incorporate working with CG/P, which means care is personalized to the informal caregivers' PLWD. Programs for nursing home settings focus more on providing individualized care through training formal caregivers to foster PLWD personhood and attending to unmet needs through individualized care plans. These programs support person-centered care structurally through training, embedding caregivers in care teams, and/or providing tools to support systematic observation of factors that enhance person-centered care.

This form of individualized care for nursing homes has been explored predominantly by non-U.S. countries. Only one recent small pilot[642] and one study from 1997 were based in the United States; these studies examined interdisciplinary team approaches to provide individualized care.[643] The remaining locations in which these programs were investigated include the United Kingdom,[644-647] Australia,[648-650] Norway,[641, 651] Germany,[652] and the Netherlands.[653] Because the programs have been tested in non-U.S. long-term care systems, we could not determine their adaptability to U.S. healthcare and support systems. Interpreting the usefulness of the findings would be challenging. For this reason, we did not further analyze these studies, but we briefly describe them in the Intervention Research Context subsection without performing further analysis.

Eligible Studies

We identified 16 unique studies from 22 publications that examined individualized person-centered care in nursing homes. (Table 8.18) We provide information on all pilot and high risk of bias studies as part of the evidence map in Appendix F.[608, 642, 644, 645, 648, 649, 651, 652, 654, 655] Five studies were rated as low to medium risk of bias.[641, 643, 647, 650, 653, 656-659] These studies enrolled

1,722 PLWD with generally moderate to severe dementia. Appendix F provides evidence tables and summary risk of bias assessments.

Table 8.18. Basic characteristics of literature set: individualized person-centered care (non-U.S.)

Characteristics	Information
Total unique studies	16 studies
Non-U.S. studies	13 studies
Evidence map studies	4 pilot studies high risk of bias studies
Analytic set studies	1 pragmatic, 2 balanced, and 2 explanatory studies
Risk of bias of analytic set	5 medium

Intervention Research Context

With the exception of one study from 1996, this literature is relatively recent, with the eight studies published within the last 5 years. The predominant research design involved assigning care facilities to treatment or control study arms. Using the NIH Stage Model, these studies were assessed as Stage 4 and more pragmatic in study design. Problems with ensuring the intervention was actually delivered to the PLWD residents was a common cause of high risk of bias. Study authors were frequently very transparent regarding reporting fidelity to the interventions.

The largest set of literature examined person-centered care based on Kitwood’s framework, generally coupled with Dementia Care Mapping™ (DCM™).[644, 653] DCM™ is an intervention that promotes care practice development. It involves training formal caregivers to apply a systematic approach to observing factors associated with PLWD well-being, and then share the information with staff to support care planning. DCM™ is a trade-marked tool that has been used in several countries including Europe, the United Kingdom, and Australia. Over 60 percent of published trials of DCM™ are in the evidence map as pilots or high risk of bias studies, and results were mixed.[649, 651, 652, 654] Recently, two large pragmatic trials both found no benefit for DCM™, but these trials also reported challenges with ensuring that the intervention was fully and widely implemented.[644, 653]

A few studies in the analytic set used a different structural approach and supported person-centered care within interdisciplinary teams.[641, 647] These larger studies, published in 2018, stemmed from prior work presented in the evidence map, and showed indications that the research was developing along a distinct line of inquiry. These studies noted small improvement in PLWD quality of life and reduction in agitation over 8 weeks to 9 months. However, these program approaches will require further investigation into their sustainability.

Care Staff Education and Support Needs

As noted above, specialized service provision requires qualified staff members to be regularly available to perform the services offered to PLWD or their CG/P. Interventions addressing staff education and support needs include approaches targeted at helping informal and formal caregivers work together to support PLWD well-being.

Caregiver Staff Training

We considered training programs as being at the pilot stage if the training was not embedded in the organizational structure, such that the knowledge or skills developed by the training will sustain across staff turnover.

Key Points

- Studies of training interventions to improve formal caregiver staff knowledge and skills were described in the evidence map but not considered for analysis due to limitations in study designs.

Intervention Description

Formal staff training is intended to improve staff knowledge and facilitate skill-building.

Eligible Studies

We identified 22 unique studies from 23 publications that examined the use of training interventions for formal caregiver staff.[214, 660-680] (Table 8.19) No studies were assessed as low or moderate risk of bias, while two were assessed as high risk of bias. Remaining studies were all pilot or small sample studies. We provide information on all studies in the evidence map in Appendix F.

Table 8.19. Basic characteristics of literature set: formal caregiver staff training

Characteristics	Information
Total unique studies	22 studies
Non-U.S. studies	12 studies
Evidence map studies	12 pilot studies 3 small sample studies 4 training pilot studies (without evidence of sustained training) 3 high risk of bias studies
Analytic set studies	0

Intervention Research Context

Training topics in the evidence map included general education about dementia and dementia care,[668, 669, 678, 680] communication techniques,[660, 663, 671, 672, 679] bathing techniques,[667, 676] identifying and addressing pain,[666, 680] morning care,[677] integrating physical activity into daily routines,[665] sleep,[673] and feeding skills.[661] Several used activities or taught skills targeted at improving behavioral issues,[664, 674] including apathy.[670] One intervention examined training to identify signs of awareness in PLWD with severe dementia.[662] While nursing homes or other long-term care facilities were the most common settings, one study examined education on dementia for acute care hospital staff,[675] and another study examined education for community-based care staff.[663] One examined an online training portal on dementia care available to both formal and CG/P.[668] Non-U.S. locations included Australia, Canada, France, Germany, Taiwan, the United Kingdom, and the European Union.

The research is largely preliminary across a varied set of training interventions. Most interventions stopped at the pilot stage or did not embed the training intervention into the care organization in order that new skills and knowledge would be sustained over time even with staff turnover. Research activity grew between 1999 and 2017, with new unrelated pilot studies scattered throughout the whole period and across locations. We found, however, one small indication of research progressing through the NIH Stage Model. One training intervention (Bathing Without a Battle) published both a small sample initial study[676] and a later larger multisite study that enrolled PLWD with a broader range of dementia severity.[667]

Informal Caregiver Staff Training

Training interventions for CG/P differ from interventions in Chapter 6 because they do not incorporate any psychoeducation or therapy to support CG/P' well-being. They consist, instead, of dementia education and training focused on skill-building with an emphasis on role-training.

Key Points

- Studies of training interventions to improve CG/Ps' knowledge and skills were described in the evidence map but not considered for analysis due to limitations in study designs.

Eligible Studies

We identified 12 unique studies from 12 publications that examined training interventions to improve CG/P skills.[668, 681-691] (Table 8.20) Three pilot studies and five small sample studies were excluded from the analytic study set. Four additional studies were assessed as high risk of bias. We provide information on all pilot studies and high risk of bias studies as part of the evidence map in Appendix F.

Table 8.20. Basic characteristics of literature set: CG/P training

Characteristics	Information
Total unique studies	12 studies
Non-U.S. studies	6 studies
Evidence map studies	3 pilot studies 5 small sample studies 4 high risk of bias studies
Analytic set studies	0

Intervention Research Context

The research is largely preliminary and includes studies examining a varied set of training interventions. Most interventions in the evidence map stopped at the small sample or pilot stage. Research spanned over 20 years, from 1994 to 2015. Studies conducted in the United States were older, from 1994 to 2007, and mostly focused on the role of caregiving, building general dementia caregiver skills, or skills for behavioral management.[681, 684-686, 689, 691] Non-U.S.-based studies, conversely, were published from 2001 to 2015 and were balanced across general care[683, 690] and communication-specific skills.[682, 687, 688] Studies also examined portable training materials in the United States[684] and internet-accessible training materials in the European Union.[668]

Family Education and Partnering

Key Points

- Studies of training interventions to improve formal caregiver staff knowledge and skills were described in the evidence map but not considered for analysis due to limitations in study designs.

About the Intervention

Family involvement interventions provide education, training, and other supports to establishing a collaborative relationship between family members and formal caregivers of PLWD in nursing homes. These interventions seek to improve PLWD well-being through: 1) improving the partnership between the staff and family members to identify unmet needs among

PLWD, and 2) helping family members structure visits to avoid triggering behavioral symptoms in PLWD. Training in communication techniques is prominent.

Eligible Studies

We identified five unique studies from five publications that examined family education and partnership interventions.[76, 692-695] (Table 8.21) Three studies were pilots and two were assessed as high risk of bias, thus none were included in the analytic set. We provide information on all studies as part of the evidence map in Appendix F.

Table 8.21. Basic characteristics of literature set: family education and partnering

Characteristics	Information
Total unique studies	5 studies
Non-U.S. studies	1 study (Australia)
Evidence map studies	3 pilot studies 2 high risk of bias studies
Analytic set studies	0

Intervention Research Context

The research is preliminary, comprising pilot or explanatory studies with design or conduct challenges. Studies conducted in the United States were published from 1999 to 2007. Family Involvement in Care was examined in several studies,[692-694] including a 2011 study in Australia.[76] The 1999 study was a foundation for the Family Involvement in Care program.[694] The Partners in Caregiving adaptation for Special Care Units in the 2007 publication added concurrent staff and family training, thereby broadening the intervention focus beyond primarily family members.[695] PLWD outcomes were not prominent in this literature set; outcomes primarily applied to family members and staff.

Multitier Training

Multitier training interventions involve formal caregivers being trained to provide training to CG/P for specific care needs of the PLWD.

Intervention Description

This literature set comprises mostly practice guideline-based interventions encompassing multidisciplinary care interventions. These interventions aimed to improve communication between PLWD and their caregivers, and used nutrition and activity planning to help improve various aspects (psychosocial, physical, and behavioral) related to better functioning among PLWD and their caregivers.

Key Points

- Evidence was insufficient to draw conclusions about the effect of multi-tier training on PLWD and their caregiver.

Eligible Studies

Table 8.22 summarizes the characteristics of the literature set. We identified seven unique studies from nine publications that examined the use of training plus delivery of evidence-based guidelines/protocols for caregivers, with the goal in improving their own health outcomes as well as the health outcomes of PLWD.[696-702] One study was assessed as high risk of bias[697] and five were pilots.[696, 698, 700-702] Only one study was included in the analytic set.[699] We provide information on the high risk of bias studies in the evidence map in Appendix F.

The included study (n=95) was a randomized controlled trial targeted toward family (informal) caregivers. The trial compared STAR-C (interactive sessions between community consultants and caregivers) with routine medical care.[699] It was assessed as medium risk of bias and categorized as explanatory. PLWD were eligible if they were community dwellers living with their caregivers and had a probable diagnosis of AD (with moderate cognitive impairment). Family caregivers were also enrolled in the study. Appendix F provide evidence tables, summary risk of bias assessments, and strength of evidence for key comparisons and outcomes.

Table 8.22. Basic characteristics of literature set: multitier training

Characteristics	Information
Total unique studies	7 studies
Non-U.S. studies	2 studies
Evidence map studies	5 pilot studies 1 high risk of bias studies
Analytic set studies	1 randomized controlled trial
Risk of bias of analytic set	1 medium
Number of PLWD in analytic set	95
Dementia type/definition	Moderate cognitive impaired probable Alzheimer's disease
Caregiver type (number)	Informal caregivers (95)

Intervention Research Context

The literature on multitier training interventions comprises mostly pilot and high risk of bias studies. Four studies were conducted in United States[697, 699, 701, 702] while the others occurred in the United Kingdom[696, 700] and Finland.[698] We identified a manual-based intervention targeted at improving caregiver's understanding of sleep and dementia.[696] We also identified a study that provided caregivers with instruction on how to recognize pain among PLWD.[697] Also evaluated was an intervention that used tailored nutritional guidance on the basis of the food diaries to prevent weight gain among PLWD.[698]

PLWD Outcomes

Evidence was insufficient to draw conclusions on quality of life and memory or behavioral problems of PLWD using the STAR-C intervention versus routine medical care (n=95).[699] Table 8.23 summarizes the primary findings.

Table 8.23. Summary of findings for PLWD outcomes: multitier training

Outcome Comparison	# Studies/ Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
RMB-PC STAR-C vs RMC	1 RCT[699] (n=95) 2 months	Probable Alzheimer's disease	0 found benefit 1 found no difference	Insufficient
Quality of life STAR-C vs RMC	1 RCT[699] (n=95) 2 months	Probable Alzheimer's disease	0 found benefit 1 found no difference	Insufficient

*Insufficient ratings due to study limitations and imprecision in the findings.

Abbreviations: n=number; RCT=randomized controlled trial; RMB-PC=revised memory and behavior checklist; RMC=routine medical care

Caregiver Outcomes

Evidence was insufficient to draw conclusions about using the STAR-C intervention versus RMC (n=95) training plus delivery of evidence-based guidelines/protocols targeted toward caregivers. (Table 8.24)

Table 8.24. Summary of findings for caregiver outcomes: multitier training

Outcome Comparison	# Studies/ Design (n analyzed) Timing	Population	Findings	Strength of Evidence*
CES-D STAR-C vs RMC	1 RCT (n=95) 2 months	Primary family caregivers	1 found benefit 0 found no difference	Insufficient
HDRS STAR-C vs RMC	1 RCT (n=95) 2 months	Primary family caregivers	0 found benefit 1 found no difference	Insufficient
Caregiver burden STAR-C vs RMC	1 RCT (n=95) 2 months	Primary family caregivers	1 found benefit 0 found no difference	Insufficient
Caregiver reaction STAR-C vs RMC	1 RCT (n=95) 2 months	Primary family caregivers	1 found benefit 0 found no difference	Insufficient
Caregiver sleep questionnaire STAR-C vs RMC	1 RCT (n=95) 2 months	Primary family caregivers	0 found benefit 1 found no difference	Insufficient

Abbreviations: CES-D=Center for Epidemiological Studies Depression Inventory; HDRS=Hamilton Depression Rating scale; N=number; PLWD= Persons with Dementia; RCT=Randomized Controlled Trial; RMC= Routine medical care; STAR-C= staff training in assisted living residences-caregivers

Conclusion

We found 123 unique studies that investigated 11 care delivery interventions to improve how care is delivered. We grouped the 11 intervention categories into three main themes of care service delivery, care delivery models and programs, and care staff education and support needs. These care delivery interventions conform well to the framework for care interventions from the NASEM Families Caring for an Aging America 2016 report (Figure 1.1 in Chapter 1), delivering the interventions at the system level.

We found collaborative care models (i.e. discrete adaptations of the ACCESS[620] or Care Ecosystem[618]) may improve PLWD quality of life. It is difficult to estimate an effect size from a qualitative synthesis of study results. The largest, rigorously designed study found a statistically significant improvement in quality of life, but the effect size was very small. Based on reported data, we could not determine whether the average effect was broadly distributed across the full study population, but too small of a benefit to be noticeable by PLWD, or if the benefits were largely concentrated in some not yet identified subgroup of PLWD for whom the improvement would be noticeable. The other pragmatic trial also found improvement in health-related quality of life, with the average change being greater than what is considered a minimally detectable difference. These two studies may represent the range of possible effect sizes.

We also found collaborative care models may improve system-level markers, including guideline-based quality indicators and reduction in emergency department visits. Cost was not presented as an outcome. Cost data for the interventions was provided, but a cost-effectiveness analysis is outside the scope of this review.

For the remainder of the PLWD and CG/P outcomes for collaborative care, and for all other care delivery interventions, we found the uncertainty of the evidence was too high to draw conclusions. However, our being unable to draw a conclusion does not mean that the intervention has no effect. Research on interventions to change behavioral and psychological outcomes is challenging, and many factors can influence the outcomes. Future research may reduce uncertainty enough to allow for conclusions about the effect of these interventions, including potential benefits.

Chapter 9. Implementation of Care Interventions

This chapter addresses Guiding Question 1 on providing context for implementation and dissemination of care interventions. We present the results of the grey literature search conducted to provide resources for care interventions which may not have been empirically studied using study designs required by the review inclusion criteria. Because so few interventions were assessed to have at least low-strength evidence to support our review findings, we were concerned that providing implementation and dissemination information based only on those studies would leave readers with an unbalanced or skewed view of implementation and dissemination. Therefore, we do not report on this evidence here.

Grey Literature Search

We searched 15 different sources from the grey literature (i.e., research or other written material produced outside of traditional academic publishing) during April, 2019 to identify repositories of care interventions and criteria for evaluating and/or categorizing care interventions for people living with dementia (PLWD) and their caregivers. Most of these sources provided educational materials, webinars, and information on research and policy. However, three housed lists or libraries of interventions: the Benjamin Rose Institute on Aging, Family Caregiver Alliance, and Rosalynn Carter Institute for Caregiving. Subsequently, the Benjamin Rose Institute on Aging, in partnership with the Family Caregiver Alliance and the Gerontological Society of America, has formally launched their online resource for caregiving for dementia, the Best Practice Caregiving resource (see https://www.benrose.org/best-practice-caregiving). The Rosalynn Carter Institute has since discontinued their online resource.

The Best Practice Caregiving resource, a free online searchable database, provides information about programs for informal caregivers. The standard of evidence used by this resource differs substantially from that of this review. To be listed in the Best Practice database, a program needed to have at least one published statistically significant benefit for a caregiver outcome from a study of any empirical research design, plus have been implemented in at least one organization's regular service portfolio. The published research needed to be U.S.-based and have at least 50 percent of the informal caregivers providing care to PLWD.

The Family Caregiver Alliance provides a list of interventions (formerly their "Innovations Clearinghouse") for family caregivers of people with chronic disabling conditions. Housed under an umbrella of "program development," this list groups interventions into three categories: evidence-based practices, emerging practices, and model programs. The list is partially searchable, and the options under the program development umbrella can be narrowed by caregiver role or specific topics. Again, the standard of evidence used by this resource differs substantially from that of this review. The website does not provide uniform criteria to evaluate implementation readiness of level of evidence. Practices categorized as evidence-based are published in the literature after 1990, and must provide credible evidence for improved caregiver outcomes. Additionally, included publications must provide adequate information on methodology to allow for replication (see https://www.caregiver.org/evidence-based-practices). Emerging practices must use innovative methods and/or focus on underserved populations in diverse settings and populations (see https://www.caregiver.org/emerging-practices). Model programs are selected based on expert input, and must have been proven effective, replicated, or adapted, and provide training materials (see https://www.caregiver.org/model-programs). Both emerging practices and model programs must be from a credible source and remain available for the foreseeable future.

A fourth source, the Administration for Community Living (ACL), through its National Alzheimer's and Dementia Resource Center (NADRC) (see https://nadrc.acl.gov/node/140) provides a report compendium listing dementia specific evidence-based and evidence-informed interventions that have been implemented through its grant programs. The interventions meet the ACL criteria and have been implemented by Alzheimer's Disease Supportive Services Program (ADSSP), Alzheimer's Disease Initiative Specialized Supportive Services (ADI-SSS) and Alzheimer's Disease Program Initiative (ADPI) grantees from 2007 to 2018.

Chapter 10. Discussion

Overview

This systematic review sought to assess the evidence base for effective care interventions for people living with dementia (PLWD) and their caregivers. Our findings were intended to support the task of identifying which approaches are ready for wider dissemination and implementation. In a society experiencing unprecedented population longevity, this is a crucial task. To accomplish it, we tried to identify interventions and programs supported by evidence that met a minimum threshold of quality. We identified 595 unique eligible studies discussed in 850 publications, in which we found a remarkably diverse set of interventions. We used the NIH Stage Model framework to classify the interventions into pilot, explanatory, and "real world" pragmatic trials. This classification method allowed us to focus on the studies within this literature set that were best designed to look for real-world effects. We also removed from consideration studies with the potential to bias the outcomes due to concerns with study design or conduct.

Ultimately, we uncovered no moderate- or high-strength evidence to support care interventions and programs for active, widespread dissemination. We found low-strength evidence that collaborative care models(i.e. Care Ecosystems or discrete adaptations of the ACCESS models), may improve quality of life for PLWD and health system-level markers, including improvements in guideline-based quality indicators and reduction of emergency room visits, but the evidence was insufficient for informal caregiver outcomes. We also found low-strength evidence that an intensive multicomponent intervention, REACH II or discrete adaptations, improved informal caregiver depression and quality of life at 6 months.

For all other interventions and outcomes, we found the evidence was insufficient. This does not mean that none of the individual interventions described are potentially useful for individual PLWD, their caregivers, or healthcare systems. Rather, it means that current available evidence cannot yet provide clear answers about which interventions offer consistent benefits. Therefore, the uncertainty of the evidence is too high for us to draw conclusions, at present. Further, when the evidence overall does not find a difference between groups, uncertainty is even higher about whether the lack of difference is truly because the interventions being compared did not differ in effect, or because the studies were designed to detect *differences* rather than *no difference*.

The lack of sufficient evidence to support widespread dissemination of all other interventions analyzed in this review leaves PLWD, caregivers, programs that support PLWD and caregivers, funders, and policymakers without clear answers. These groups, when deciding whether to disseminate or implement these interventions, will continue to depend on subjective observations, low-quality evidence, economics, and local and institutional policies. For individual PLWD and caregivers, trial and error with interventions, either one at a time or in combination, will likely continue as the norm.

Strengths and Weaknesses of the Review

We determined the methods for this review in order to best answer the question of readiness for broad dissemination. Decisionmaking through this lens has implications for our findings.

We also adopted a review scope based on concerns about whether results from a literature search would give a biased view of interventions to address symptoms, safety, or quality of life, all of which overlap with frailty in older adults. For example, if falls risk and prevention differs greatly between older adults with and without dementia, then research that specifically targets dementia would be useful. Without a big difference in outcomes, study populations likely remained mixed and these studies were screened out. Therefore, some specific approaches for a particular intervention, or even whole classes of interventions, may not have been captured. Similarly, we may have missed some community services and support approaches such as tool kits, referral services and links, or awareness-raising outreach. The case management literature revealed some of these studies, but search terms are diffuse and may have resulted in some studies being overlooked.

Our approach not to advance pilot, small sample, and high risk of bias studies to full analysis resulted in a very high-level assessment of the state of the science. It is possible that in many instances, the inclusion of the preliminary literature may have provided enough data for quantitative pooling for specific outcomes. Systematic reviews of specific interventions can investigate and report very fine details. This review was not intended for that purpose. Our use of the NIH Stage Model as a framework to focus on studies that would best support broad dissemination precluded reporting deeply on pilot studies. Additionally, current guidance for EPC program methods supports not looking to studies assessed as high risk of bias to fortify what is already at best low-strength evidence.[703] Lastly, small-study bias in reporting large effect sizes presents an important issue in a literature set where the majority of research is preliminary.[704]

Because we excluded studies with fewer than 10 participants per study arm, we may not have identified some interventions with very preliminary research supporting them. We accepted this limitation because exact precision for the research context findings was not feasible due to the wide range of care approaches and large literature set. Likewise, our decision not to include single-arm pre/post or evaluation studies limited our ability to address practices supported through evaluation studies.

Our approach to risk of bias assessment was generous, compared with how risk of bias is assessed in more targeted systematic review topics. In part, we based this decision on the unusually varied studies included in this review as well as the complexity of dementia and its associated care approaches. We allowed attrition to reach relatively high levels before assigning high risk of bias. Likewise, we treated fidelity generously, giving credit based on relatively brief mention. Concurrent treatments for specific interventions aimed at PLWD, especially for behavioral and psychiatric symptoms of dementia, were given a secondary position in the assessment. Unfortunately, studies rarely presented such information in a way that would allow for a sound evaluation of the implication for bias.

We also used the truncated risk of bias approach for studies assessed as pragmatic. The use of the PRECIS-2 tool in systematic reviews is preliminary for classifying and understanding the relative pragmatism in research design. We conservatively used a threshold approach, classifying studies as mostly explanatory, pragmatic, or balanced. We further labeled studies that were mostly pragmatic as good, fair, or marginal based on the analytic techniques. All of this represents modifications to EPC systematic review methods as we expand the boundaries of the topics systematic reviews are being asked to address. We cannot say with certainty how the practices used here affect the findings, regardless of whether we used more or less conservative methods for any particular finding. Nonetheless, as systematic reviews attempt to answer increasingly complex questions, we must find novel ways to answer them. The experiences from this review process may help inform future efforts.

Finally, given the already expansive breadth of this topic, our systematic review and meta-analysis is naturally reductionist in nature. That is, small but true differences may exist between many of the interventions within the various intervention categories we created for summarizing outcomes.

Future Research

The questions of “what works” in dementia care and how to deliver that care greatly interests researchers, funders, care providers, healthcare systems, and PLWD and their families. The intensive investment in dementia funding at the federal level reflects the increasing public health importance not only of finding a way to prevent and treat dementia, but also of developing and eventually disseminating optimal dementia care and caregiver programs. While our review offers no firm conclusions, our findings provide valuable insights for the further development and improvement of dementia care science.

Current practice regarding how PLWD are diagnosed, treated, and supported throughout the disease trajectory are underpinned by concurrent and sometimes overlapping streams of research on dementia diagnosis and medical treatment, geriatric and chronic disease models of care, and dementia care support. [705] Together, these streams of research have informed best practice recommendations for dementia care,[706, 707] including the central idea that support for needs of family caregivers should be incorporated into any care plan.[707]

Methodological Rigor

Dementia care research has been slow to incorporate key elements of rigorous intervention design. Until relatively recently, many dementia care and caregiver intervention studies were not held to pre-registration of trials, data safety and monitoring boards, or other standards more common in other areas of clinical science including reporting standards required by journals (e.g., the Consolidated Standards of Reporting Trials (CONSORT) statement). As a direct result, despite a few positive findings, we reached the global conclusion that the evidence is insufficient to say with certainty that interventions were beneficial or not.

Federal funding requirements have instigated change in favor of oversight and reporting mechanisms that will likely lead to more transparent and reproducible research. However, many of these improvements in rigor did not occur until late 2015 and 2016, which coincided with increased investment in research on dementia care interventions. Therefore, many of the trials initially subject to more stringent data monitoring oversight and reporting are just now ending, and their findings have yet to be captured in reviews such as this one. This new, more rigorous research base will hopefully propel future comprehensive reviews to draw conclusions beyond insufficient evidence. Indeed, we did note an improvement in rigor from 2016 to 2017 in the published eligible studies.

In order for federal funders and stakeholders to fulfill their goal of expediting the translational pipeline of idea development to implementation, critical improvements must be made in dementia care and caregiver research. Only with such improvements will we be able to draw clearer, less ambiguous conclusions related to efficacy.

Populations

During the topic refinement period for this review, we received many requests to ensure that certain groups that experience dementia were included as research participants in the examined literature. However, the published research rarely included many important populations. For example, people with Down syndrome aging into dementia were absent, despite our later *ad hoc* literature searches to assure no relevant studies were missed. People with frontotemporal dementia were rarely included, and the few identified studies were limited to pilot or small sample studies. Few studies addressed racial or ethnic differences, and those that did were limited to major race/ethnic categories of Black/African American or Hispanic/Latinx. No study specifically studied LGBTQ populations. Likewise, culturally sensitive or culturally adapted interventions were rare. Some identified non-U.S. based research may help inform future intervention adaptations for PLWD or caregivers with immigrant or related racial/ethnic heritages.

Lastly, we identified very few studies of interventions specifically designed for low-resource areas (including rural and/or tribal communities) beyond pilot or small sample studies, which could not reach any level of certainty of the finding. All of these populations represent areas for future research.

Outcomes

Ultimately, care interventions aim to support quality of life and well-being and prevent harm for PLWD and caregivers, while enabling both to continue in their roles within their families and society. Unfortunately, quality of life was often not measured, and rarely as the outcome of primary interest. Further, PLWD and caregivers exist in relationships with one another, and this literature offers little to help us understand how they change in concert within their dyadic relationship. We attempted to address this issue by placing PLWD and caregiver outcomes adjacent to one another within the results section for each intervention; however, no clear patterns emerged. However, research would be improved by better measures for psychosocial outcomes in PLWD, and better methods of measurement.

Harms were rarely assessed. Although studies frequently measured caregiver burden, they far more often sought to observe reduction in burden than to check for increased burden. Other harms, such as elder abuse, were completely absent.

Additionally, the progressive nature of dementia and the anticipated increase in care needs complicates this research. Studies may be challenged to identify improvement in caregiver burden scales, because the goal of the intervention may in fact be to slow the rate of burden. Studies may be underpowered to detect such a small effect, or small benefits may be overwhelmed by the larger context, including social and financial implications, of caring for a person with a progressive condition.

Lastly, even within intervention categories, outcomes were variably measured and reported. More consistency in the outcomes measured would make it easier to assess bodies of evidence for specific interventions, or to understand how outcomes may differ by setting.

Interventions

The wide range of identified interventions, and the relationships between PLWD and caregivers, highlight the importance of understanding potential intervention mechanisms. We found low-strength evidence that multicomponent interventions may improve select outcomes, but the underlying question of what drives the benefit (i.e., the specific set of components, the mere presence of a multicomponent approach, or both) remains unanswered.

One anomaly of note in our findings is that while evidence was insufficient for all individual interventions, low-strength evidence showed that multicomponent interventions (i.e. discrete adaptations of REACH II) or collaborative care models (i.e. Care Ecosystems or discrete adaptations of the ACCESS) could improve some outcomes. On the surface, this finding appears contradictory to our global finding of insufficient evidence for all individual interventions. After all, theoretically, multicomponent interventions incorporate individual intervention components that have been shown to work. This discrepancy in our findings suggests two possibilities to explore with further research. One is that adequate support structures at the health system level, such as those provided by the REACH II[519] or Care Ecosystems interventions,[618] are crucial factors in addressing the needs of PLWD and their caregivers. Another possibility is that the particular set of interventions may matter less than whether PLWD and caregivers feel supported adequately at the health-system level. Perhaps such structural supports, although not specifically examined or measured in this literature, add significant value to the interventions applied within them.

Lack of consensus about taxonomies to classify interventions hampers the work of assessing this evidence base. We found a lack of precision in how individual interventions were described within specific intervention classifications, and this imprecision inhibits understanding. Many research publications used vague and inconsistent terminology for what constituted a specific intervention, especially given the broad range of baseline dementia severity. For example, we found lack of clarity in the differentiation between cognitive rehabilitation (aimed at restoring daily activity function) and cognitive training activities (cognitive drills that lack direct relationship to completion of daily activities). Authors often used both terms to describe intervention components within a single article. Clearly defining the classes of cognitive rehabilitation interventions would improve comparability across studies, as would specifying which interventions are suitable for PLWD with varying degrees of dementia-related impairment. This is made evident by the extent of misclassification across various systematic reviews and meta-analysis of the effectiveness of dementia caregiving interventions[13] For example, in a synthesis of reviews, Gaugler and colleagues found that among eight meta-analyses and systematic reviews that considered psychoeducation/skills building, 45 individual interventions were inconsistently classified. One review classified them as psychoeducational/skills building interventions, another placed them in an entirely different category.[13] Although taxonomies exist to improve the reporting of elements of dementia care and caregiver support interventions,[708] studies often neglect to use them. Improved reporting of dementia care interventions through the use of taxonomy strategies, either in outcome evaluations or protocol reports, would enhance the ability of reviews such as this one to better classify interventions and thus improve inferences of efficacy/effectiveness.

Complex Interventions for Complex Systems

Most importantly, the care approaches examined in this review represent complex interventions nested within complex systems. The framework for care interventions from the NASEM Families Caring for an Aging America 2016 report displayed in Figure 1 in the Introduction sought to display this idea graphically. Complex systems, by their nature, always encompass some level of uncertainty; indeed, such irreducible uncertainty is a defining element of complex systems. In this literature, the multiple levels of uncertainty are difficult or impossible to overcome. Therefore, we must emphasize again that low-strength evidence is already a difficult bar to reach. Insufficient evidence, places where the evidence is very uncertain, means we could not, with integrity, say that a care approach is beneficial or not—which, as we have noted, is different from saying it does not work.

For example, even when a care approach focuses on a “lower” complex system level—such as the simple addition of aromatherapy to help a person feel calmer—the challenge is still steep to design a study that rules out all competing influences on that person’s sense of calmness. And if the effect is small, or moderate but for only a very select group of people, that effect becomes difficult to see in the data, and uncertainty in the findings remains high.

A further problem with researching complex interventions is that complex systems tend to be self-preserving.[709] Traditional research rests on an assumption that the way the overall process functions does not change as a result of being intervened upon. Yet, a defining feature of a complex system is its ability to adapt to change, even if it takes great effort to propel it from one state of homeostasis toward another, different one. And, when the system does arrive at a new state, it may not be the desired one, but instead an unanticipated adaptation. As a simple example, an intervention may teach staff how to do a new task intended to bring about a desired outcome. But the staff may look for ways to preserve the familiarity of their previous methods, and therefore devise work-arounds. Or they may feel the need to preserve efficiency overall, and make trade-offs in other areas of work. These modifications may multiply across the system as people adapt to the new approaches or requirements.

Many care approaches may actually be aimed, at least in part, at shifting the care culture. As the apex of complex systems, culture is highly diffuse. Yet, culture tends to shift through specific activities that gain traction over time. We see clear examples of this in Veteran-centered care in the United States, or person-centered care in non-U.S. settings. In both examples, training focuses on a relationship-based approach that reframes how caregivers perceive PLWD. Specific activities and tasks are considered secondary, and perhaps even a natural outcome, of this shift in perception and relationship.

Certainly, research is lacking in regard to how components in complex interventions interact to influence key outcomes. The prevailing approach in the dementia care literature is to develop an intervention with multiple components, and deliver it to determine efficacy on caregiver or PLWD outcomes; whether a single or select number of components are essential to an effect (if it exists) is generally unanswered. This has important and adverse implications for the field as a whole, and reduces the dissemination and implementation potential of dementia care interventions. This problem escalates as interventions increase in complexity due to the time, cost, and training requirements to deliver them successfully. In other domains of the intervention literature, approaches such as the Multiphase Optimization Strategy (MOST) have been applied to increase understanding of how singular intervention components interact to influence key outcomes prior to efficacy testing.[710] Such approaches may expedite the timeline from intervention development to potential implementation by crafting and evaluating interventions that are distilled to their essential components. Additionally, these approaches may offer greater insight into not just *whether* an intervention works, but *why*. It would also be helpful if researchers were to conduct and publish process evaluations of dementia care interventions that better described the mechanisms of benefit. Relatedly, basing dementia care and caregiver interventions on theories or conceptual models to test such mechanisms is an essential component of the NIH Stage Model. These theories and conceptual models should inform the design and evaluation of future dementia care interventions.

Intervention Fidelity

Whether interventions are simple or complex, problems with fidelity are significant for this research. Many studies reported no differences between groups. If an intervention showed benefit, delivery of a sufficient dose is assumed. Conversely, if no difference could be demonstrated, the reader is left with uncertainty about whether the dose was large enough. We used a liberal approach to fidelity while assessing risk of bias. Had we imposed a firm restriction on some form of fidelity measure, much or most of the literature would have been excluded.

Even so, problems with fidelity often contributed to high risk of bias. Unfortunately, fidelity assessment approaches lack consensus regarding both the components and how to measure them.

Further, we note that this research treats the concept of fidelity to intervention in training and formal caregiving differently than fidelity to intervention by informal caregivers. Informal caregivers have arguably the best incentives to help PLWD, which would motivate fidelity. However, many factors may inhibit fidelity even when desired. Although companion publications may use mixed-methods research to probe informal caregivers' views on an intervention, the question of whether interventions are delivered as designed and trained is rarely tracked for informal caregivers.

Implementation

Overall, the evidence we reviewed suggests that to consider questions related to dissemination and implementation at the outset of intervention design would result in more dementia care and caregiver interventions becoming ready for rapid implementation in real-world settings. For example, incorporating measures or indicators of implementation (e.g., appropriateness, feasibility, acceptability, cost) alongside clinical outcomes of efficacy/effectiveness would expedite the timeline from dementia care intervention development and evaluation to dissemination and implementation. That, in turn, would help the interventions that demonstrate efficacy to reach and benefit those who need and desire them.[711]

Threats to scalability in dementia care include reliance on interventions that require extensive training and fidelity monitoring; too great a need to rely on the original developers of the intervention; a requirement for highly trained and skilled professionals to deliver the intervention; highly complex, intense, and costly interventions; lack of implementation manuals; and lack of payment mechanisms to ensure sustainability.[712]

Further, implementation will also differ by setting. Future attempts to transfer or modify interventions to assisted living facilities could be helped by a better understanding of implementation factors. Assisted living facilities were among the least studied settings in the included literature.

Another important question pertains to the evidentiary standard that should apply to the complex interventions so overwhelmingly represented in this literature set. AHRQ EPC guidance provides, as does the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) working group, clear principles and guidelines to apply to medical treatment or therapies that come with benefits weighed against potential harms. Complex interventions applied to complex whole-person and community systems in varied and often complex settings can be exceedingly difficult to implement with fidelity and potential for replication and dissemination. In addition, the study of these interventions is challenged by the appropriateness of basic assumptions that underlie research designs and statistical tools.

One approach to many of these issues is better use of community-based research methods. Involving PLWD and caregivers in planning, implementing, and disseminating research is increasingly recognized as valuable for addressing the populations for which interventions are intended. Applying this approach to PLWD and their caregivers was recognized at a Health and Human Services Summit in 2017.[713]

Broader Research Context

Another concern is how informal caregivers are perceived, and the way in which this perception informs research designs. While caregiving for PLWD presents challenges, burdens, and risks to the health of caregivers, it is not a pathological condition. Interventions aimed at mitigating burdens for informal caregivers can also recognize and build on the rewards of caregiving and the bonds it nurtures between caregivers/partners and care recipients.

Additional questions to consider pertain to how dementia care science might be conducted more efficiently and effectively. Perhaps it is possible to create an environment that encourages experimenting with care solutions while maximizing the ability to learn from those efforts. One avenue for growth may lie in more collaborative, open science with collective impact approaches to its development. This represents a different form of "big science," in which resources such as Benjamin Rose Institute on Aging's (BRI) Best Practice Caregiving resource (see https://www.benrose.org/best-practice-caregiving) could be an important asset, allowing us another way to close feedback loops and gain knowledge from real-world applications. Innovation requires something more than status quo behavior, as does the research needed to push toward paradigm growth or adoption. Innovation in research involves maximizing discovery while minimizing the risk of locking in solutions that are only *currently* relevant or *partially* accurate. Perhaps we can find easier ways for researchers and care systems to test new things efficiently, without overburdening coordination and/or oversight. Many researchers are already thinking deeply about these kinds of questions, including the Center for Open Science (see https://cos.io/ or http://www.unesco.org/new/en/communication-and-information/portals-and-platforms/goap/) or MetaScience (see https://www.metascience2019.org/) initiatives.

Much research has limited impact because it is conducted in isolation, among small groups, and with variable timing for study endpoints to measure outcomes. However, demonstration projects have been conducted to examine specific research questions being crowdsourced by the research community, with peer review processes built in prior to and during analysis, rather than through an extensive research and publication process.[714] This type of collaborative research can prioritize outcome measurement tools and timing in a way that leads to science that others can measure and replicate.

Many aspects of care interventions for PLWD and their caregivers need more thorough exploration. We hesitated to give an exhaustive list for fear of overwhelming the readers. We were instead guided by peer and public comments on the draft version of this report to specifically mention the following areas: functional and health status limitations, access to care and intervention services and supports as well as accessibility, transportation, culture, racial/ethnic, and related factors. Public commentators to this report who are living with dementia noted an urgent need for more research on interventions that support personhood, purpose and meaning, social and peer supports, proactive approaches to living with a chronic, progressive illness, and lifestyle and spirituality interventions.

Importantly, we do note a gap in the literature for interventions that address the early stages of dementia and being an informal caregiver, just at the time of diagnosis, when problems associated with disconnection, denial, and misinformation may be most urgent.

In the end, high-level discussions of how future research might be structured should not distract us from the primary need to provide research that is relevant to all of the populations that matter. With the exception of a handful of studies, the current research is silent for many social groups, whether by race/ethnicity, citizen status, geographic locations, or dementia types, to name some of the larger categories. Much crucial work remains to be done.

Abbreviations and Acronyms

ACP	Advance Care Planning
AD	Alzheimer's Disease
ADL	Activities of Daily Living
ADRD	Alzheimer's Disease and Related Dementias
AHRQ	Agency for Healthcare Research and Quality
AMSTAR	Assessment of Multiple Systematic Reviews
BPSD	Behavioral and Psychological Symptoms of Dementia
CAM	Complementary and Alternative Medicine
CONSORT	Consolidated Standards of Reporting Trials
CST	Cognitive Stimulation Therapy
D&I	Dissemination and Implementation
DCMTM	Dementia Care Mapping^{TM}
EPC	Evidence-based Practice Center
HHS	Health and Human Services
HMD	Health and Medicine Division
HRSA	Health Resources and Services Administration
IMPACT	IMbedded Pragmatic Alzheimer's disease and Related Dementias Clinical Trials
KQ	Key Question
MMSE	Mini Mental State Examination
MOST	Multiphase Optimization Strategy
MSS	Multi-Sensory Stimulation
N	Number
NASEM	National Academies of Sciences, Engineering, and Medicine
NIA	National Institutes on Aging
NIH	National Institutes of Health
NPI	Neuropsychiatric Inventory
PICOTS	Population, Intervention, Comparison, Outcomes and Timing
PRECIS-2	PRagmatic Explanatory Continuum Indicator Summary-2 tool
PRISMA	Preferred Reporting Items for Systematic Review and Meta-Analysis
PLWD	People Living With Dementia
QAPI	Quality Assessment and Performance Improvement
QoL	Quality of Life
QOL-AD	Quality of Life-Alzheimer's Disease
RAPT	Readiness assessment for pragmatic trials
RCT	Randomized Controlled Trial
RDAD	Reducing Disability in Alzheimer's Disease

REACH II	Resources for Enhancing Alzheimer’s Caregivers Health
RMC	Routine Medical Care
SMD	Standardized Mean Difference
STAR-C	Social learning theory and principles of behavior analysis of caregivers
UK	United Kingdom
US	United States

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Appendixes

II. Care Delivery Models and Programs - Collaborative Care
III. Care Staff Education and Support Needs
    a. Caregiver Staff Training
    b. Informal Caregiver Staff Training
    c. Family Education and Partnering
    d. Multitier Training

Appendix A. Methods

I. Example Interventions

Essentially, interventions are automatically included unless *specifically* stated as excluded. Note that the list is *not* divided by KQs 1-10. Some interventions may be aimed at both PWD and PWD Caregivers; some may be aimed at one or the other. The list is not intended to be exhaustive, and is a simple categorization based on what may be a more likely classification. The actual distinction between whether an intervention is examining **what** care is delivered or **how** to deliver care would be determined by the study purpose.

- Memory evaluation
- Driving evaluation or encouraging driving cessation
- Meaningful activities
- Advance care planning
- Behavior management
- ADL support
- Home modifications
- Wandering and fall risk management
- Palliative care
- Caregiver support and support groups
- Sensory-based interventions
- Changing the physical environment/environmental modification across settings (e.g., in hospitals, in people's homes)
- Mindfulness training
- Interventions focused on the development of Dementia Friendly Training (e.g., training of police officers in local communities)
- Wandering and Wayfinding
- Reminiscence Therapy
- Prompts and Multicomponent Interventions
- Engagement Interventions
- Exercise Interventions
- Psychoeducational
- Art therapy
- Dance movement therapy
- Music therapy
- Cognitive behavior therapy
- Counseling/care management (including emotionally focused couples therapy)
- General support
- Respite
- Training of PWD
- Psychosocial interventions/studies
- Caregiver support groups
- Therapeutic counseling

- Support interventions, including involving informal caregiver social network to support the primary caregiver
- Cognitive reframing (changing caregivers' maladaptive behaviors or beliefs)
- Web-based multimedia intervention
- Caregiver-therapist e-mail support
- Educational and peer-support website
- Bereavement support
- Improving acute care systems
- Skill training, including for CNAs, home health aides, and/or informal caregivers
- Training for CNAs, home health aides, and/or informal caregivers
- Improving care transitions
- Care coordination
- Multicomponent interventions

II. Common Outcome Measures

Test Name	Domain	Data Source	Reference
BEHAVE-AD	General behavior scales & global BPSD		Reisberg et al. 1987
Neuropsychiatric Inventory (NPI)	General behavior scales & global BPSD	informant	Cummings et al 1994
Cohen-Mansfield Agitation Inventory (CMAI)	Agitation/ aggression	informant	Cohen-Mansfield, 1986
Cornell Scale	Depression	patient or informant	Alexopoulos et al. 1988
Patient Health Questionnaire (PHQ-9)	Depression	patient	Spitzer et al., 1999
Geriatric Depression Scale (GDS) 30-item	Depression	patient	Yesavage et al. 1983
Geriatric Depression Scale (GDS) 15-item	Depression	patient	
Montgomery Asberg Depression Rating Scale (MADRS)	Depression		Montgomery & Asberg, 1979
Hamilton Depression Rating Scale (HDRS)	Depression	patient	Hamilton, 1960
Beck Anxiety Inventory (BAI)	Anxiety	patient	
Brief Psychiatric Rating Scale (BPRS)	Mood; Psychosis	clinician administered interview	Overall 1962; Beller 1984
Schedule for Affective Disorders and Schizophrenia (SADS)	Mood; Psychosis	clinician administered interview	Endicott 1978
Schedule for Affective Disorders and Schizophrenia -Lifetime version (SADS-L)	Mood; Psychosis	clinician administered interview	Endicott 1978
Schedule for Affective Disorders and Schizophrenia -Change version (SADS-C)	Mood; Psychosis	clinician administered interview	Endicott 1978
Behavioral Syndromes Scale for Dementia (BSSD)	General behavior scales & global BPSD	informant	Devanand 1992
Barthel index	ADLs	informant	Mahoney and Barthel, 1965
Bristol Activities of Daily Living Scale (BADLS)			Bucks et al. 1996
Direct Assessment of Functional Status	ADLs + IADLs	performance-based	Loewenstein, Amigo, & Duara, 1989
Disability Assessment for Dementia (DAD) Scale		informant	
Functional Activities Questionnaire (FAQ)		informant	Pfeffer et al 1982
Functional Independence Measure (FIM)	ADLs + (social, cogn, etc)	informant	Keith et al. 1987
Health Assessment Questionnaire (HAQ)			
Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE)		informant	Jorm and Jacomb,1989
Instrumental Activities of Daily Living scale	IADLs		Lawton and Brody, 1969
Katz Index of Independence in ADLs	ADLs		Katz et al. 1963
Modified Health Assessment Questionnaire (MHAQ)			
Older Americans Resources and Services (OARS)	ADLs + IADLs	self-report	George & Fillenbaum, 1985
Physical Self-Maintenance Scale (PSMS)	ADLs		Lawton and Brody, 1969

Minimum Data Set (MDS)-ADL Self Performance Scale	ADLs		
Progressive Deterioration Scale (PDS)	ADLs + IADLs	informant	DeJong 1989
AD-related Quality of Life scale (QoL-AD)		patient or informant	Logsdon et al. 1999
DEMQOL		patient	Smith et al. 2007
DEMQOL		informant	Smith et al. 2007
EuroQol measure		patient or informant	EuroQol Group, 1990
Short Form-36 (SF-36)		patient	Ware & Sherbourne, 1992
General Health Questionnaire (GHQ)	Global Distress		Goldberg & Williams 1988
Zarit Burden Interview	Caregiver Burden		Zarit et al. 1980
Neuropsychiatric Inventory – Distress Scale	Caregiver Distress		Cummings et al 1994
Revised Memory and Behavior Problem Checklist (RMBPC)		informant	Terie et al 1992

III. Search Strategy

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R) <1946
Search Strategy:
----
1 exp Alzheimer Disease/
2 Dementia/
3 (dementia or alzheimer*).ti.
4 1 or 2 or 3
5 limit 4 to "therapy (best balance of sensitivity and specificity)"
6 limit 5 to english language
7 limit 6 to (addresses or autobiography or bibliography or biography or case reports or clinical conference or comment or comparative study or congresses or consensus development conference or consensus development conference, nih or dataset or dictionary or directory or editorial or evaluation studies or "expression of concern" or festschrift or government publications or guideline or historical article or interactive tutorial or interview or lectures or legal cases or legislation or letter or news or newspaper article or observational study or patient education handout or periodical index or personal narratives or portraits or "review" or "scientific integrity review" or validation studies or video-audio media or webcasts)
8 limit 7 to (adaptive clinical trial or clinical study or clinical trial, all or clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or clinical trial or controlled clinical trial or randomized controlled trial)
9 6 not 7
10 8 or 9
11 limit 10 to ("all child (0 to 18 years)"
12 limit 11 to ("middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)" or "aged (80 and over)")
13 10 not 11
14 12 or 13

Database: Embase Classic+Embase <1947
Search Strategy:
----
1 exp *Alzheimer disease/
2 *dementia/
3 (alzheimer* or dementia*).ti.)
4 1 or 2 or 3
5 limit 4 to english language
6 limit 5 to "therapy (best balance of sensitivity and specificity)"
7 limit 6 to "reviews (best balance of sensitivity and specificity)"
8 6 not 7
9 limit 8 to (embryo <first trimester> or infant <to one year> or child <unspecified age> or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>)
10 limit 9 to (adult <18 to 64 years> or aged <65+ years>)
11 8 not 9

12 10 or 11
13 limit 12 to (book or book series or conference proceeding or trade journal)
14 12 not 13
15 limit 14 to conference abstracts
16 14 not 15
17 limit 16 to (abstract report or books or "book review" or chapter or conference abstract or "conference review" or editorial or letter or note or patent or reports or "review" or short survey or tombstone)
18 16 not 17
19 limit 18 to (amphibia or ape or bird or cat or cattle or chicken or dog or "ducks and geese" or fish or "frogs and toads" or goat or guinea pig or "hamsters and gerbils" or horse or monkey or mouse or "pigeons and doves" or "rabbits and hares" or rat or reptile or sheep or swine)
20 18 not 19

Database: PsycINFO <1806
Search Strategy:
----
1 exp *ALZHEIMER'S DISEASE/
2 *dementia/
3 (dementia* or alzheimer*).ti.
4 1 or 2 or 3 (64340)
5 limit 4 to "therapy (best balance of sensitivity and specificity)"
6 limit 5 to (childhood <birth to 12 years> or adolescence <13 to 17 years>)
7 limit 6 to adulthood <18+ years>
8 5 not 6
9 7 or 8
10 limit 9 to animal
11 9 not 10
12 limit 11 to (100 childhood <birth to age 12 yrs> or 120 neonatal <birth to age 1 mo> or 140 infancy <2 to 23 mo> or 160 preschool age <age 2 to 5 yrs> or 180 school age <age 6 to 12 yrs> or 200 adolescence <age 13 to 17 yrs> or 320 young adulthood <age 18 to 29 yrs> or 340 thirties <age 30 to 39 yrs>)
13 limit 12 to (360 middle age <age 40 to 64 yrs> or "380 aged <age 65 yrs and older>" or "390 very old <age 85 yrs and older>")
14 11 not 12
15 13 or 14
16 limit 15 to (abstract collection or bibliography or chapter or clarification or "column/opinion" or "comment/reply" or dissertation or editorial or encyclopedia entry or interview or letter or obituary or poetry or publication information or review-book or review-media or review-software & other or reviews)
17 15 not 16
18 limit 17 to ("0200 book" or "0240 authored book" or "0280 edited book" or "0300 encyclopedia" or "0400 dissertation abstract")
19 17 not 18
20 limit 19 to english language
21 limit 20 to "therapy (maximizes specificity)"

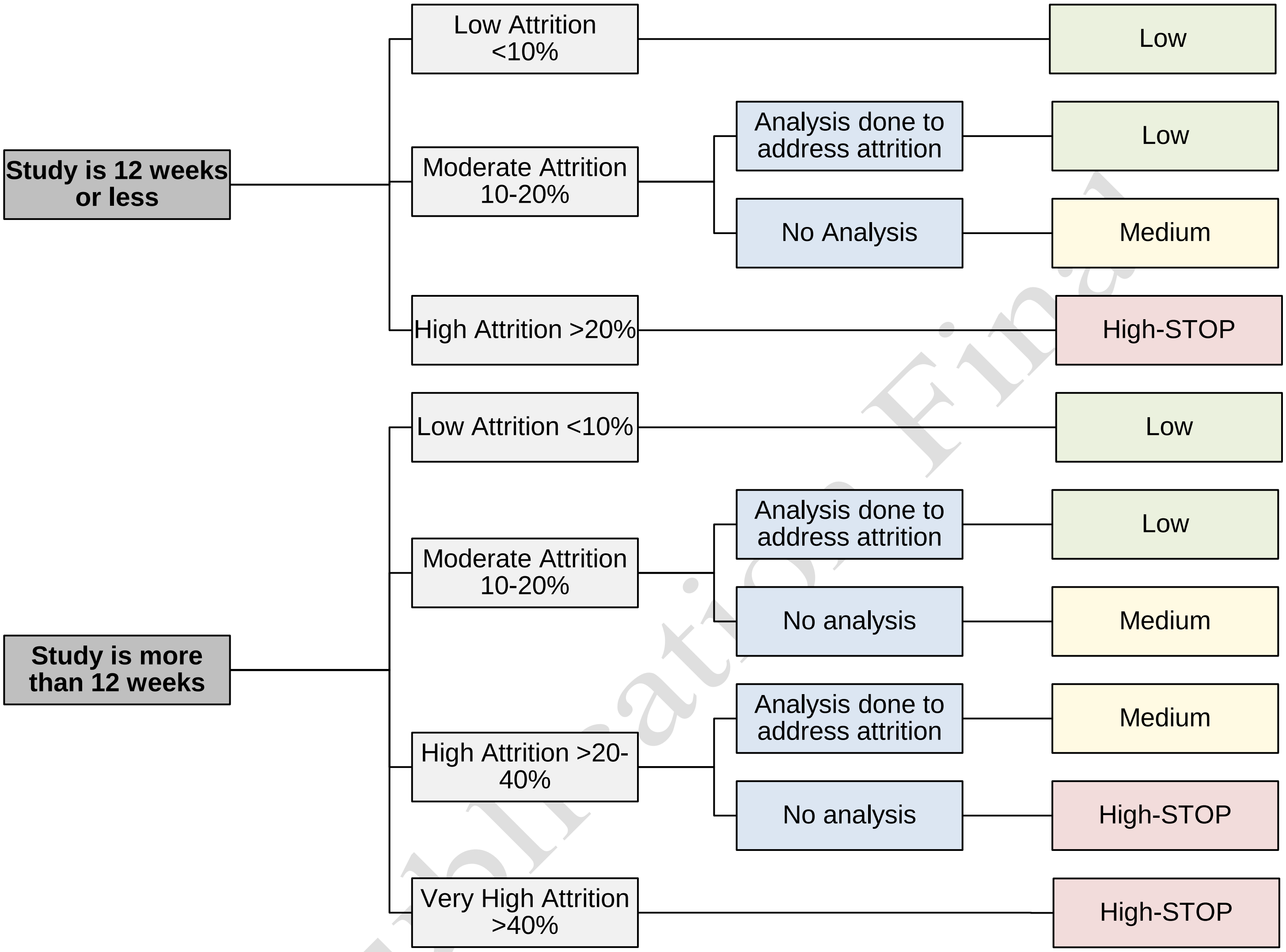
IV. Risk of Bias Assessment Guide – Traditional Studies

INSTRUCTIONS: Review the methods of each trial and assess each risk of bias component as described in these instructions. You may need to have separate assessments for different outcomes (i.e. different measures; different time points may have different attrition rates).

1) ATTRITION Bias

Description/Guiding Questions	Notes
▪ Systematic differences in the loss of participants from the study and how they were accounted for in the results (e.g., incomplete follow-up, differential attrition). Those who drop out of the study or who are lost to follow-up may be systematically different from those who remain in the study. Attrition bias can potentially change the collective (group) characteristics of the relevant groups and their observed outcomes in ways that affect study results by confounding and spurious associations. Reasons for incomplete/missing data adequately explained? Do the author's attempt to address attrition in the analysis?	▪ Attrition assessment is dependent on overall study duration (see flowchart) Report attrition rate in spreadsheet. If a study reports outcomes at multiple intervals (e.g., 6 months, 12 months, 18 months) assess attrition at the first relevant time point and the last time-point separately, you do not need to do every time point. Analysis should be done with appropriate method (i.e. sensitivity analysis with various scenarios); last value forward would only be appropriate for interventions that are supposed to improve the outcomes (i.e. memory training that intends to improve memory).

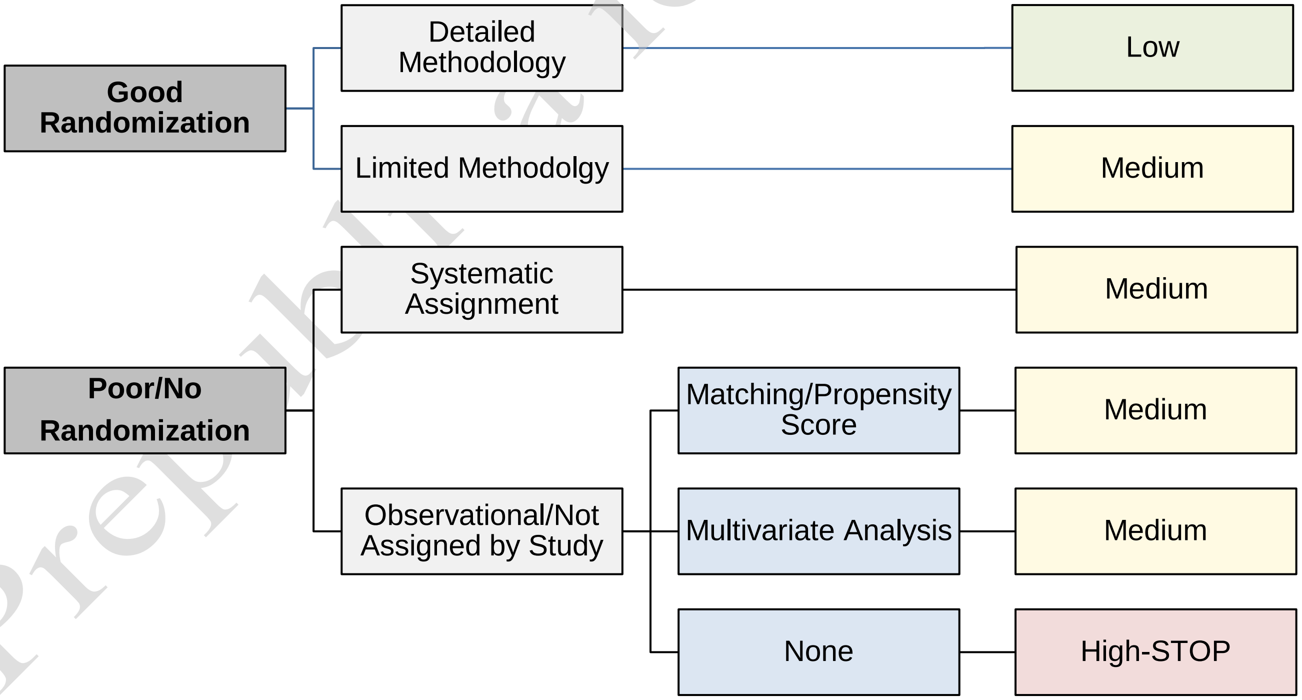
ATTRITION BIAS ASSESSMENT GUIDANCE



2) SELECTION BIAS

Description/Guiding Questions	Notes
▪ Systematic differences between baseline characteristics of the groups that arise from self-selection of treatments, physician-directed selection of treatments, or association of treatment assignments with demographic, clinical, or social characteristics. Did method of randomization create biased allocation to interventions (inadequate randomization)?	▪ "Good" Randomization: ***Detailed methodology*** would include providing method of randomization such as use of a random numbers table, or computer random number generator. ***Limited methodology*** would be the study saying simply saying they randomized in the methods or provided limited detail such as randomizing by a 2:1 ratio. "Poor"/No Randomization: Randomized based on week of the month of birthday or a non-randomized clinical trial, observational study.

SELECTION BIAS ASSESMENT GUIDANCE



3) ATTRITION AND SELECTION BIAS OVERALL

Assess joint selection and attrition bias. If either selection or attrition bias is high, the risk of bias is HIGH.

Attrition Bias	Low	Low	Medium	Low	Medium	Medium	High
Selection Bias	Low	Medium	Low	High	Medium	High	■
Action	Assess other biases	Assess other biases	Assess other biases	STOP*	Assess other biases	STOP*	STOP*

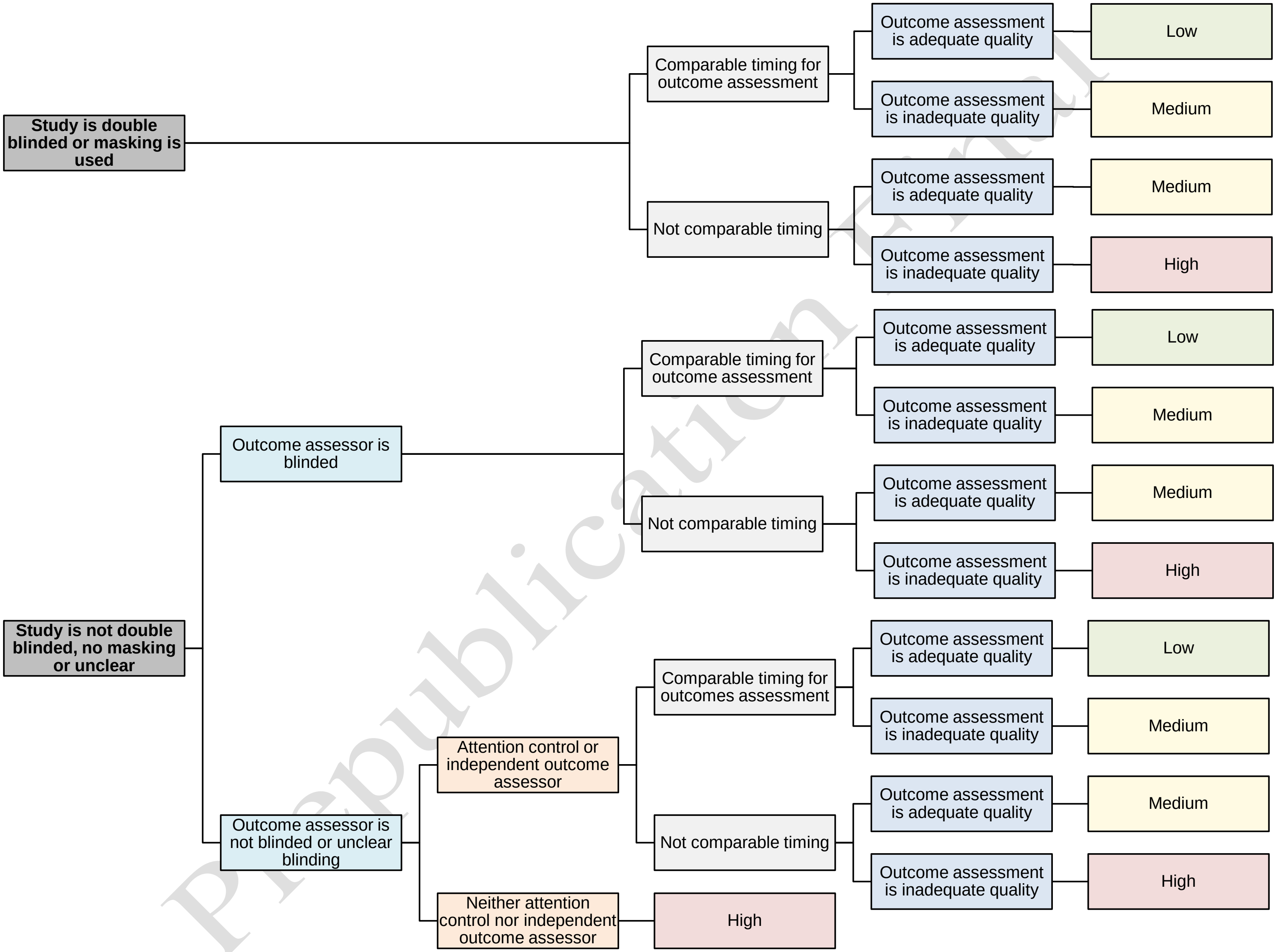
*Send to evidence map

*****PRIOR TO ASSESSING OTHER BIASES, CHECK PUBLICATION TO MAKE SURE OUTCOMES ARE ABSTRACTABLE. IF OUTCOMES ARE NOT ABSTRACTABLE (e.g., DATA IS PRESENTED AS GRAPHS ONLY), STOP ASSESSMENT AND CHECK WITH TEAM TO CONFIRM THAT PUBLICATION BELONGS IN EVIDENCE MAP*****

4) OTHER BIASES

A. DETECTION BIAS

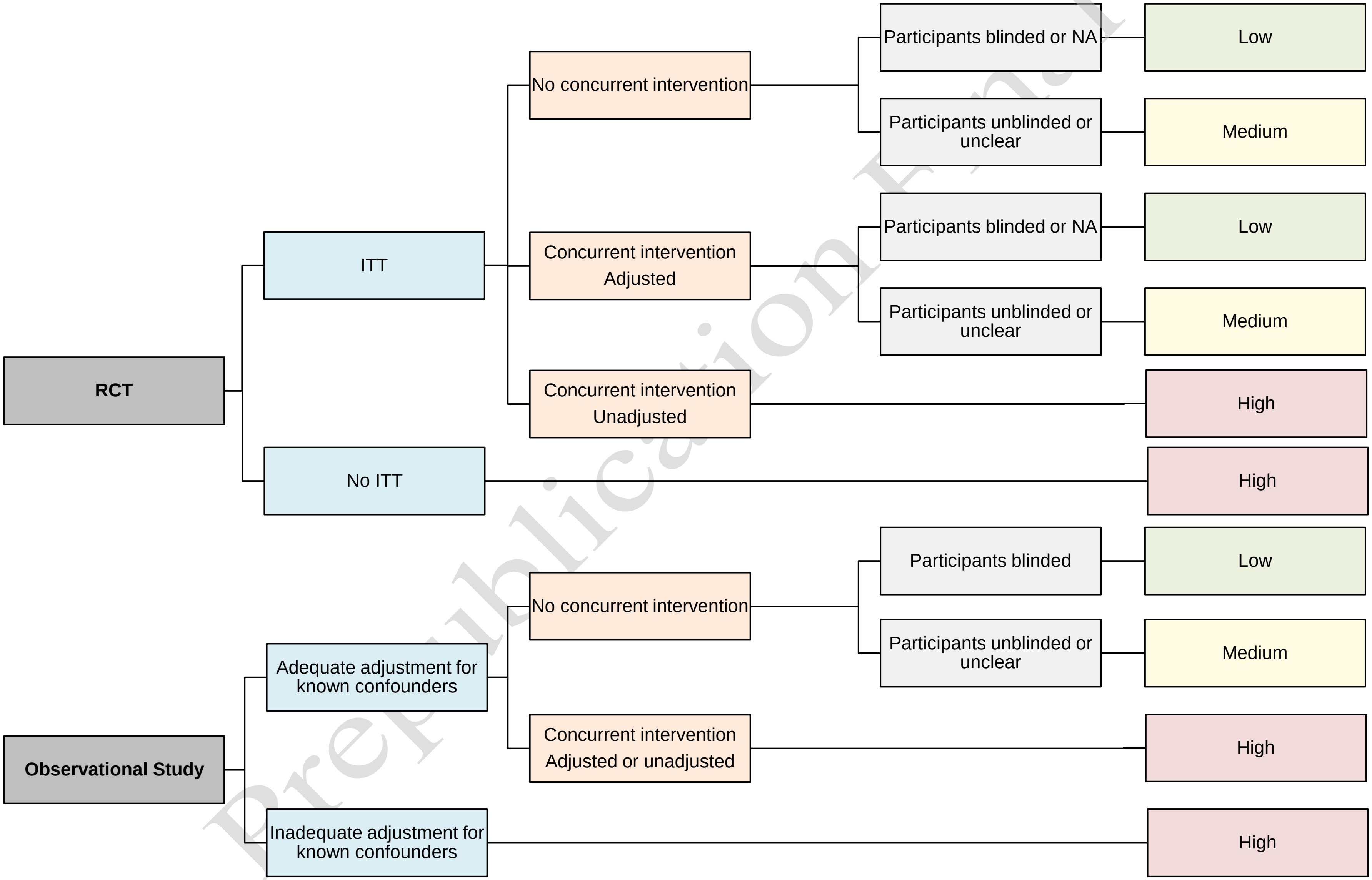
Description/Guiding Questions	**Notes**
▪ *Systematic differences in outcomes assessment among groups being compared, including systematic misclassification of the exposure or intervention, covariates, or outcomes because of variable definitions and timings, diagnostic thresholds, recall from memory, inadequate assessor blinding, and faulty measurement techniques. Erroneous statistical analysis might also affect the validity of effect estimates.* Were the outcome assessors blinded to the intervention ("outcome assessor blinded")? Was the timing of the outcome assessment similar in all groups ("comparable timing outcomes assessment")? Was the scale used to measure outcomes validated, reliable? Were outcomes measured in clinically meaningful ways?	▪ X


Study is double blinded or masking is used
Comparable timing for outcome assessment
Outcome assessment is adequate quality
Low
Outcome assessment is inadequate quality
Medium
Not comparable timing
Outcome assessment is adequate quality
Medium
Outcome assessment is inadequate quality
High
Study is not double blinded, no masking or unclear
Outcome assessor is blinded
Comparable timing for outcome assessment
Outcome assessment is adequate quality
Low
Outcome assessment is inadequate quality
Medium
Not comparable timing
Outcome assessment is adequate quality
Medium
Outcome assessment is inadequate quality
High
Outcome assessor is not blinded or unclear blinding
Attention control or independent outcome assessor
Comparable timing for outcomes assessment
Outcome assessment is adequate quality
Low
Outcome assessment is inadequate quality
Medium
Not comparable timing
Outcome assessment is adequate quality
Medium
Outcome assessment is inadequate quality
High
Neither attention control nor independent outcome assessor
High

B. PERFORMANCE BIAS

Description/Guiding Questions	Notes
Systematic differences in the care provided to participants and protocol deviation. Examples include contamination of the control group with the exposure or intervention, problems with fidelity to the intervention, unbalanced provision of additional interventions or co-interventions, difference in co-interventions, and inadequate blinding of providers and participants.	▪ Intention-to-Treat (ITT): Includes every subject according to randomized treatment assignment. Ignores noncompliance, protocol deviations, withdrawal, and anything that happens after randomization. Concurrent Intervention: Study participants are receiving another intervention (i.e., treatment) that is not part of the intervention being tested. Example: Participants are randomized to a physical activity intervention (or no intervention), but are also dieting.

PERFORMANCE BIAS ASSESSMENT GUIDANCE



C. REPORTING BIAS

Description/Guiding Questions	Notes
▪ Systematic differences between reported and unreported findings (e.g., differential reporting of outcomes or harms, incomplete reporting of study findings, potential for bias in reporting through source of funding). Was a select group of outcomes reported?	▪ Compare results to methods section and/ or protocol. Check if some results are reported in a different publication.

REPORTING BIAS ASSESSMENT GUIDANCE

Domain	Options	Rating
All outcomes reported	Yes	Low
	No	Medium
	Not Reported	Medium

CHECK OVERALL ROB RATING BEFORE ASSESSING FIDELITY TO INTERVENTION. IF THE COMBINATION OF PREVIOUS DOMAINS INDICATES HIGH RISK OF BIAS, YOU DO NOT NEED TO ASSESS FIDELITY

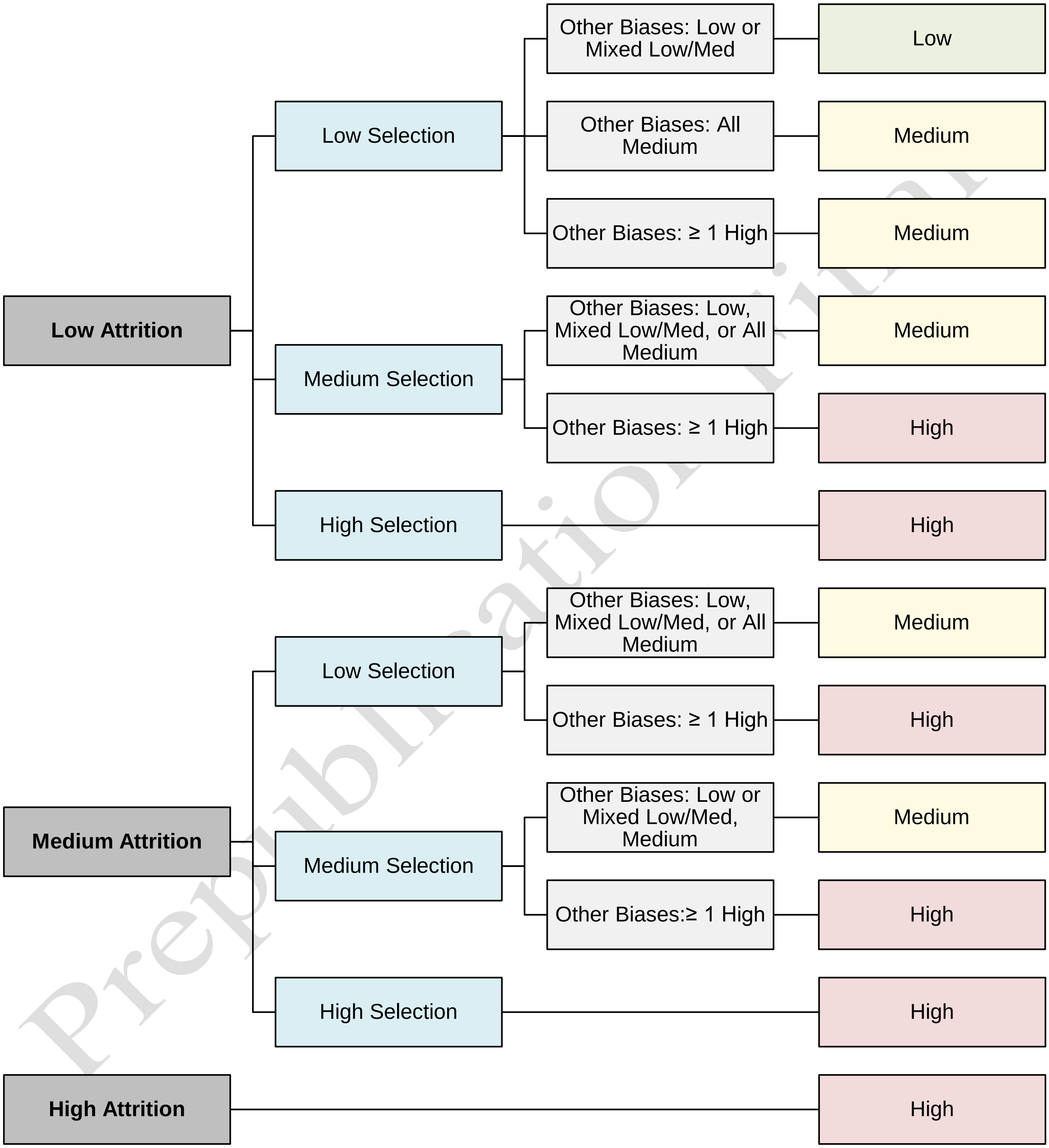
D. FIDELITY TO INTERVENTION

Description/Guiding Questions	Notes
▪ We anticipate that care delivery studies will generally fall in the range of NIH Stage 3 to 4, with the possibility that one or a few may be carried out as quality improvement and thus Stage 5. Since the Stage Model is explicitly designed to balance, or trade off, internal and external validity, we will approach risk of bias assessment as a threshold requirement rather than a continuum. Look for reporting on intervention compliance, any data reported on consistency of intervention use, or any mechanisms used to ensure compliance (e.g., reminders, guides, manuals).	▪ Information may appear in methods, results, or discussion sections.

FIDELITY TO INTERVENTION ASSESSMENT GUIDANCE

Domain	Options	Rating
Fidelity to intervention	Yes (at least 70%)	Low
	Yes-adaptation planned/ replicable	Medium
	No-adaptation not planned	High
	Unclear/Not Reported	Medium

OVERALL RISK OF BIAS ASSESSMENT GUIDANCE

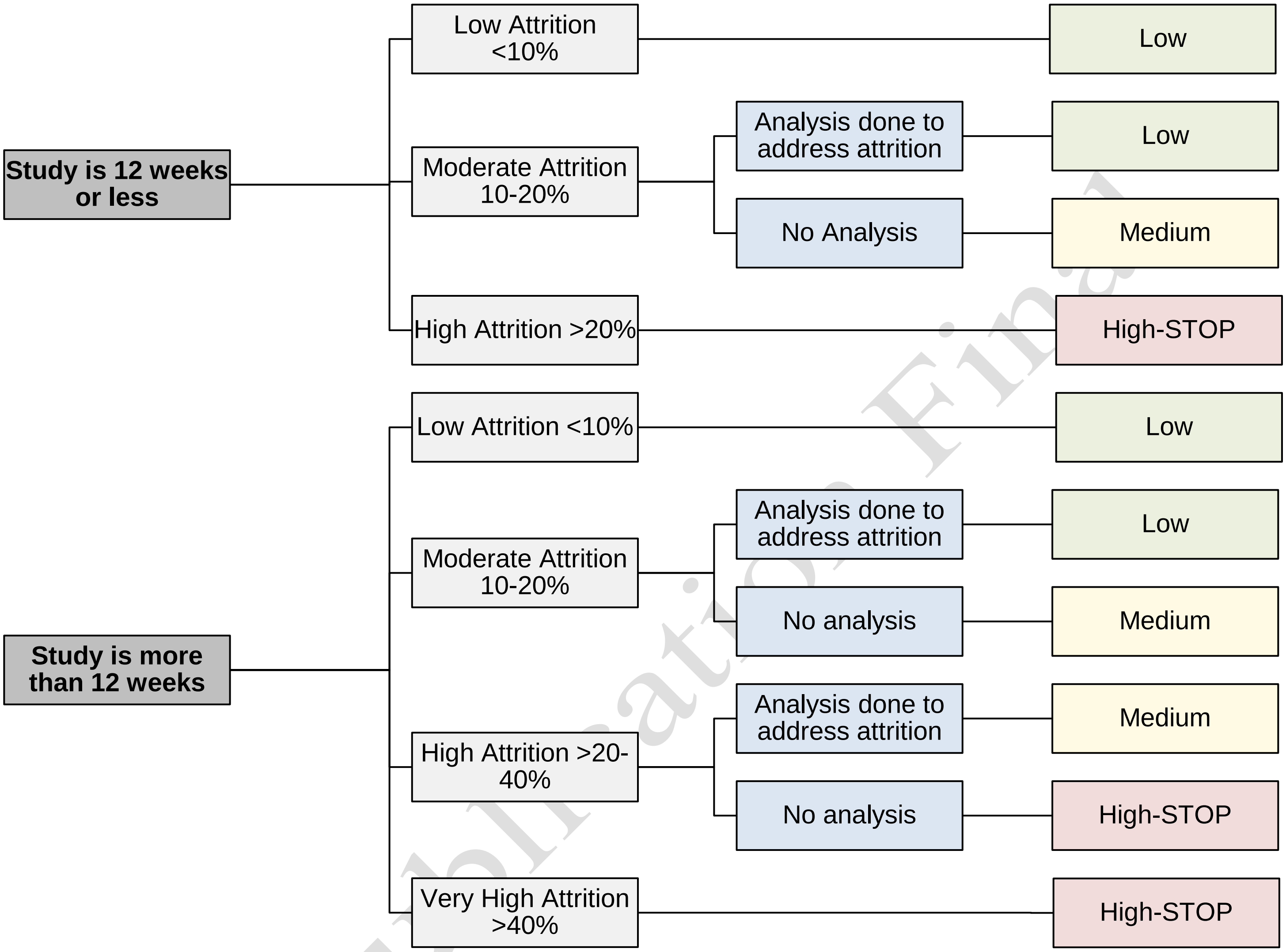


V. Risk of Bias Assessment Guide – Cluster Trials

1) ATTRITION Bias

Description/Guiding Questions	Notes
▪ Systematic differences in the loss of participants from the study and how they were accounted for in the results (e.g., incomplete follow-up, differential attrition). Those who drop out of the study or who are lost to follow-up may be systematically different from those who remain in the study. Attrition bias can potentially change the collective (group) characteristics of the relevant groups and their observed outcomes in ways that affect study results by confounding and spurious associations. Reasons for incomplete/missing data adequately explained? Do the author's attempt to address attrition in the analysis?	▪ Attrition assessment is dependent on overall study duration (see flowchart) Report attrition rate in spreadsheet. If a study reports outcomes at multiple intervals (e.g., 6 months, 12 months, 18 months) assess attrition at the first relevant time point and the last time-point separately, you do not need to do every time point. Analysis should be done with appropriate method (i.e. sensitivity analysis with various scenarios); last value forward would only be appropriate for interventions that are supposed to improve the outcomes (i.e. memory training that intends to improve memory).

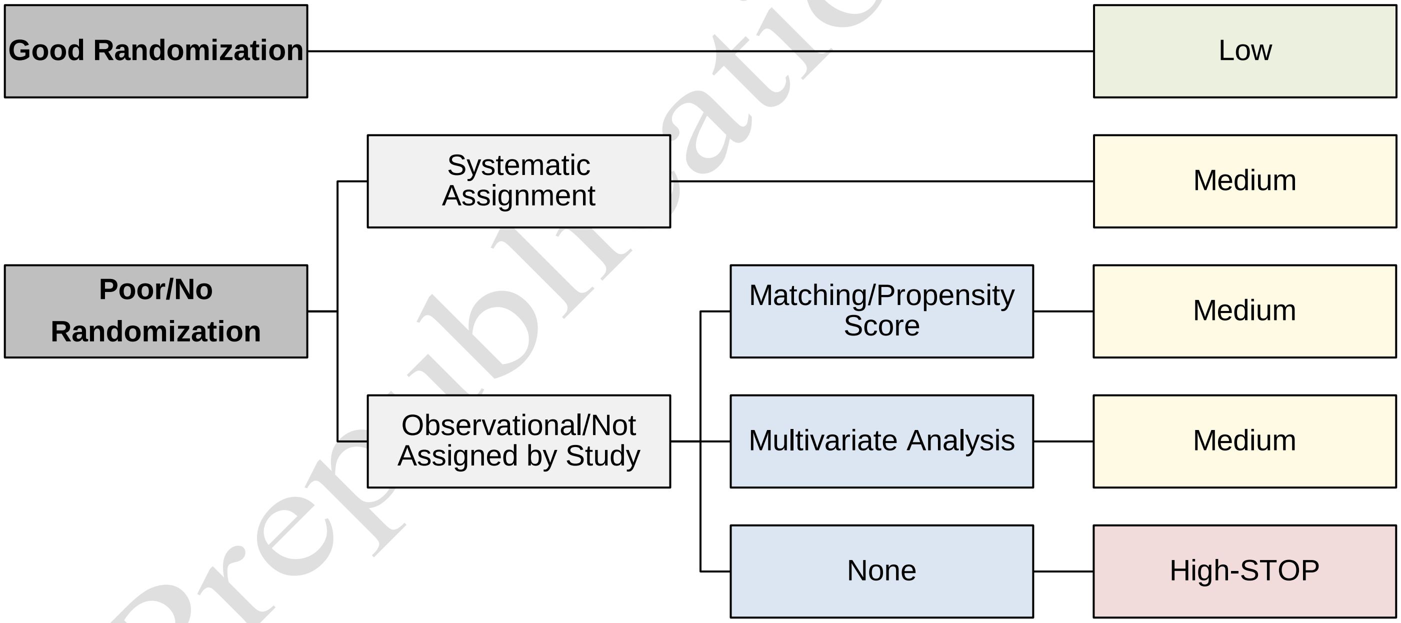
ATTRITION BIAS ASSESSMENT GUIDANCE



3) SELECTION BIAS

Description/Guiding Questions	Notes
▪ Systematic differences between baseline characteristics of the groups that arise from self-selection of treatments, physician-directed selection of treatments, or association of treatment assignments with demographic, clinical, or social characteristics. Did method of randomization create biased allocation to interventions (inadequate randomization)?	▪ “Good” Randomization: Random numbers table, computer random number generator “Poor” Randomization: Randomized based on week of the month of birthday No Randomization: Non-randomized clinical trial, observational study

SELECTION BIAS ASSESMENT GUIDANCE



3) ATTRITION AND SELECTION BIAS OVERALL

Assess joint selection and attrition bias. If either selection or attrition bias is high, the risk of bias is HIGH.

Attrition Bias	Low	Low	Medium	Low	Medium	Medium	High
Selection Bias	Low	Medium	Low	High	Medium	High	■
Action	Assess other biases	Assess other biases	Assess other biases	STOP*	Assess other biases	STOP*	STOP*

*Send to evidence map

*****PRIOR TO ASSESSING OTHER BIASES, CHECK PUBLICATION TO MAKE SURE OUTCOMES ARE ABSTRACTABLE. IF OUTCOMES ARE NOT ABSTRACTABLE (e.g., DATA IS PRESENTED AS GRAPHS ONLY), STOP ASSESSMENT AND CHECK WITH TEAM TO CONFIRM THAT PUBLICATION BELONGS IN EVIDENCE MAP*****

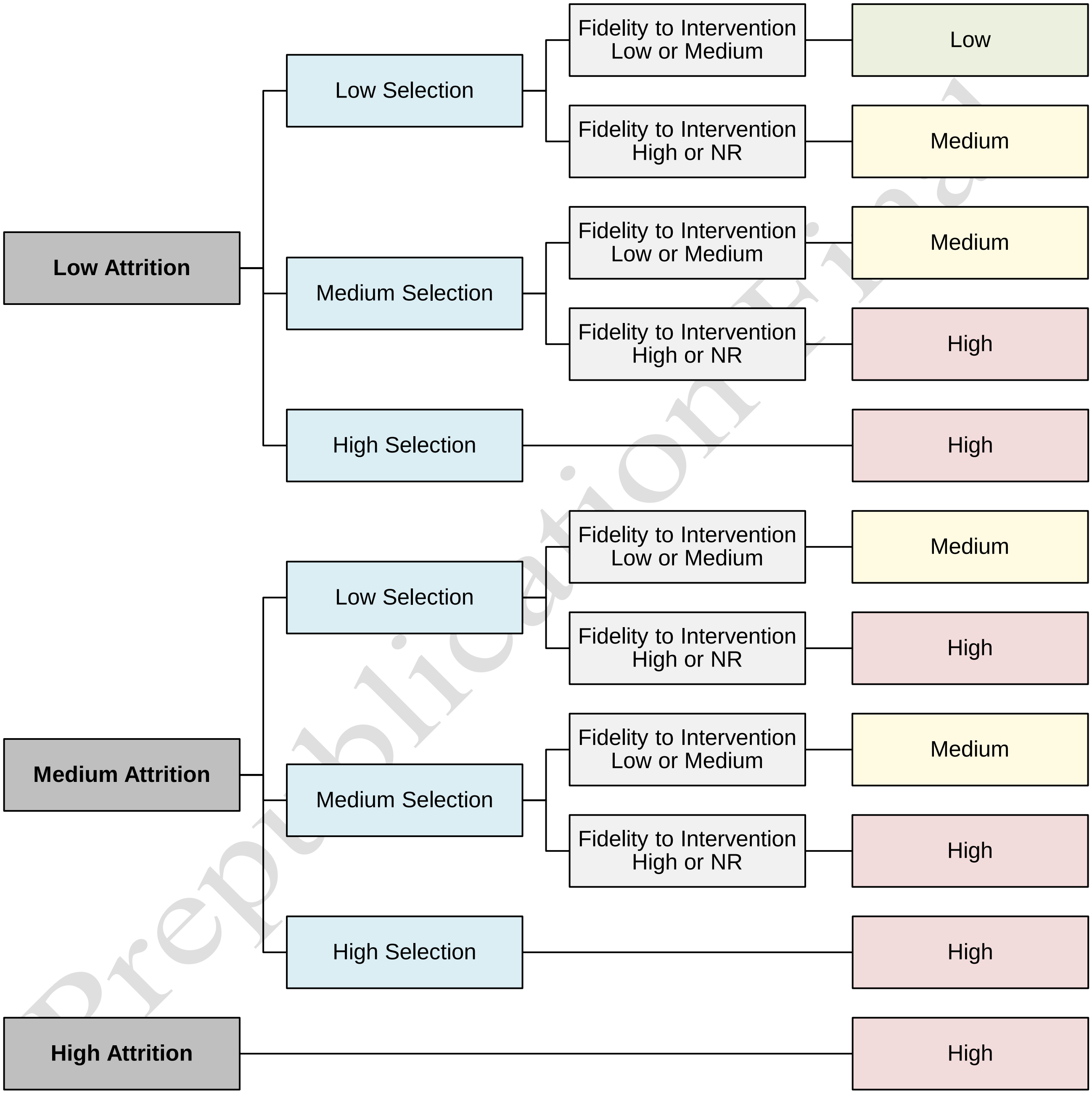
4) FIDELITY TO INTERVENTION

Description/Guiding Questions	Notes
We anticipate that care delivery studies will generally fall in the range of NIH Stage 3 to 4, with the possibility that one or a few may be carried out as quality improvement and thus Stage 5. Since the Stage Model is explicitly designed to balance, or trade off, internal and external validity, we will approach risk of bias assessment as a threshold requirement rather than a continuum.	▪ X

FIDELITY TO INTERVENTION ASSESSMENT GUIDANCE

Domain	Options	Rating
Fidelity to intervention	Yes (at least 70%)	Low
	Yes-adaptation planned/ replicable	Medium
	No-adaptation not planned	High
	No/Not Reported	NR

OVERALL RISK OF BIAS ASSESSMENT GUIDANCE



VI. PRECIS-2 – Modified for Care Delivery Intervention literature

Domain	Score (1-5)	Rationale for score	Modified prompts, with examples
Eligibility criteria			To what extent are trial participants similar to PWD who would receive the intervention as part of usual care? [5= identical to usual care; 1=many exclusions (highly selected sample, uncommon tests used, exclude noncompliant or non-responders, etc.)] <u>Example considerations</u>: PWD: Other comorbidities allowed? Health or behavior restrictions? Mobility or language restrictions? Dementia severity range? Small percentage of eligible chose to participate. Insurance restrictions? Participant had to opt in? Caregiver: Level of mobility/health/cognition necessary? How much time/work loss required?
Recruitment path			How much extra effort is required to recruit participants over usual care? [5=pragmatic, usual care (appt. or clinic); 1=targeted invitation letters, public media announcements, incentives] <u>Example possible scores:</u> 5: Invited during routine clinic visit 4: Invitation letter/call from doctor 3: Identified PWD via diagnosis/billing code(s)→sent letter 2: Incentive(s) for participation 1: Worker hired to find participants (clinic, health plan)
Setting			How different is the trial setting from usual care for PWD? [5=identical to usual care; 1=single center, special trial or academic center, etc.] <u>Example considerations</u> (*if setting not part of study question*): Urban only, or likely available in rural settings? Multiple settings included (private group practice, academic, HMO) Components: training for PWD/Caregiver on-site, but implemented at home via case manager?
Intervention organization			How different are intervention resources, provider expertise, and care organization from those available in usual care? How easy to implement without major changes (new staff, funding, policy)? <u>Example possible scores:</u> 4: Multicomponent + requires community partners 3: Multicomponent + requires new software 2-4: Requires new staff and funding (some) 1-2: Requires new or proprietary software (1+ sites), policy change, major new staff and funding
Flexibility of intervention: delivery			How different is flexibility of intervention delivery from usual care for PWD? <u>Example possible scores:</u> 5: Suggested services obtained based on ability to pay 4-5: Care manager calls/care coordination per care

Domain	Score (1-5)	Rationale for score	Modified prompts, with examples
			manager/participant discretion 2-3: short training required of PWD/Caregiver (at clinic) 1: lengthy/intensive training required of PWD/Caregiver, or at academic center 2-3: Scheduled calls from case manager (1-2 if frequent; 1 if frequent + case manager calls when needed)
Flexibility of intervention: adherence			How different is the flexibility of intervention adherence requirement from usual care? How rigorous are measures to increase adherence? (Note: rate adherence studies too) <u>Example possible scores:</u> 5: usual encouragement; 1-2: prompts/measures to improve adherence
Follow-up			How different is trial follow-up or measurement intensity from usual care? Does trial follow-up (frequency, intensity, content) result in care that differs from usual care? <u>Example possible scores</u> 5: measurement from usual follow up. 3-4: in home assessment every 6 months by case manager 1: extensive data collection, longer/more frequent clinic visits, event(s) triggered visits
Primary outcome			To what extent is the primary outcome relevant to participants? [5=obviously important; 1=intermediate or physiologic outcome, requires expert assessment, outcome timing/measure differs from usual care] <u>Example possible scores:</u> 5: important to PWD and routinely assessed in usual care 4-5: important to PWD and longer term 3-4: composite primary outcome, some elements unimportant to PWD 2-3: important to PWD but measured earlier than usual care/short-term 1-2: assessment expertise differs from usual care; surrogate, intermediate outcomes.
Primary analysis			To what extent are all data included in the analysis of the primary outcome? <u>Example possible scores:</u> 4-5: ITT or modified ITT 1-2: exclude PWD with low intervention adherence (when adherence ≠ an outcome) 1-2: post hoc-derived subgroup analysis; secondary endpoints 1-2: data merged from > 1 study 1: compliant completer analysis
MN EPC			
Applicability			Population: PWD and/or PWD Caregivers: -narrow or broadly generalizable for PWD?
Qualifier(s)			Setting/implementation: -urban setting, practices with linked electronic health records -health plan level with trained case managers -modest vs. intensive electronic health record data extraction required?

Domain	Score (1-5)	Rationale for score	Modified prompts, with examples
			-needs proprietary software -costs not reported but startup likely intensive -costs not reported but likely feasible addition to usual care -not likely feasible in US health system -not likely feasible in (some) rural areas

Appendix B. Excluded Studies

Could not locate

1. Cameron H, du Toit S, Richard G, et al. Using lemon balm oil to reduce aggression and agitation in dementia: results of a pilot study. Journal of Dementia Care. 2011;19(5):36-8. PMID: 108258536. Language: English. Entry Date: 20111104. Revision Date: 20150712. Publication Type: Journal Article.
2. Essence A. A double blind, placebo controlled trial of aromatherapy using melissa/lavender compared to aricept for the treatment of significant agitation in people with severe dementia.
3. LÃ³pez-Almela As, GÃ³mez-Conesa A. Intervention in dementias by multisensory stimulation (snoezelen). In Fisioterapia
4. Lukaszewska B, Tomaszewski W, Mirski A, et al. An evaluation of social isolation of people with dementia of the alzheimer type in the process of neurorehabilitation. In Psychogeriatria polska
5. Lyu J, Gao T, Li M, et al. The effect of music therapy on memory, language and psychological symptoms of patients with mild Alzheimer's disease. In Chinese journal of neurology
6. Reuster T, Jurjanz L, Schutzwohl M, et al. A randomized controlled trial on occupational therapy for patients with dementia and their caregivers (ERGODEM). In Zeitschrift fur gerontopsychologie & -psychiatrie
7. Yang D-L, Li X, Su N, et al. Family medical intervention model of senile dementia with behavioral and psychological symptoms. In Journal of shanghai jiaotong university (medical science)

Not English language

8. Correction: northern Manhattan Hispanic Caregiver Intervention Effectiveness Study: protocol of a pragmatic randomised trial comparing the effectiveness of two established interventions for informal caregivers of persons with dementia (BMJ Open (2016) 6 (e014082) DOI: 10.1136/bmjopen-2016-014082). In BMJ Open
9. Ban S-h, Jun S-S. Spaced Retrieval Effects in Older Adults with Mild Alzheimer's Disease. Korean Journal of Adult Nursing. 2012;24(4):398-405. PMID: 104400737. Language: English. Entry Date: 20130125. Revision Date: 20180305. Publication Type: Journal Article.
10. Bang M, Kim O. Effect of the Family Resilience Reinforcement Program for Family Caregivers of the Elderly with Dementia. In Korean j adult nurs
11. Chae K. Effects of Laughing and Music Therapy on Depression and Activities of the Autonomic Nervous System in the Elderly with Dementia. In J korean biol nurs sci
12. Chu J, Bao Y, Zou C. Effect of long-time retention of scalp needle on the abilities of cognition, daily living activity and P300 in vascular dementia patients. In Zhen CI yan jiu = acupuncture research
13. Delphin-Combe F, Rouch I, Martin-Gaujard G, et al. Effect of a non-pharmacological intervention, Voix d'Or(®), on behavior disturbances in Alzheimer disease and associated disorders. In Geriatrie ET psychologie neuropsychiatrie du vieillissement
14. Dijk A, Weert J, Droes R. Theatre as communication method in psychogeriatric care: effects on behaviour, mood and quality of life of people with dementia]. [Dutch. In Tijdschrift voor gerontologie en geriatrie
15. Etxeberria AI, Garcia SA, Iglesias DSA, et al. Effects of training in emotional regulation strategies on the well-being of carers of Alzheimer patients]. [Spanish. In Revista espanola de geriatria y gerontologia
16. Fernández-Calvo B, Rodríguez-Pérez R, Contador I, et al. Efficacy of cognitive training programs based on new software technologies in patients with Alzheimer-type dementia. In Psicothema
17. Fischer-Terworth C, Probst P. Effects of a psychological group intervention on neuropsychiatric symptoms and communication in Alzheimer's dementia. In Z Gerontol Geriatr
18. Fleiner T, Dauth H, Zijlstra W, et al. Effects of a Days-structured Training Program on mental and Behavioral Symptoms in Dementia Patients (BPSD) - Results of a randomized controlled Study. In Z Gerontol Geriatr
19. Garzon-Maldonado FJ, Gutierrez-Bedmar M, Serrano-Castro V, et al. An assessesment of telephone assistance systems for caregivers of patients with Alzheimer's disease. Neurologia. 2017 Nov - Dec;32(9):595-601. doi: https://dx.doi.org/10.1016/j.nrl.2016.03.009. PMID: 27293022.
20. Geschke K, Scheurich A, Schermuly I, et al. Effectivity of early psychosocial counselling for family caregivers in general practioner based dementia care. In Deutsche medizinische wochenschrift (1946)
21. Gok Ugur H, Orak OS, Yaman Aktas Y, et al. Effects of Music Therapy on the Care Burden of In-Home Caregivers and Physiological Parameters of Their In-Home Dementia Patients: A Randomized Controlled Trial. Complementary Med. 2018 Nov 30;30:30. doi: https://dx.doi.org/10.1159/000490348. PMID: 30497077.
22. Goudour A, Samson S, Bakchine S, et al. Semantic memory training in Alzheimer's disease. In Geriatrie ET psychologie neuropsychiatrie du vieillissement
23. Graff M, Vernooy-Dassen M, Thijssen M, et al. Home based ergotherapy in patients with dementia. In Nederlands tijdschrift ergotherapie
24. Grassel E, Behrndt E, Straubmeier M. Resource-sustaining therapy in dementia: the MAKS study. In Public health forum
25. Haberstroh J, Neumeyer K, Schmitz B, et al. Development and evaluation of a training program for nursing home professionals to improve communication in dementia care. In Z Gerontol Geriatr
26. Hong S. Effects of Multi-Component Exercise and Retraining after Detraining on Functional Fitness and Cognitive Function in Elder People with Mild Dementia. In Korean j health promot
27. Hori M, Kubota M, Ando K, et al. The effect of videophone communication (with skype and webcam)for elderly patients with dementia and their caregivers. In Gan to kagaku ryoho Cancer & chemotherapy
28. Knight S, Singh I. Profile of inpatient falls in patients with dementia: a prospective comparative study between

100% single rooms and traditional multibedded wards. In Journal of clinical gerontology and geriatrics
29. Li X, Sun Y, Yan Y. Observation on effect of application of sleep restriction therapy for Alzheimer's disease patients with sleep disorders. In Chinese nursing research
30. Lopez N, Veliz A, Soto-Anari M, et al. Effects of a combined program of physical activity and cognitive training in Chilean patients with mild Alzheimer. In Neurologia argentina
31. Lukas A, Kilian R, Hay B, et al. Maintenance of health and relief for caregivers of elderly with dementia by using "initial case management". Experiences from the lighthouse project on dementia, ulm, ultdem-study. Z Gerontol Geriatr. 2012 June;45(4):298-309. doi: http://dx.doi.org/10.1007/s00391-012-0337-z. PMID: 51981666.
32. Menezes A, Aguiar A, Alves E, et al. Effectiveness of a cognitive-motorphysiotherapeutical therapy intervention in institutionalized older adults with mild cognitive impairment and mild dementia. In Ciencia & saude coletiva
33. Morgenstern U, Ketelhut K, Rösler D. Concentration enhancement for retaining daily living competence in dementia. In Z Gerontol Geriatr
34. Muller B, Staudinger B. Evaluation of an inpatient multimodal treatment concept for people with dementia. In Pflegewissenschaft
35. Negovanska V, Hergueta T, Guichart-Gomez E, et al. Beneficial effect of a cognitive behavioral and multidisciplinary program in Alzheimer Disease on spouse caregiver anxiety: french study ELMMA. In Revue neurologique
36. Pickel S, Grässel E, Luttenberger K. Efficacy of an occupational group therapy in degenerative dementias: a controlled study in the nursing home setting. In Psychiatrische praxis
37. Pitteri F, Soulas T, Essertaise A, et al. Contribution of relaxation to a psychoeducational intervention program for family carers of persons with Alzheimer's disease. In Geriatrie ET psychologie neuropsychiatrie du vieillissement
38. Quibel C, Bonin M, Bonnet M, et al. Evaluation of the animal-assisted therapy in Alzheimer's disease. In Soins Gerontologie
39. Ravari A, Mirzaei T, Salamizadeh A, et al. Effect of the spiritual care training on anxiety reduction in home caregivers of the elderly with alzheimer disease. In Koomesh
40. Rexhausen E. Psychosocial care assistants caring for residents with dementia according to section 87b SGB XI. Emotional and cognitive effects. In Pflege zeitschrift
41. SeungHyun C, Young-ae Y. The Effect of Occupational Therapy Based Multimodal Cognitive Rehabilitation Therapy on Cognitive Function in Elderly People With Mild Dementia: a Randomized Controlled Trial.
42. Song J. Effects of a robot pet-assisted program for elderly people with dementia. In Journal of korean academy of nursing
43. Steinert T, Bohnet U, Flammer E, et al. Effects of a training of power and balance on the use of mechanical restraint among in-patients with dementia. In Psychiatrische praxis
44. Stemmer R, Grassel E, Schmid M. Individual activation of dementia sufferers in a home setting. A randomized controlled study. Z Gerontol Geriatr. 2019;52(3):256-63. PMID: CN-01954578.
45. Tannen A. Effectiveness of a case management program for the elderly in early stage dementia and their caregivers. In Pflege zeitschrift
46. Todri J, Lena O, Martinez Gil JL. A single blind randomized controlled trial of global postural re-education: Cognitive effects on Alzheimer disease patients. European Journal of Psychiatry. 2019. doi: http://dx.doi.org/10.1016/j.ejpsy.2019.01.001. PMID: 2001581733.
47. Wan C, Hu Z, Sun Y. Application of acupoint massage in nursing care of community dementia patients. In Chinese nursing research
48. Wang Y, Chiu C, Chen Y, et al. The efficacy of multi-sensory environment therapy on psychological, behavioral symptoms among elderly patients with dementia]. [Chinese. In Hu li za zhi [journal of nursing]
49. Zhang HZLHCHKLJ. Clinically multi-central randomized controlled study on scalp electroacupuncture for treatment of vascular dementia. In Zhongguo zhen jiu [Chinese acupuncture & moxibustion]
50. Zhou Y, Han H, Jia J. Correlation analysis on changes between cognitive ability and brain fMRI after acupoint thread embedding in Alzheimer's disease patients. In Zhongguo zhong xi yi jie he za zhi zhongguo zhongxiyi jiehe zazhi = chinese journal of integrated traditional and western medicine

Ineligible Intervention

51. Aasmul I, Husebo BS, Flo E. Staff Distress Improves by Treating Pain in Nursing Home Patients With Dementia: Results From a Cluster-Randomized Controlled Trial. J Pain Symptom Manage. 2016 Dec;52(6):795-805. doi: https://dx.doi.org/10.1016/j.jpainsymman.2016.07.004. PMID: 27524403.
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Appendix C. Treatment for BPSD

Assisted Therapy

Appendix Table C.1. Risk of bias assessment: assisted therapy

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Moyle 2017[1] (28780395) Jones 2018[2] (29656838) Mervin 2018[3] (29325922) Moyle 2018[4] (29563027)	10 weeks	Low 10 weeks: 4.3% 15 weeks: 7.0%	Low	Medium	Medium	Medium	Medium	Funder	Medium
Peterson 2017[5] (27716673)	3 months	Medium NR	Medium	High	Medium	High	X	NR	High
Olsen 2016[6] (27155968)	12 weeks 6 months	Low 12 weeks: 1% 6 months:1%	Low	High	Medium	Low	X	Foundation	High
Olsen 2016[7] (26807956)	12 weeks 6 months	Low 12 weeks: 12% 6 months: 17%	Low	High	Medium	Low	X	Foundation	High
Bemelmans 2015[8] (26115817)	4 months	High 21.9%	X	X	X	X	X	NR	High
Joranson 2015[9] (26096582) Joranson 2016[10] (27434512)	12 weeks 6 months	Medium 12 weeks: 10% 6 months: 16.7%	Medium	High	High	Low	X	Government	High
Travers 2013[11] (NA)	11 weeks	Medium 17.9%	Medium	Low	High	Low	X	Foundation	High

X indicates that domain was not assessed due to high risk of bias.
Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Appendix Table C.2. Characteristics of included studies: assisted therapy

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Moyle 2017[1] (28780395) Australia Medium Explanatory Jones 2018[12] (29656838) Mervin 2018[3] (29325922) Moyle 2018[4] (29563027)	Individual, non-facilitated sessions with PARO (robotic seal) for PLWD over 10 weeks; three afternoon sessions per week, 15 minutes/session	1. Standard care for PLWD at respective facilities 2. Push toy (PARO with robotic features disabled) for PLWD over 10 weeks; three	Long-term care facilities approved and accredited by the Australian government Cluster RCT Multisite 18 Clusters 415 PLWD	Any dementia type or severity. RUDAS ≤ 22 and documented dementia diagnosis	N=415 76% Female 85 years Race NR Education NR	None	NA	NA	NA	NA	10 weeks 15 weeks	Agitation (observed) CMAI-SF Positive behavioral engagement Using object for social engagement Positive verbal engagement Visual engagement	NA

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
		afternoon sessions per week, 15 minutes/session											

* High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: Char=characteristics; CMAI-SF=Cohen-Mansfield Agitation Inventory; FC=formal caregiver; IC=informal caregiver; PMID=PubMed Identification Number; PLWD=Persons Living with Dementia; Rob=Risk of Bias; RUDAS=Rowland Universal Dementia Assessment Scale; SES=socioeconomic status; RS=Reporting Status

Appendix Table C.3. Modified PRECIS-2: assisted therapy

Study (PMID)	Eligibility Criteria	Recruitment Path	Setting	Intervention Organization	Flexibility of Intervention: Delivery	Flexibility of Intervention: Adherence	Follow-up	Primary Outcome	Analysis	Overall Category Applicability and/or Qualifiers
Moyle 2017[1] (28780395) Jones 2018[2] (29656838) Mervin 2018[3] (29325922) Moyle 2018[4] (29563027)	Balanced	Mostly Explanatory	Mostly Explanatory	Explanatory	Explanatory	Mostly Explanatory	Mostly Explanatory	Mostly Explanatory	Balanced	Explanatory

Abbreviations: NA=Not Assessed; PMID=PubMed Identification Number

Appendix Table C.4. PLWD outcomes summary low and medium risk of bias studies: assisted therapy

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Moyle 2017[1] (28780395) PARO vs. usual care Medium Explanatory	Adjusted Mean Difference (95% CI) Reduction in agitation (observed via video recording) 10 weeks	3.3 (0.9, 5.8)	NR	NR	p=0.008
Moyle 2017[1] (28780395) PARO vs. usual care Medium Explanatory	Adjusted Mean Difference (95% CI) CMAI-SF 10 weeks	-1.9 (-5.8, 2.0)	NR	NR	p=0.34
Moyle 2017[1] (28780395) PARO vs. usual care Medium Explanatory	Mortality % (N) 15 weeks	NR	5.1% (7)	3.6% (5)	NR
Moyle 2017[1] (28780395) PARO vs. plush toy Medium Explanatory	Adjusted Mean Difference (95% CI) Reduction in agitation (observed via video recording) 10 weeks	1.3 (-1.7, 4.2)	NR	NR	p=0.39
Moyle 2017[1] (28780395) PARO vs. plush toy Medium Explanatory	Adjusted Mean Difference (95% CI) CMAI-SF 10 weeks	-0.99 (-5.8, 3.8)	NR	NR	p=0.68

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Moyle 2017[1] (28780395) PARO vs. plush toy Medium Explanatory	Adjusted Mean Difference (95% CI) Positive behavioral engagement (observed via video recording) 10 weeks	6.3 (-0.8, 13.5)	NR	NR	p=0.08
Moyle 2017[1] (28780395) PARO vs. plush toy Medium Explanatory	Adjusted Mean Difference (95% CI) Using object for social engagement (observed via video recording) 10 weeks	1.2 (-0.6, 3.0)	NR	NR	p=0.18
Moyle 2017[1] (28780395) PARO vs. plush toy Medium Explanatory	Adjusted Mean Difference (95% CI) Positive verbal engagement (observed via video recording) 10 weeks	3.6 (0.81, 6.40)	NR	NR	p=0.01
Moyle 2017[1] (28780395) PARO vs. plush toy Medium Explanatory	Adjusted Mean Difference (95% CI) Visual engagement (observed via video recording) 10 weeks	13.1 (9.06, 17.05)	NR	NR	p<0.0001
Moyle 2017[1] (28780395) PARO vs. plush toy Medium Explanatory	Mortality % (N) 15 weeks	NR	5.1% (7)	10% (14)	NR

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: CI=Confidence interval; NR=Not Reported; PMID=PubMed Identification Number; RoB=Risk of Bias

Appendix Table C.5. Summary of strength of evidence for PLWD outcomes: robot-assisted therapy

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
PARO vs. usual care Agitation	10 weeks	1 clustered RCT (n=257)	Evidence was mixed for agitation reduction. Observation via video recordings favored PARO; however, CMAI-SF showed no difference between groups.	Moderate	Unknown	Direct	Imprecise	Insufficient
PARO vs. plush toy Agitation	10 weeks	1 clustered RCT (n=278)	No difference between groups in measures of agitation.	Moderate	Unknown	Direct	Imprecise	Insufficient
PARO vs. plush toy Engagement	10 weeks	1 clustered RCT (n=278)	Observation via video recordings showed improvements in PARO for positive verbal engagement and visual engagement compared to plush toy; however, there was no difference for positive behavioral engagement and using the object for social engagement.	Moderate	Unknown	Direct	Imprecise	Insufficient

Abbreviations: n=Number, CMAI-SF=Cohen-Mansfield Agitation Inventory-Short Form; RCT=Randomized controlled trial.

Evidence Map: Assisted Therapy

Appendix Table C.6. Characteristics of evidence map studies: assisted therapy

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Pu, 2020[13] (32122797) Pu (31738463)[14] Australia Pilot	PARO robotic pet, 30 minutes 5 times a week for 6 weeks individually in bedrooms	Usual care	Long-term care facilities RCT 43 PLWD	Probably or possible dementia and chronic pain	N=43 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	6 weeks	PAINAD CMAI-SF Medication use	NA
Balzotti 2019[15] (30136743) Italy Small sample	Gesture verbal treatment: develop PLWD interactive use of gestures with other communication strategies. 2 1-hour group sessions weekly for 12 weeks. Doll therapy: 1 hour daily for 12 weeks.	Usual rehabilitative care	AD care home Quasi-experimental 30 PLWDs	Dementia diagnosis based on DSM-V criteria;	N=30 Mean age: yes % Female: yes % majority race: no Education: yes	None	NA	None	NA	NA	12 weeks	NPI-Q	NA
Menna, 2019[16] (30740833) Italy Pilot	Dog-assisted group therapy; 12 weekly sessions	Unclear	Adult daycare center RCT 22 PLWD	Mild to moderate AD (per MMSE)	N=22 Age: no Sex: no Race: no Education: no	None	NA	NA	NA	NA	3 months	Cortisol level GDS	NA
Moyle, 2019[17] (30474401) Australia Pilot	Life-like baby doll-assisted therapy; 3 30 minute sessions per week for 3 weeks	Usual care	Long-term care facilities RCT 35 PLWD	Dementia with recent history of BPSD	N=35 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	3 months	CMAI-SF OERS	NA
Cantarella 2018[18] (622559552) Italy Pilot study	Doll therapy, 60 minute sessions 5 times/week for 1 month	Hand warmers, 60-minute sessions 5 times/week for 1 month	Nursing home RCT, single site 32 PLWD	Severe AD or vascular dementia (≥5 Short Portable Mental Status Questionnaire) with BPSD	N=32 Age: yes Sex: yes Race: no Education: yes	None	NA	NA	N=NR Age: no Sex: no % majority race: no Education: no	None	1 month	NPI Eating Behavior Scale	NPI-Distress

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Liang 2017[19] (28668664) New Zealand Pilot	PARO robotic pet at day care and at home, 30-minute group sessions 2-3 times a week for 6 weeks at day care	Facilities' standard of care	Dementia day care centers and at home RCT; Multisite 30 PLWD 30 informal caregivers	Not specified	N=30 Age: yes Sex: yes Race: no Education: no	None	N=30 Age: yes Sex: yes % majority race: no Education: no	None	NA	NA	12 weeks	CMAI-SF NPI Brief Questionnaire CSDD	NA
Petersen 2017[5] (27716673) US High RoB	PARO robotic pet, 20 minutes 3 times a week for 3 months	Facilities' standard of care	Senior living facilities RCT; Multisite 61 PLWD	Mild to moderate dementia according to DSM or NIA criteria	N=61 Age: yes Sex: yes Race: yes Education: no	None	NA	NA	NA	NA	3 months	RAID CSDD GDS	NA
Olsen 2016[6] (27155968) Norway High RoB	Group animal therapy sessions with a dog, 2 times/week for 12 weeks	Usual care	Adult day care centers Cluster RCT 16 clusters 80 PLWD	Dementia diagnosis or MMSE <25	N=80 Age: yes Sex: yes Race: no Education: yes	Prior disability: yes	NA	NA	NA	NA	12 weeks 6 months	Berg Balance Scale CDR QUALID	NA
Olsen 2016[7] (26807956) Norway High RoB	Group animal therapy sessions with a dog, 2 times/week, 30 minutes/session, for 12 weeks	Usual care	Nursing homes Cluster RCT 10 clusters 58 PLWD	Dementia diagnosis or MMSE <25	N=58 Age: yes Sex: yes Race: no Education: yes	Prior disability: yes	NA	NA	NA	NA	12 weeks 6 months	CSDD QUALID Brief Agitation Rating Scale CDR	NA
Bemelmans 2015[8] (26115817) Netherlands High RoB	PARO robotic pet to provide comfort individually to distressed PLWD; as needed over 4 months	PARO robotic pet incorporated in daily activities for care support; as needed over 4 months	Care institutions for intramural psychogeriatric care Quasi experimental time series; multisite 91 PLWD	All dementia severity	N=91 Age: no Sex: yes Race: no Education: no	None	NA	NA	NA	NA	4 months	Individually Prioritized Problems Assessment	NA
Joranson 2015[9] (26096582) Norway High RoB Joranson 2016[10] (27434512)	PARO robotic pet, 30-minute group sessions 2 times a week for 12 weeks	Usual care	Nursing homes Cluster RCT; Multisite 60 PLWD	Dementia diagnosis with cognitive impairment or score lower than 25/30 on Norwegian MMSE	N=69 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	12 weeks 6 months	Norwegian BARS Norwegian CSDD QUALID	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Valenti Soler 2015[20] (26388764) Spain Pilot	PARO robotic pet, 30-40-minute group sessions 2 times a week for 3 months	1. Facility's standard of care 2. Humanoid robot, 30-40-minute group sessions 2 times a week for 3 months 3. Animal therapy with dogs, 30-40-minute group sessions 2 times a week for 3 months	Public nursing home RCT; Single site 117 PLWD	Diagnosis of neurodegenerative dementia, all dementia types	N=117 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	3 months	GDS NPI APADEM-NH Apathy Inventory QUALID	NA
Moyle 2013[21] (23506125) Australia Pilot	PARO robotic pet, 45-minute group sessions 3 times a week for 5 weeks	Reading group, 45-minute group sessions 3 times a week for 5 weeks	Residential care facility Crossover RCT; Single site 18 PLWD	Diagnosis of mid to late stage dementia or DSM-IV criteria for probable dementia	N=18 Age: yes Sex: no Race: no Education: No	None	NA	NA	NA	NA	5 weeks 10 weeks	QoL-AD RAID AES GDS AWS OERS	NA
Travers 2013[11] (NA) Australia High RoB	Group animal therapy with a dog, 40-50-minute sessions 2-3 times/week for 11 weeks	Group therapy, 40-50-minute sessions 2-3 times/week for 11 weeks	Nursing home RCT, multisite 67 PLWD	Mild to moderate dementia (any type)	N=67 Age: yes Sex: yes Race: no Education: yes	None	NA	NA	NA	NA	11 weeks	QoL-AD SF-36 GDS-SF Multidimensional Observational Scale for Elderly Subjects	NA
Majic 2013[22] (23831177) Germany Pilot	Animal therapy with a dog, one 40-minute session/week for 10 weeks	Usual Care	Nursing home Case-Control 75 PLWD	Dementia diagnosis (DSM-IV criteria) and MMSE <25	N=75 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	10 weeks	CMAI Dementia Mood Assessment Scale	NA

Abbreviations: AES=Apathy Evaluation Scale; APADEM-NH=Apathy Scale for Institutionalized Patients with Dementia Nursing Home; AWS=Revised Algase Wandering Scale–Nursing Home version; BARS=Brief Agitation Rating Scale; BPSD=Behavioral and Psychological Symptoms of Dementia; CDR=Clinical Dementia Rating; Char=characteristics; CMAI=Cohen Mansfield Agitation Inventory; CMAI-SF=Cohen-Mansfield Agitation Inventory-Short Form; CSDD=Cornell Scale for Depression in Dementia; DSM IV=Diagnostic and Statistical Manual; EM=Evidence Map; FC=formal caregiver; GDS=Geriatric Depression Scale; GDS=Global Deterioration Scale; GDS-SF=Geriatric Depression Scale Short Form; IC=informal caregiver; MMSE=Mini-mental State Exam; N=number; NA=Not Applicable; NIA=National Institute on Aging; NPI=Neuropsychiatric Inventory; OERS=Observed Emotion Rating Scale; PAINAD=Pain Assessment in Advanced Dementia; PMID=PubMed Identification Number PLWD=Persons Living with Dementia; QoL-AD=Quality of Life in Alzheimer's Disease; QUALID=Quality of Life in Late-stage Dementia; RAID=Rating for Anxiety in Dementia; RCT=Randomized controlled trial; RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status; SF-36=Medical Outcomes Study 36-Item Short Form Health Survey;

Multi-Sensory Stimulation/Snoezelen

Appendix Table C.7 Risk of bias assessment: Multi-Sensory Stimulation

Study (PMID)	**Outcome Timing**	**Attrition Bias Attrition %**	**Selection Bias**	**Detection Bias**	**Performance Bias**	**Reporting Bias**	**Fidelity Bias**	**Funder**	**Overall Rating**
Strom 2017)[23] (28553314)	24 weeks	Medium 12.5%	Medium	Medium	Medium	Medium	Medium	NR	Medium
Baker 2003[24] (12919265)	0 weeks 4 weeks	Low 6.62%	Low	Medium	Medium	Medium	High	NR	Medium
Van Weert, 2005[25] (15667372)	72 weeks	Medium 27.61%	Medium	High	High	Low	Low	Netherlands government	High

X indicates that domain was not assessed due to high risk of bias.
Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Appendix Table C.8. Characteristics of included studies: Multi-Sensory Stimulation

Study (PMID) **Country** **RoB*** **Type**	**Intervention** **Intervention Focus** **Theoretical Model** **Delivery Person** **Intervention Target Recipient** **Mode** **Components** **Frequency** **Duration**	**Comparison** **Target** **Mode** **Components** **Frequency** **Duration**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics** **Dementia Types** **Dementia Severity** **Diagnostic Criteria** **Age of Diagnosis**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Strom, 2017[23] (28553314) Republic of Ireland Medium Explanatory	Group Sonas sessions led by a licensed practitioner; two 45-minute sessions per week for 24 weeks	Group newspaper reading sessions; two 45-minute sessions per week for 24 weeks Usual nursing facility care	Nursing facilities approved and accredited by the Republic of Ireland RCT Multisite 120 PLWD	Diagnosis of dementia, moderate to severe cognitive impairment (MMSE ≤ 20)	N=120 Age: Mean age 84.8 Sex: 77.5% female Race: NR Education NR	NR	NA	NA	NR	NR	12 weeks post-intervention 24 weeks post-intervention	Function	None
Baker 2003)[24] (12919265) (11317951)[26] United Kingdom, Netherlands, and Switzerland Medium Explanatory	Individual, non-directed sessions in a Snoezelen room, facilitated by a nursing staff, occupational therapist, or psychology assistants; two 30-minute sessions per week for 4 weeks	Individual activity sessions chosen according to participant's interests, e.g. playing cards, quizzes, looking at cards; facilitated by a nursing staff, occupational therapist, or psychology assistants; two sessions per week for	Day hospital, psycho-geriatric ward RCT Multisite 136 PLWD randomized, 120 analyzed	Diagnosis of Alzheimer's, vascular, or mixed dementia, moderate to severe cognitive impairment (MMSE ≤ 17)	N=136 Age: 82 years Sex: not reported Education: NR	NR	NA	NA	NR	NR	0 weeks post intervention 4 weeks post intervention	Neuropsychiatric symptoms	None

Study (PMID) **Country** **RoB*** **Type**	**Intervention** **Intervention Focus** **Theoretical Model** **Delivery Person** **Intervention Target Recipient** **Mode** **Components** **Frequency** **Duration**	**Comparison** **Target** **Mode** **Components** **Frequency** **Duration**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics** **Dementia Types** **Dementia Severity** **Diagnostic Criteria** **Age of Diagnosis**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
		4 weeks, 30 minutes per session											

* High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: Char=characteristics; FC=formal caregiver; IC=informal caregiver; MMSE=Mini-mental State Exam; N=number; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RCT=Randomized controlled trial RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status

Appendix Table C.9. PLWD outcomes summary low and medium risk of bias studies: Multi-Sensory Stimulation

Study (PMID) **Comparison** **RoB** **Category***	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Baker 2003[24] (12919265) Explanatory	Unadjusted Mean Difference Reduction in neuropsychiatric symptoms (REHAB general behavior scale, UK participants only) 4 weeks (immediately post-intervention)	-1.9 points, CI not reported	Snoezelen	Active control	Not reported, but described as no difference
Baker 2003[24] (12919265) Explanatory	Unadjusted Mean Difference Reduction in neuropsychiatric symptoms (REHAB deviant behavior subscale, UK participants only) 4 weeks (immediately post-intervention)	0.5 points, CI not reported	Snoezelen	Active control	Not reported, but described as no difference
Baker 2003[24 (12919265)] Explanatory	Unadjusted Mean Difference Reduction in neuropsychiatric symptoms (GIP scale, Dutch participants only) 4 weeks (immediately post-intervention)	-2.4 points, CI not reported	Snoezelen	Active control	Not reported, but described as no difference
Strom 2017[23] (28553314) Explanatory	Unadjusted mean difference Reduction in communication difficulty (HCS total score)(higher is worse) 24 weeks	3.0 points, CI not reported	Sonas	Active control	P=0.019
Strom 2017[23] (28553314) Explanatory	Unadjusted mean difference Reduction in communication difficulty (HCS total score) 24 weeks	4.0 points, CI not reported	Sonas	Inactive control	P=0.001

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; REHAB=Rehabilitation Evaluation Hall and Baker Scale; GIP=Behavior Observation Scale for Intra-Mural Psycho-Geriatrics; HCS=Holden Communication Scale

Appendix Table C.10. Summary of strength of evidence for PLWD outcomes: Multi-Sensory Stimulation

Comparison **Outcome**	**Timing**	**# Studies/ Design (n analyzed)**	**Finding or Summary Statistic**	**Study Limitations**	**Consistency**	**Directness**	**Precision**	**Overall Grade/ Conclusion**
MSS vs. Active control Neuropsychiatric symptoms	4 weeks	1 RCT (n=120)	No significant difference in measures of neuropsychiatric symptoms (UK population)	Moderate	Unknown	Indirect (BPSD were assessed using instruments that are not standard in the ADRD field (appear to be designed for psychiatric settings) and that contain other domains (e.g. mood, physical function))	Imprecise	Insufficient

Abbreviations: ADRD=Alzheimer's disease and related disorders; BPSD=behavioral and psychological symptoms of dementia; MSS=multisensory stimulation; n=number; RCT=randomized controlled trials

Evidence Map: Multi-Sensory Stimulation

Appendix Table C.11. Characteristics of evidence map studies: Multi-Sensory Stimulation

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Maseda 2018[27] (29843244) Spain Small sample	Snoezelen	Individualized music sessions	Nursing home; single site 21 PLWD	N=21 Diagnosis of dementia and severe cognitive impairment (GDS=6 or 7)	N=21 Sex: yes Age: yes Race: no Education: yes	None	NA	NA	NA	NA	12 weeks	No validated outcomes	NR
Collier 2008[28] (21131677) United Kingdom Small sample	Multi-sensory environment	Gardening	Nursing homes or continuing care wards; multisite 30 PLWD	N=30 Moderate to severe dementia Mean MMSE 10.0	N=30 Sex: yes Age: yes Race: no Education: no	None	NA	NA	NA	NA	4 weeks	AMPS motor and process scales	NA
Staal 2007[29] (18441625) US Pilot	Snoezelen	Activity sessions	Geriatric psychiatric unit; single site 24 PLWD	N=24 Admitting diagnosis of dementia, criteria NR Mean MMSE 15.5	N=24 Sex: yes Age: yes Race: no Education: no	None	NA	NA	NA	NA	Unclear	PAS MAI, physical health domain SANS-AD Katz Index of ADLs RADL	NA
Van Weert 2005[25] (15667372) (15050851)[30] Netherlands High RoB	Snoezelen	Usual care	Nursing home psychogeriatric wards; multisite 125 PLWD	N=125 Moderate to severe dementia, DSM-III criteria	N=125 Sex: yes Age: yes Race: no Education: no	None	NA	NA	NA	NA	18 months	BIP, 8 of 14 subscales CMAI CSDD	NA
Baillon 2004[31] (15481068) United Kingdom Small sample	Snoezelen	Reminiscence therapy	Nursing home; single site	N=25 Median MMSE 4.0 among completers	N=25 Sex: yes Age yes Race: no Education: no	None	NA	NA	NA	NA	1 day (note: comparisons were done before and after each individual session)	ABMI	NA
Van Diepen 2002[32] (35396447) United Kingdom Pilot	Snoezelen	Reminiscence therapy	Day hospital; single site 15 PLWD	N=15 Mean MMSE 7.7	N=15 Sex: no Age no Race: no Education: no	None	NA	NA	NA	NA	8 weeks post intervention	CMAI ABMI	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Baker 1997[33] (12519587) United Kingdom Small sample	Snoezelen	Activity sessions	Day hospital; multisite 31 PLWD	Mean MMSE approximately 6	N=31 Sex: yes Age: no Race: no Education: no	None	NA	NA	NA	NA	8 weeks post intervention	REHAB deviant behavior REHAB speech BRS social disturbance	NA

Abbreviations: ABMI=Agitation Behavior Mapping Instrument; ADL=Activities of Daily Living ; AMPS=Assessment of Motor and Process Skills; BIP=Behavior Observation Scale for Psychogeriatric In-Patients; BRS=Behavior Rating Scale; Char=characteristics; CMAI=Cohen-Mansfield Agitation Inventory; CSDD=Cornell Scale for Depression in Dementia; DSM=Diagnostic and Statistical Manual; EM=Evidence Map; FC=formal caregiver; GDS=Global Deterioration Scale; IC=informal caregiver; MAI=Multi-level Assessment Instrument; MMSE=Mini-mental State Exam; N=number; NA=Not Applicable; NR=Not Reported; PAS=Pittsburgh Agitation Scale; PMID=PubMed Identification Number; PLWD=Persons Living with Dementia; RADL=Refined Activities of Daily Living Assessment Scale; REHAB=Rehabilitation Evaluation Hall and Baker; RS=Reporting Status; SANS-AD=Scale for the Assessment of Negative Symptoms in Alzheimer's Disease; SES=socioeconomic status;

Complementary and Alternative Medicine (CAM) Therapy

Appendix Table C.12. Risk of bias assessment: CAM Therapy

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Overall Rating
Kwan 2017[34] (25346026)	8 weeks	Low 8 weeks: 0%	Medium	High	High	Low	Medium	High
Yang 2016[35] (27319407)	8 weeks	Low 8 weeks: 5%	Low	Medium	High	Low	Medium	Medium
Yang 2015[36] (25880034)	3 weeks	High 3 weeks: 33%	X	X	X	X	X	High
Moyle 2014[37] (24216598)	3 weeks	Low 3 weeks: 3.64%	Low	Low	Low	Low	Low	Low
Burns 2011[38] (21335973)	4 weeks	Medium 4 weeks: 16%	Low	Medium	Low	Low	Low	Medium
Lin 2007[39] (17342790)	8 weeks	Low 8 weeks: 0%	Low	Medium	Medium	Low	Low	Medium
Ballard 2002[40] (12143909)	4 weeks	Low 4 weeks: 1.4%	Low	Low	Medium	High	Low	Medium

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: NA=Not Applicable; PMID=PubMed Identification Number

Appendix Table C.13. Characteristics of included studies: CAM Therapy

Study (PMID) **Country** **RoB*** **Type**	**Intervention** **Intervention Focus** **Theoretical Model** **Delivery Person** **Intervention Target Recipient** **Mode** **Components** **Frequency** **Duration**	**Comparison** **Target** **Mode** **Components** **Frequency** **Duration**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics** **Dementia Types** **Dementia Severity** **Diagnostic Criteria** **Age of Diagnosis**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Yang 2016[35] (27319407) Taiwan Medium Explanatory	PLWD; got 30 minutes of aromatherapy massage with lavender oil and orange oil once per week for 8 weeks f	PLWD, Usual Care	Long-term care facilities in Taiwan RCT 59 PLWD	Mild to severe dementia based on (score ≤8) (SPMSQ; or (MMSE);	N=29 61% Female 92 years Race NR High school education or higher: 38% Use of psychotropic meds: 70%	None	NA	NA	NA	NA	5 weeks 9 weeks	CCMAI CSDD-C	NA
Moyle 2014[37] (24216598) Australia Low Explanatory	PLWD, Trained massage therapists provided 5 minutes massage on each foot using unscented sorbolene for 3 weeks	PLWD, Trained assistants sat quietly near the participant's feet for 10 minutes without talking or making physical contact or any deliberate touching or conversation with the participant	Long-term care facilities in South Queensland Crossover RCT 55 PLWD	Moderate to late stage dementia, MMSE score of less than 18 with a recent history of agitation (PAS >3);	N=55 66% Female 86.5 years Race NR Education NR	None	NA	NA	NA	NA	3 weeks	CMAI OERS	NA
Burns 2011[38] (21335973) The United Kingdom (UK) Medium Explanatory	PLWD; 10% Melissa (lemon-balm) oil mixed with base lotion was gently massaged on hands and upper-arms twice a day	PLWD; Sunflower oil mixed with base lotion was gently massaged on hands and upper arms twice a day	Clinical centers – Manchester, London and Southampton, UK RCT 77 PLWD	PLWD with agitation for a minimum of 4 weeks, a score of 13 9 on the CMAI, and satisfied the NINCDS/ADRDA criteria for probable or possible Alzheimer's disease; or was a resident in a nursing home or NHS continuing care facility, had a clinical dementia rating of 3, age over 60 years and were free of	N=38 43% Female 85 years Race NR Education NR	None	NA	NA	NA	NA	4 weeks 12 weeks	PAS NPI Blau-QoL Barthel index	NA

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
				psychotropic medication (antipsychotics and/ or cholinesterase inhibitors) for at least 2 weeks									
Lin 2007[39] (17342790) Hong Kong Medium Explanatory	PLWD, lavender oil inhalation for 3 weeks. with a washout period of 2 weeks; 2 drops of oil placed on cotton using dropper in an aromatic diffuser. Two such diffusers are placed at each side of pillow for 1 h every night	PLWD, Sunflower oil inhalation for 3 weeks. with a washout period of 2 weeks; 2 drops of oil placed on cotton using dropper in an aromatic diffuser. Two such diffusers are placed at each side of pillow for 1 h every nigh	Care and attention homes in Hong Kong Crossover RCT 70 PLWD	Dementia diagnosis based on DSM-IV, APA 1994 with clinically significant agitation evaluated using CCMAI	N=35 41% Female 82 years Race NR Education NR Use of psychotropic meds: 51%	None	NA	NA	NA	NA	3 weeks 5 weeks 8 weeks	CCMAI CNPI	NA
Ballard 2002[40] (12143909) The United Kingdom Medium Explanatory	PLWD; 10% Melissa (lemon-balm) oil mixed with base lotion was gently applied (0.16-0.17g) onto PLWD face and arms, twice a day for 6 doses per day by care assistants	PLWD; Sunflower oil mixed with base lotion was gently applied (0.16-0.17g) onto PLWD face and arms, twice a day for 6 doses per day by care assistants	National Health Service nursing homes in UK RCT 72 PLWD	Severe dementia with agitation characterized by CMAI and also screened by NPI and CDR	N=36 60% Female 78.5 years Race NR Education NR Use of psychotropic meds: 92%	None	NA	NA	NA	NA	4 weeks	CMAI NPI	NA

* High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: APA=American Psychiatric Association; Barthel index=Barthel scale of Activities of Daily Living; char=characteristics; FC=formal caregiver; IC=informal caregiver; CCMAI=Cohen-Mansfield Agitation Inventory-Chinese version; CDR=Clinical dementia rating scale; CNPI=Neuropsychiatric Inventory-Chinese version; CSDD-C=Cornell Scale for Depression in Dementia–Chinese Version; DSM-IV=Diagnostic and Statistical Manual of Mental Disorders, 4th edition; MMSE=Mini-Mental State Examination; g=grams; h=Hour; N=Number; NHS=National Health Service; NINCDS/ADRDA=National Institute of Neurological and Communicative Disorders and Stroke/ Alzheimer's Disease and Related Disorders Association; NA=Not applicable; NR=Not reported; OERS=Observed Emotion Rating Scale; PAS=Pittsburgh Agitation Scale; PMID=PubMed Identification Number; PLWD=Persons Living with Dementia; QoL=Quality of life; RCT=Randomized controlled trial; RoB=Risk of Bias; RS=Reporting Status; SPMSQ=Short Portable Mental Status Questionnaire

Appendix Table C.14. PLWD outcomes summary low and medium risk of bias studies: CAM Therapy

Study (PMID) **Comparison** **RoB** **Category***	**Outcome** **Timing**	**Summary Finding**	**Overall p-value**	**Intervention**	**p-value**	**Comparator**	**p-value**
Yang 2016[35] (27319407) Lavender and orange oil vs. Usual care Medium Explanatory	Mean Difference (95% CI) CCMAI 5 weeks	NR	0.316	3.65 (NR)	NR	7.08 (NR)	NR
Yang 2016[35] (27319407) Lavender and orange oil vs. Usual care Medium Explanatory	Mean Difference (95% CI) CCMAI 9 weeks	NR	0.316	3.41 (NR)	NR	6.3 (NR)	NR
Yang 2016[35] (27319407) Lavender and orange oil vs. Usual care Medium Explanatory	Mean Difference (95% CI) CSDD-C 5 weeks	NR	<0.001	0.51 (NR)	NR	3.04 (NR)	NR
Yang 2016[35] (27319407) Lavender and orange oil vs. Usual care Medium Explanatory	Mean Difference (95% CI) CSDD-C 9 weeks	NR	<0.001	0.62 (NR)	NR	6.45 (NR)	NR
Lin 2007[39] (17342790) Lavender oil vs. sunflower oil Medium Explanatory	Mean Difference (95% CI) CNPI 3 weeks	NR	NR	6.91 (NR)	<0.001	-0.08 (NR)	p=0.24
Lin 2007[39] (17342790) Lavender oil vs. sunflower oil Medium Explanatory	Mean Difference (95% CI) CCMAI 3 weeks	NR	NR	4.4 (NR)	<0.001	0.04 (NR)	p=0.52
Burns 2011[38] (21335973) Melissa oil vs sunflower oil Medium Explanatory	Median Difference (95% CI) PAS 4 weeks	NR	0.94	0.0 (-1.3, 0.3)	NR	-0.3 (-1.7,0)	NR
Burns 2011[38] (21335973) Melissa oil vs sunflower oil Medium Explanatory	Median Difference (95% CI) PAS 12 weeks	NR	0.56	-0.7 (-1.7, 0)	NR	-0.7 (-1.7, 0)	NR
Burns 2011[38] (21335973) Melissa oil vs sunflower oil Medium Explanatory	Mean Difference (95% CI) NPI 4 weeks	NR	0.54	-4.8 (-11.3, 1.6)	NR	-9.8 (-18.8, 1.3)	NR
Burns 2011[38] (21335973) Melissa oil vs sunflower oil Medium Explanatory	Mean Difference (95% CI) NPI 12 weeks	NR	0.52	-7.2 (-12.6, -1.7)	NR	-10.0 (-17.2, -3)	NR
Burns 2011[38] (21335973) Melissa oil vs sunflower oil Medium Explanatory	Mean Difference (95% CI) QoL 4 weeks	NR	0.24	14 (-15, 42)	NR	-12.0 (-42, 18)	NR
Burns 2011[38] (21335973) Melissa oil vs sunflower oil Medium Explanatory	Mean Difference (95% CI) QoL 12 weeks	NR	0.033	17.0 (-13, 47)	NR	-2.0 (-34, 30)	NR
Burns 2011[38] (21335973) Melissa oil vs sunflower oil Medium Explanatory	Mean Difference (95% CI) Barthel index 4 weeks	NR	0.91	0.2 (-0.7, 1)	NR	-0.1 (-0.9, 0.7)	NR

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Overall p-value	Intervention	p-value	Comparator	p-value
Burns 2011[38] (21335973) Melissa oil vs sunflower oil Medium Explanatory	Mean Difference (95% CI) Barthel index 12 weeks	NR	0.72	-0.8 (-1.8, 0.1)	NR	-0.3 (-1.2, 0.6)	NR
Ballard 2002[40] (12143909) Melissa oil vs sunflower oil Medium Explanatory	Mean Difference (95% CI) CMAI 4 weeks	NR	NR	23.1 (NR)	<0.0001	7.3 (NR)	p=0.005
Moyle 2014[37] (24216598) Foot massage vs quiet presence Low Explanatory	Mean Difference (95% CI) OERS 3 weeks	NR	NR	NR	NR	NR	NR
Moyle 2014[37] (24216598) Foot massage vs quiet presence Low Explanatory	Mean Difference (95% CI) CMAI 3 weeks	NR	0.03	-1.28 (NR)	NR	-7.79 (NR)	NR

Abbreviations: Barthel index=Barthel scale of Activities of Daily living; CCMAI=Cohen-Mansfield Agitation Inventory-Chinese version; Living; CI=Confidence interval; CNPI=Neuropsychiatric Inventory-Chinese version; CSDD-C=Cornell Scale for Depression in Dementia–Chinese Version; NR=Not Reported; NPI=Neuropsychiatric Inventory; OERS=Observed Emotion Rating Scale; PAS=Pittsburgh Agitation Scale; PMID=PubMed Identification Number; QoL=Quality of life; RoB=Risk of Bias

Appendix Table C.15. Summary of strength of evidence for PLWD outcomes: CAM Therapy

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Lavender vs sunflower oil Agitation	3 weeks	1 RCT (n=70)	Intervention favors for agitation reduction.	Moderate	Unknown	Direct	Imprecise	Insufficient
Lavender vs sunflower oil NPI	3 weeks	1 RCT (n=70)	Intervention favors for reduction of behavioral disturbances measured using NPI.	Moderate	Unknown	Direct	Imprecise	Insufficient
Lavender and orange oil vs. Usual care Agitation	5 weeks 9 weeks	1 RCT (n=59)	No difference between intervention and placebo groups in measures of agitation.	Moderate	Unknown	Direct	Imprecise	Insufficient
Lavender and orange oil vs. Usual care Depression	5 weeks 9 weeks	1 RCT (n=59)	Intervention favors for depression reduction	Moderate	Unknown	Direct	Imprecise	Insufficient
Melissa oil vs sunflower oil Agitation	4 weeks 12 weeks	2 RCT (n=149)	Mixed results with 1 RCT favoring intervention (4 weeks) while the other one (12 weeks) shows no difference between intervention and placebo groups	Moderate	Inconsistent	Direct	Imprecise	Insufficient
Melissa oil vs sunflower oil NPI	12 weeks	1 RCT (n=77)	No difference between intervention and placebo groups in reduction of behavioral disturbances measured using NPI	Moderate	Inconsistent	Direct	Imprecise	Insufficient
Melissa oil vs sunflower oil QoL	12 weeks	1 RCT (n=77)	Intervention favors in improvement of QoL	Moderate	Inconsistent	Direct	Imprecise	Insufficient
Melissa oil vs sunflower oil Barthel index	12 weeks	1 RCT (n=77)	No difference between intervention and placebo groups in Barthel index	Moderate	Inconsistent	Direct	Imprecise	Insufficient
Foot massage vs quiet presence Agitation	3 weeks	1 RCT (n=55)	Both Intervention and comparison causes an increase in agitation, but the increase is greater in the comparator group than in the intervention group (p=0.03)	Low	Unknown	Direct	Imprecise	Insufficient

Abbreviations: Barthel index=Barthel scale of Activities of Daily living; n=Number; NPI=Neuro psychiatry inventory; RCT=Randomized controlled trial; QoL=Quality of life

Evidence Map: CAM Therapy

Appendix Table C.16. Characteristics of evidence map studies: CAM therapy

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Kouzuki 2019[41] (31578055) Japan Small sample	0.1% aroma bath salts (n=15) 0.5% aroma bath salts (n=14) 1% aroma bath salts (n=14) where aroma oil added to the bath salt was a 2:1 blend of true lavender and sweet orange and baths were taken once daily (>10 minutes) for 24 weeks	NA	Outpatient clinic of Shinsei Hospital (Kurayoshi, Japan) 3-arm RCT 43 PLWD	AD diagnosis according DSM-V or MCI that met Petersen's diagnostic criteria	N=43 Mean age: 79 years Female: 51% % majority race: no Education: no	None	NA	None	NA	NA	4 weeks 16 weeks 28 weeks 32 weeks	TDAS OSIT-J PSQI-J	NA
Takahashi 2019[42] **(32037737)** **Japan** **Small samples**	**Aromatherapy: Low pressure, 50% ethanol extract of Akita cedar leaves diffusdr in rattan sticks and as spray for 4 weeks (The room fragrance type is placed in the resident space (living room and bedroom), and the spray type is used to mist the patients' clothing and bedding.)**	**Control group: Ethanol without cedar leaves extract**	**PLWDs** **RCT** **36 PLWD**	**Diagnosis of AD**	**N=36** **Age: yes** **Sex: yes** **Race: no** **Education: yes**	**None**	**NA**	**None**	**NA**	**NA**	**8 weeks**	**FAST** **NPI** **ADAS-cog** **J-ZBI**	**NA**

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Watson 2019 **(30670268)** **Australia** **Small sample**	**1.Aromatherapy with Lavender oil** **2.Aromatherapy with Lemon-balm oil** **2 drops of oil was applied to a cotton patch and then placed on the participant's collar area. The patch was removed after 2 hours for 2 weeks. Washout period of 2 weeks were maintained**	**3. Same procedure was followed with sunflower oil**	**Residents of residential aged care facility** **RCT** **39 PLWD**	**Diagnosis of dementia and MMSE score of ≤10; agitated behaviors recorded on at least one of ACFI domains;**	**N=39** **Mean age: no** **% Female: no** **% majority race: no** **Education: no**	**None**	**NA**	**None**	**NA**	**NA**	**0 week** **2 weeks** **4 weeks** **6 weeks** **8 weeks** **10 weeks**	**CMAI** **NPI**	**NA**
Zalomonson 2019[43] (30328781) Israel Pilot	2 drops of lavender oil were applied by the study nurse for no more than 1-2 minutes, 3 times a day for 16 weeks	Same procedure using sunflower oil	Psychogeriatric long-term care departments at the Center for Mental Health of the Israel Ministry of Health, Beer-Sheva Crossover Placebo-Controlled Study 42 PLWD	Diagnosis of dementia of any type	N=42 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	4 weeks 8 weeks 12 weeks 16 weeks	NPI	NA
Fung 2018[44] (28986942) Hong-Kong Small sample	Aroma-massage with acupressure: Trained carers or therapists provided no more than 20 minutes of aromatherapy, combining	Cognitive training: Trained care staff or therapists provided 20 minutes of cognitive training (n=20)	Long-term non-government geriatric care facilities 3 arm RCT 60 PLWD	BPSD PLWD scored below 18 (illiterate), 19 (1-2 years of education) and 20 (> 2years education) in CMMSE	N=20 Age: yes Sex: yes Race: yes Education: yes	None	NA	NA	NA	NA	Unclear 3-months Follow-up	CMMSE CCMAI NPI BI20	NA

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
	therapeutic massage with blended 2% lavender essential oil plus sunflower-oil. Acupressure on the selected acu-points was integrated into the massage treatment in a biweekly session.	Exercise: 20 minutes of stretching exercises, as outlined by a physiotherapist. (n=20)											
Kwan 2017[34] (25346026) Hong Kong High RoB Kwan 2014[45] (25346026) Hong Kong Study Protocol	9 minutes acupressure sessions	Sham acupressure; Usual care	Residential care homes 3 arm RCT 119 PLWD	PLWD showing dementia in medical records and displayed agitated behavior	N=119 Age: yes Sex: yes Race no Education: no	None	NA	NA	NA	NA	2 weeks	CMAI Salivary cortisol	NA
Jia 2017[46] (29284465) China Pilot	Acupuncture was performed using needles of 0.25 mm and a length of 40 mm at various acu-points for 3 times a week for 12 weeks	5 mg/day of donepezil hydrochloride for the first 4 weeks and 10 mg/day thereafter	Community residents (older PLWD with dementia) who participated in survey from Tianjin City, China RCT 87 PLWD	Diagnosis based on DSM-IV and NINCDS-ADRDA with MMSE score between 10 and 23 and HAMD score<7, a HIS score≤4, and have a reliable caregiver to accompany the participant to all study visits	N=43 Age: yes Sex: yes Race: no Education: yes	None	NA	NA	NA	NA	16 weeks 28 weeks	ADAS-cog CIBIC-Plus ADCS-ADL$_{23}$ NPI	NA
Moorman Li 2016[47] (28265482) US Pilot	Lavender aromatherapy twice a day for 20 min during a two-month period during active clinic days.	None	Adult Day Care Center quasi-experimental 23 PLWD	Clinical diagnosis of dementia	N=23 Age: yes Sex: yes Race: yes Education: no	None	NA	NA	NA	NA	Daily for 2 months pre-observation phase and 2 months intervention period	Behavior/Intervention Monthly Flow Record	NA
Yang 2015[48] (26556080) Taiwan High RoB	Aroma-acupressure: each acupoint was pressed for	Control: Received daily routine as usual	Retirement homes for veterans and long-term care	Diagnosis according to DSM-IV criteria	N=82 Age: yes Sex: yes	None	NA	NA	NA	NA	weekly	CCMAI HRV index	NA

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
	2 minutes with 2.5% lavender oil and a warm-up exercise was completed for 5 minutes, once per day for 5 days for 4 weeks Aromatherapy: 2.5% lavender oil was applied at five acupoints with the same operation time as the aroma-acupressure group(n=106)	without intervention (n=88)	facilities 3 arm RCT 276 PLWD	CMAI>35 (extreme agitation)	Race: no Education: no								
Chieh-Yu 2013[49] (23837414) Australia Small sample	Aromatherapy and hand massage (n=22): Three sprays of lavender mist (3% lavender mist) applied on chest twice a day, for 6 weeks and 5 minutes of hand massage twice a day for 10 days: each hand was massaged for 2.5 minutes. Aromatherapy only (n=23): Three sprays of lavender mist (3% lavender mist) applied on chest twice a day, for 6 weeks	Placebo (n=22) water spray similar to aromatherapy	Long term care facilities in Brisbane 3 arm RCT 67 PLWD	MMSE score ≤ 24 and AD diagnosis according DSM-IV with a documented history of a minimum of two weeks of agitation or aggression within the past three months, requiring physical and/or chemical restraint	N=67 Mean age: 84 years Female: 59% % majority race: no Education: no	None	NA	None	NA	NA	6 weeks	MMSE CMAI-SF	NA
Fu 2013[50] (23837414)	3 sprays of lavender mist	Water mist sprayed in	Long-term care facilities	DSM-IV criteria (confirmed by a	N=23 Age: yes	None	NA	NA	NA	NA	3 months	Disruptive behavior:	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Australia Small sample	(3%) twice daily 7 days a week for 6 weeks 3 sprays of lavender mist (3%) Plus 5 minutes of hand massage (n=22)	the same way (n=22).	3 arm RCT 67 PLWD	medical practitioner and a university Alzheimer's clinic) Moderate to severe-MMSE	Sex: yes Race: yes Education: no							CMAI-SF Cognition: (MMSE)	
Lu 2013[51] (23972540) USA Pilot	Along with usual medical and care regimen, HT and BTC protocols were given for the 6 months treatment period on weekly basis	PLWD got usual medical and care regimens	Recruited from long-term nursing care facilities and from the community RCT 22 PLWD	Early AD (information regarding their doctor's diagnosis was acquired from the subjects, their caregivers, or nursing staff)	N=12 Age: yes Sex: yes Race: yes Education: no	None	NA	None	NA	NA	3 months 6 months	MoCA POMS-BF PHQ-9	NA
Rodriguez-Mansilla 2013[52] (24187866) Spain Pilot Rodriguez-Mansilla 2015[53] (25322869) Spain Pilot	20 minutes of back and lower limb massage with moisturizing cream; Ear-acupuncture at various points (n=40)	Control (did not receive any experimental treatment n=40)	Residents institutionalized in 'CARE' elderly residential homes in Extremadura 3-arm-RCT 120 PLWD	PLWD were diagnosed using the DSM-VI criteria	N=40 Age: yes Sex: yes Race: no Education yes	None	NA	NA	NA	NA	12 weeks	Behavioral alteration and sleep disturbances: Self-designed structured questionnaire with closed ended questions GDS MMSE DOLOPLUS2 CSDD Campbell scale	NA
Jimbo 2009[54] (20377818) Japan Pilot	Aroma exposure of 0.04 ml lemon and 0.08 ml rosemary oil in the morning for 2 hours. 0.08 ml Lavender and 0.04 ml orange oil in the evening for 1.5	None	Setting: NR Quasi-experimental (crossover) 28 PLWD	Diagnosis based on DSM-IV and NINCDS-ADRDA or DSM-IV and NINCDS-AIREN.	N=28 Age: yes Sex yes Race: no Education: No	None	NA	NA	NA	NA	4 weeks 9 weeks	HDS-R GBSS-J FAST CT Scans TDAS Zarit Blood and biochemical examination	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	hours for 4 weeks												
Hawranik 2008[55] (18272750) Canada Small sample	TT once per day for 5 days	Simulated TT once per day for 5 days (n=16) Usual care for 5 days (n=18)	Residents from personal care and special needs units of one long-term care facility 3 arm RCT 51 PLWD	Diagnosis of senile dementia of the Alzheimer type, score 23 or less in MMSE; with a history or consistent agitated behavior during last 30 days	N=17 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	2 hours; 24 hours 1 week 2 weeks	CMAI MMSE	NA
Woods 2005[56] (15712768) Canada Small sample	TT was performed with contact on the neck and shoulders through an experienced practitioner for 5-7 minutes twice daily for 3 days	Sham TT (n=19) Routine care (n=19)	Long-term care facilities 3-arm-RCT 57 PLWD	Diagnosis of moderate to severe AD according to DSM-IV criteria; MMSE<20;	N=19 Age yes Sex; yes Race: yes Education: yes	None	NA	NA	NA	NA	3 days	RPMBC ABRS	NA
Smallwood 2001[57] (11607948) UK Small sample	Aromatherapy massage Conversation and aromatherapy Massage only for twice weekly	None	PLWD were recruited from district general hospital ward 3-arm RCT 21 PLWD	Clinical diagnosis of dementia	N=21 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	weekly	Qualitative assessment of behavior using video recorded sessions	NA

Abbreviations: ABRS=Agitated Behavior Rating Scale; ACFI=Aged Care Funding Instrument; ADAS-cog=Alzheimer's disease Assessment Scale-Cognitive; AD=Alzheimer's Disease; ADCS-ADL$_{23}$=23-Item Alzheimer's disease Cooperative Study Activities of Daily Living Scales; BI20=Barthel Index-20; BPSD=Behavioral and Psychological Symptoms of Dementia; BTC=Body Talk Cortices; CCMAI=Cohen-Mansfield Agitation Inventory-Chinese version; CIBIC-Plus=Clinician's Interview-Based Impression of Change-Plus; CMAI-SF=Cohen-Mansfield Agitation Inventory-Short Form; CMMSE=Mini-Mental State Examination -Chinese version; CSDD=Cornell Scale for depression in dementia; CT=Computed Tomography; DOLOPLUS2=Behavioral pain assessment scale for the elderly presenting with verbal communication disorders; DSM-IV=Diagnostic and Statistical Manual of Mental Disorders, 4th edition; FAST=Functional Assessment Staging of Alzheimer's disease; GBSS-J=Gottfries, Brane, Steen Scale; GDS=Global Deterioration Scale; HDS-R=Hasegawa's Dementia Scale; HRV-index=Heart Rate Variability Index; HT=Healing Touch; J-ZBI=Japanese version of Zarit Caregiver Burden interview; mg=milligram; ml=milliliter; mm=millimeter; MMSE=Mini-Mental State Examination; MoCA=Montreal Cognitive Assessment test; N=Number; NINCDS/ADRDA=National Institute of Neurological and Communicative Disorders and Stroke/ Alzheimer's Disease and Related Disorders Association; NINCDS/AIREN=National Institute of Neurological Disorders and Stroke/ Association Internationale pour la Recherche et l'Enseignement en Neurosciences criteria; NPI=Neuro psychiatry inventory; NA=Not Applicable; PHQ-9=Patient health questionnaire-9; PMID=PubMed Identification Number; POMS-BF=Profile of Mood States-Brief Form; PLWD=Persons Living with Dementia; RCT=Randomized controlled trial; RoB=Risk of Bias; RPMBS=The Revised Memory and Behavior Checklist; T-DAS=Touch Panel-type Dementia Assessment Scale; TT=Therapeutic touch
Bright Light Therapy

Bright Light Therapy

Appendix Table C.17. Risk of bias assessment: bright light

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Onega 2016[58]	8 weeks	Medium 15%	Low	High	Low	Medium	X	Government	High
Rixt F. Riemersma-van der Lek 2008 (18544724) [59]	6 weeks	Low 6 weeks:7.4% High 6 months+: >21%	Low	6 weeks: Medium 6+ Months: High	Low	High	Medium	Government	High
Hickman 2007[60] Barrick 2010 (20104513)[61]	3 weeks	Medium NR	Medium	High	Medium	X	X	Government	High
Ancoli-Israel 2003[62]	18 days	High 23.9%	X	X	X	X	X	Government	High

X indicates that domain was not assessed due to high risk of bias.
Abbreviations: PMID=PubMed Identification Number

Evidence Map: Bright Light Therapy

Appendix Table C.18. Characteristics of evidence map studies: bright light

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Figueiro, 2019[63] (318551610 United States Small sample	Tailored lighting to maximally affect circadian system	Low intensity lights	4 Assisted Living Facilities RCT 52 PLWD	Dementia per MMSE; unspecified	N=60 Age: Yes Sex: Yes Race: no Education: no	None	NA	NA	NA	NA		Sleep and circadian rhythms CSDD CMAI	NA
Lisa Onega 2016[58] United States High ROB	Bright light exposure	Low intensity light	Long-term care facility (N=4) RCT (bright light N=30; low intensity light N=30) PLWD	None	N=60 (treatment N=30 vs control N=30) Age: Yes Sex: Yes Race: Yes Education: Yes	SES Health problems Marital status	NA	NA	NA	NA	8-weeks)	Depression (DSAOA; DMAS-17; CSDD) Agitation (CMAI-F; CMAI-D; PAS; BARS)	NA
Burns 2009[64] United Kingdom Small sample	Full spectrum bright light therapy (BLT)	Normal light	Nursing homes RCT (standard light N=26; BLT N=22) PLWD	Dementia and behavioral disturbances	N=48 (22 treatment vs 26 control) Age: Yes Sex: Yes	Cataracts	NA	NA	NA	NA	Baseline week, and in weeks 4 and 8	Agitation (Cohen-Mansfield Agitation Inventory; CMAI)	NA
Riemersma-van der Lek 2008[59] (18544724) Netherlands	Bright light therapy, 8 hours daily,	Usual care (double placebo)	Group care facility Cluster RCT 12 Long-term	Clinical diagnosis for dementia and dementia sub-types	N=94 Age: yes Sex: yes	None	NA	NA	NA	NA	6 weeks	MMSE CSDD PGCMS PGCARS	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Medium Explanatory	exposure of ±1000 lux		care facilities 94 PLWD		Race: no Education: no							MOSES, Withdrawn Behavior NPI-Q CMAI NIADL Total Sleep Duration	
Dowling 2007 [65] Dowling 2005 (16050432)[66] Dowling 2005 (16035127)[67] United States Small sample	Bright light exposure	Usual indoor light	Nursing home RCT (morning light N=29; afternoon light N=24; or control N=17) PLWD	Rest-activity disruption and were diagnosis with Alzheimer's disease	N=71 (54 treatment vs 17 control) Age: Yes Sex: Yes Race: Yes	None	NA	NA	NA	NA	End of the baseline week and after the last week of intervention (study protocol 11 weeks)	Neuropsychiatric behaviors (Neuropsychiatric Inventory nursing Home version; NPI-NH)	NA
Hickman 2007[60] 20104513 Barrick 2010[61] United States High ROB	Ambient bright light (high-intensity, low glare) in public areas, applied morning, evening, or all day	Standard lighting	Geriatric unit in 2 state-operated psychiatric hospitals, Cluster-unit crossover intervention trial with 8 study periods in one, 22 in the other ; PLWD	Severe or very severe dementia	N=66 Age: Yes Sex: Yes Race: Yes Education: Yes	None	NA	NA	NA	NA	Last week of each 3-week period (multiple periods)	CSDD	NA
Ancoli-Israel 2003[62] United States High ROB	Bright light exposure	Morning dim red light	Nursing home Randomized to treatment groups (morning bright light N=30; morning dim red light N=31; or evening bright light N=31) PLWD	Diagnosis of possible or probable Alzheimer's disease	N=92 (61 treatment vs 31 control) Age: Yes Sex: Yes Education: No	Current diagnoses (e.g. eye disease; cataracts, glaucoma)	NA	NA	NA	NA	3 days of baseline, 10 days of treatment (treatment days 1-5 and 6-10) and 5 days of posttreatment follow-up	Sleep and circadian activity rhythms	NA
Paola Fontana Gasio 2003[68] Switzerland Pilot	Low intensity dawn-dusk simulation (DDS)	Dim red light	Nursing homes Randomly assigned (DDS N=9; Control	Symptoms/diagnosis of dementia and sleep disturbances	N=13 (treatment N=9 vs control N=4)	None	NA	NA	NA	NA	After 3 weeks of baseline; DDS or dim red light treatment	Circadian rest-activity cycle, nocturnal sleep, and cognitive function	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
			N=4) PLWD		Age: Yes Sex: Yes								
Kazuo Mishima 1998[69] Japan Small sample	Bright light therapy	None	Facility Randomized crossover PLWD	Vascular dementia (VD) and PLWD with dementia of Alzheimer's type (DAT) with sleep and behavioral disturbances	N=22 (VD N=12; DAT N=10) Age: Yes Sex: Yes	None	NA	NA	NA	NA	Pretreatment, week 1, week 2, and posttreatment	Behavioral and rest-activity (R-A) rhythm disorders	NA

Abbreviations: BARS=Brief Agitation Rating Scale; CMAI=Cohen-Mansfield Agitation Inventory; CMAI-D=Cohen-Mansfield agitation Inventory-Disruptiveness; ; CMAI-F=Cohen-Mansfield Agitation Inventory-Frequency; CSDD=the Cornell Scale for Depression in Dementia; DSAOA=Depressive Symptom Assessment in Older Adults; DMAS-17=Dementia Mood Assessment Scale-17; FC=formal caregiver; IC=informal caregiver; N=number; NPI-Q=the Neuropsychiatric Inventory; NI-ADL=the nurse-informant adaptation; MOSES=the Multidimensional Observation Scale for Elderly Subjects; NPI-NH=Neuropsychiatric Inventory nursing Home version; PAS=Pittsburgh Agitation Scale; PGCMS=the Philadelphia Geriatric Centre Morale Scale; PGCARS=The Philadelphia Geriatric Centre Affect Rating Scale; PLWD=Person Living with Dementia; PMID=PubMed Identification number; SES=socioeconomic status

Psychosocial Interventions for BPSD

Appendix Table C.19. Risk of bias assessment: Psychosocial Interventions for BPSD

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Overall Rating
Richards 2005 (16137280)[70]	3 weeks	Low 5%	Medium	Medium	Medium	Low	High	Medium
Toseland 1997 (27097884)[71]	3 months, 1 year	Medium 25%	Medium	High (30% missing data for bed/rise time)	Medium	Low	Low	High

X indicates that domain was not assessed due to high risk of bias.
Abbreviations: PMID=PubMed Identification Number

Evidence Map: Psychosocial Interventions for BPSD

Appendix Table C.20. Characteristics of evidence map studies: Psychosocial Interventions for BPSD

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Kiossis 2015[72] (26402009) US Small sample	Problem adaptation therapy based on process model of emotion regulation	Supportive therapy	Community setting, in-home RCT PLWD	Mild to moderate dementia and major depression; dementia unspecified	N=39 Age: no Sex: yes Race: yes Education: no	None	NA	NA	NA	NA	12 weeks	CSDD Suicidal ideation	NA
Spector 2015[73] (25698766) (26207801)[74] UK Pilot	Cognitive behavioral training for anxiety; up to 10 1-hour sessions	Usual care	Community setting, in-home RCT PLWD	Mild to moderate dementia; dementia unspecified	N=50 Age: yes Sex: yes Race: yes Education: yes	None	NA	NA	NA	NA	15 weeks	RAID CSDD HADS QOL-AD NPI QCPR CSRI MMSE	NA
Stanley 2013[75] (25698766) US Pilot	Cognitive behavioral training for anxiety; 12 weekly session followed by 8 brief telephone sessions	Usual care	Community-based, in-home RCT PLWD with caregiver	Mild to moderate dementia; dementia unspecified	N=32 Age: yes Sex: yes Race: yes Education: no	Marital status	NR	NR	NA	NA	6 months	NPI RAID QOL-AD PSWQ-A GAI	Caregiver distress PHQ-9
Richards 2005[70] (16137280) US High ROB	Individualized social activity intervention to improve sleep	Usual care	Nursing home RCT PLWD	Moderate to severe dementia; less than 85% sleep efficiency	N=147 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	3 weeks	Sleep measures	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Beck 2002[76] (12131234) US Small sample	ADL: 45-60 minutes of ADL assistance provided by PNA which catered to the psychosocial, cognitive and physical abilities of PLWD PSA: 30+ minutes of PSA intervention provided by PNA, which involved 25 standardized modules designed to meet the psychosocial, cognitive and physical abilities of PLWD CB: consisted of both the ADL and PSA interventions and lasted 90 minutes daily	Placebo: one-to-one interaction between the participant and PNA for 30 minutes per day No intervention: routine care with no scheduled contact between participants and the PNA	Nursing home 5 arm RCT PLWD	Dementia diagnosis with a MMSE score ≤ 20 and report of DB in previous 2 weeks	N=127 Age: yes Sex: yes Race: n Education: no	None	NA	NA	NA	NA	Videotape analysis 1-month follow-up 2-month follow-up	DBS MMSE ODAS AARS PVAS	NA
Toseland 1997[71] (27097884) US High ROB	Validation therapy or social contact; 4 30-minute sessions per week for 52 weeks	Usual care	Nursing home 3 arm RCT PLWD	Moderate to severe dementia with behavioral problems; dementia unspecified	N=88 Age: yes Sex: yes Race: yes Education: no	None	NA	NA	NA	NA	3 months, 1 year	MOSES CMAI GIPB MDS+	NR

Abbreviations: CMAI=Cohen-Mansfield Agitation Inventory; CSDD=the Cornell Scale for Depression in Dementia; FC=formal caregiver; IC=informal caregiver; GAI=Geriatric Anxiety Inventory; GDS=Geriatric Depression Scale; GIPB=Geriatric Indices of Positive Behavior; HADS=Hospital Anxiety and Depression Scale; MMSE=Mini-Mental State Examination; MOSES=Multidimensional Observation Scale for Elderly Subjects; MDS+=Minimum Data Set-Resident Assessment Protocol; N=number; NPI=the Neuropsychiatric Inventory; PHQ-9=Patient Health Questionnaire; PSWQ-A=Penn State Worry Questionnaire-Abbreviated; QCPR=Quality of Caregiver and Patient Relationship; QOL-AD=Quality of Life – Alzheimer's Disease; PLWD=Person Living with Dementia; PMID=PubMed Identification number; RAID=Rating Anxiety in Dementia scale; SES=socioeconomic status

Multicomponent Interventions for BPSD

Appendix Table C.21. Risk of bias assessment: Multicomponent Interventions for BPSD

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Overall Rating
Lin 2009[77] (19507295)	6 weeks, 14 weeks; 21-22 weeks	High Unclear	Medium	High	High	Low	Medium	High
Finnema 2005[78] (15799079)	3 months 7 months	High 25%	Medium	X	X	X	X	High
Kovach 2004[79] (15611216)	Unclear	High unclear 24%	Low	X	X	X	X	High
Schrijnemaekers 2002[80] (12325052)	3, 6, and 12 months	Medium 3 month: 9%, 6 months: 20.5%, 12 months: 38%	Medium	Medium	Medium	Low	High	High
Lawton 1998[81] (9924833)	6 months 12 months	Low 12 months: 5%	Medium	Medium	High	Low	Low	High

X indicates that domain was not assessed due to high risk of bias.
Abbreviations: PMID=PubMed Identification Number

Evidence Map: Multicomponent Interventions for BPSD

Appendix Table C.22. Characteristics of evidence map studies: Multicomponent Interventions for BPSD

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Law 2019[82] (31390090) Hong Kong Pilot	Osteoarthritis-specific knee exercises plus self-management support, 8 weeks	Routine group exercise	Community setting RCT PLWD	Dementia unspecified plus knee osteoarthritis	N=56 Age: yes Sex: yes Race: no Education: yes	Marital status	N=56 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration	NA	NA	8 weeks	NPI-Q	RSCSE
Bailey 2017[83] (26912731) US Small sample	Two 30 minutes group activity sessions, including, CBT, reminiscence, environmental supports and individualized activity for 6 weeks	Usual care (n=25)	Privately owned, for-profit urban nursing homes Cluster RCT 51 PLWD	Mild to moderate cognitive impairment (MMSE score 10-24) and symptoms of depression (GDS)	N=51 Age: yes Sex: yes Race: no Education: no	None	NA	None	NA	NA	Twice per week for 6 weeks	ABC CSDD GDS QOL-AD Activity enjoyment rating Barthel Scale MMSE	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Fischer-Terworth 2011[84] (No PMID) Germany Small sample (<25 in each arm)	TEACCH- and Music Therapy-Based Interventions (TMI): modified cognitive engagement for autism plus group music therapy for 6 months.	Nonspecific occupational therapy: Participated in nonspecific occupational therapy	Special dementia care unit Non-RCT 49 PLWD	Mild or moderate dementia (All types)	N=49 Age: No Sex: Yes Race: No Education: No	None	NA	NA	NA	NA	6 months	NPI GDS ICEA-D	NA
Lin 2009[77] (19507295) Taiwan High RoB	I1: Acupressure: acupressure at each acupoint for 2 minutes; 15-minute daily sessions 6 days per week; 4 weeks I2: Montessori based activity program: five categories associated with activities of daily living: scooping, pouring, squeezing, fine motor skills, environmental care, plus personal care; 6 days per week; 4 weeks	Attention control (Presence): for a 15-minute period each day for 6 days a week	Long-term care facilities 3 arm crossover RCT 133 PLWD	Diagnosis of dementia, CMAI score 35 or above	N=23 Age: yes Sex: yes Race: yes Education: yes	None	NA	NA	NA	NA	8 weeks 16 weeks 22 weeks	CMAI Ease of care AARS Family-visit restraint	NA
Kovach 2004[79] (15611216) US High RoB	BACE intervention: assessment; diagnose and plan a correction of the arousal imbalance; implement new activity schedule	Unclear	Long-term care facilities Pretest posttest RCT 102 PLWD	MMSE score of 15 or below and FAST stage 6 or 7 with some agitation but no chronic psychiatric diagnosis other than dementia	N=78 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	Direct observation of participants	MMSE FAST ASD Arousal Balance and Imbalance ABMI Therapeutic Activity	NA

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Finnema 2005[78] (15799079) (24337328)[85] The Netherlands High ROB	Emotion-oriented care: combination validation therapy, reminiscence, sensory stimulation	Usual care	Nursing homes RCT with matched 16 psychogeriatric wards PLWD	Moderate to severe probably Alzheimer-type dementia, mixed vascular dementia, dementia or amnestic syndrome	N=146 Age: yes Sex: yes Race: no Education: no	Duration institutionalized	NA	NA	N=99 Age: yes Sex: yes Race: no Education: yes	Position	7 months	CSDD GRGS CMAI PGCMS	GHQ-28 Organization and stress scale Absenteeism
Beck 2002[76] (12131234) US Small sample	ADL: 45-60 minutes of ADL assistance from PNA which catered to the psychosocial, cognitive and physical abilities of PLWD PSA: 30+ minutes of PSA from PNA; 25 standardized modules designed to meet the psychosocial, cognitive and physical abilities of PLWD CB: both the ADL and PSA interventions; 90 minutes daily	Placebo: one-to-one interaction between the participant and PNA for 30 minutes per day No intervention: routine care with no scheduled contact between participants and the PNA	Nursing home 5 arm RCT PLWD	Dementia diagnosis with a MMSE score ≤ 20 and report of DB in previous 2 weeks	N=127 Age: yes Sex: yes Race: yes Education: no	None	NA	None	NA	NA	Videotape analysis 1-month follow-up 2-month follow-up	DBS MMSE ODAS AARS PVAS	NR
Schrijnemaekers 2002[80] (12325052) The Netherlands High ROB	Emotion-oriented care: combination validation therapy, reminiscence, sensory stimulation	Usual care	Residential homes with structured day care units Cluster RCT 16 units	Moderate to severe cognitive impairment and behavioral problems; dementia unspecified	N=151 Age: yes Sex: yes Race: no Education: no	Duration institutionalized	NA	NA	NR	NR	3, 6, and 12 months	Dutch Behavior Observation Scale for Psycho-geriatric Inpatients ADL CMAI GRGS	NR
Lawton 1998[81] (9924833)	Stimulation-retreat model: which	Unclear	Nursing home residents	NR	N=49 Age: no Sex: no	None	NA	NA	NA	NA	6 months 12 months	GDS PSMS BEHAVE-AD	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
US High RoB	diagnosed, prescribed, and applied a package of care according to individual needs for additional stimulation or relief from stimulation ("retreat")		RCT 102 PLWD		Race: no Education: yes							CMAI MOSES TRS AARS	

Abbreviations: AARS=Apparent affect rating scale; ABC=Activity Behavior Checklist; ABMI=Agitation Behavior Mapping Instrument; ADL=Activities of daily living; ASD=Arousal States in Dementia; BACE=Balancing Arousal Controls Excesses; BEHAVE-AD=Behavioral Pathology in Alzheimer's Disease scale; CB=Combined; CBT=Cognitive-behavioral therapy; CMAI=Cohen-Mansfield Agitation Inventory; CSDD=Cornell Scale for Depression in Dementia; DB=Disruptive behavior(s); DBS=Disruptive behavior scale; ESS=Epworth Sleepiness Scale; FAST=Functional Assessment Staging Tool; GDS=Geriatric Depression Scale; GHQ-28=General Health Questionnaire; GRGS=Geriatric Resident Rating Scale; ICEA-D=Inventory to Assess Communication, Emotional Expression and Activity in Dementia; MMSE=Mini-Mental Status Exam; MOSES=Multidimensional Observation Scale for Elderly Subjects; N=Number; NA=Not Applicable; NR=Nor reported; ODAS=Observable displays of affect scale; PGCMS=Philadelphia Geriatric Center Morale Scale; PMID=PubMed Identification Number; PNA=Project nursing assistant(s); PSA=Psychosocial activity; PSMS=Physical Self-Maintenance Scale; PLWD=Persons Living with Dementia; PVAS=Positive visual analogue scale; QOL-AD=Quality of Life–Alzheimer's Disease; RCT=Randomized controlled trial; RMBPC=Revised Memory and Behavior Problems Checklist; RSCSE=Revised Scale for Caregiving Self-Efficacy; RoB=Risk of Bias; SD=Standard deviation; TRS=Therapeutic Recreation Specialist

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Appendix D. Interventions for PLWD Well-Being

Exercise

Appendix Table D.1. Risk of bias assessment: exercise

Author, year PMID	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funding	Overall Rating
Fleiner 2020[1] 32039852	2 weeks	Medium 18%	Medium	Low	High	Low	Medium	None	High
Liu 2020[2] 32084347	4 weeks	Medium 12%	Medium	Low	High	Low	Medium	Government	High
Chen 2019[3] 30301358	6 months	Low 3%	Medium	Medium	Medium	Low	Low	Government	Medium
Huang 2019[4] 31743998	10 months	Low 8%	Low	High	High	Low	Low	Government	Medium
Karssemeijer 2019[5] 31409559	12 weeks	Low 12%	Medium	High	Medium	Low	Medium	Nonprofit	High
Karssemeijer 2019[5] 31409559	24 weeks	Medium 20%	Medium	High	Medium	Low	Medium	Nonprofit	High
Henskens 2018[6] 29750023	6 months	Medium 25%	Low	High	Medium	Low	High	Unclear	High
Ho 2018[7] 30496547	8 weeks	Low (no attrition reported)	Medium	High	High	Low	Low	Government	High
Lamb 2018[8] 29769247	6 months	Low 10%	Low	Low	Medium	Low	Medium	Government	Low
Chen 2017[9] 27879982	15 months	Medium 15%	Medium	Low	High	Low	Low	Government	High
Bossers 2016[10] 27321604	9 week	Low 11%	Low	Low	High	Low	Low	NR	Medium
Cancela 2016[11] 26087884	15 months	Medium 40%	Low	High	Medium	Low	Low	Government	High
Hoffman 2016[12] 26682695	16 weeks	Low 5%	Low	Low	Medium	Low	Medium	Government Foundation	Low
Hoffman 2016[12] 26682695	12 months	Low 15%	Low	Low	Medium	Low	Medium	Government Foundation	Low
Toots 2016[13] 26782852	4 months	Low 8%	Medium	Low	Low	Low	Low	Government	Medium
Toots 2016[13] 26782852	7 months	Low 15%	Medium	Low	Low	Low	Low	Government	Medium
Telenius 2015[14] 26630910	12 week	Low 9%	Medium	Low	Medium	Low	Low	Foundation	Medium
Telenius 2015[14] 26630910	6 months	Low 18%	Medium	Low	Medium	Low	Low	Foundation	Medium
Yang 2015[15] 26556080	3 months	Low (no attrition reported)	Medium	High	Medium	Low	Medium	Government	High
Pitkala 2013[16] 23589097	6 months	Medium 14%	Low	Low	Medium	Low	Low	Government Foundation	Medium
Hauer 2012[17] 22211512	3 months	Medium 12%	Low	Low	Low	Low	Low	Foundations	Medium
Hauer 2012[17] 22211512	6 months	Medium 19%	Low	Low	Low	Low	Low	Foundations	Medium
Fan 2011[18] 21385519	12 weeks	Medium 13%	High	X	X	X	X	X	X
Roach 2011[19] 21937893	16 weeks	Medium 22%	Medium	Low	High	Low	Medium	Government	High
Eggermont 2009[20] 18926856	12 weeks	Low 9%	Medium	Low	Medium	Low	Medium	Foundation	Medium

Rolland 2007[21] 17302650	6 months	Medium 13%	Medium	Low	Medium	Low	High	Government	High
Rolland 2007[21] 17302650	12 months	Medium 18%	Medium	Low	Medium	Low	High	Government	High

X indicates that domain was not assessed due to high risk of bias.
Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Appendix Table Exercise.D.2. Characteristics of included studies: exercise

Author, year PMID Country RoB Type	Intervention: Intervention target Mode Components Frequency Duration Delivery/supervision	Comparison: Target Mode Components Frequency Duration Delivery	Setting Design Clusters N randomized	PLWD Dementia characteristics Type(s) Severity Diagnostic Criteria Age diagnosed	PLWD N Age (mean) Female % Race (% majority) Detailed Race Education (mean years)	PLWD SES Prior Disability Household Characteristics Health Insurance	Informal Caregiver N Age (mean) Female % Race (% majority) Education (mean years) Relationship	Informal Caregiver (IC) Duration Live with PLWD IC paid Health status Dementia family history Employment IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing	PLWD Outcomes Quality of Life Daily function Mobility BPSD Adverse events Services Other	Informal Caregiver Outcomes
Chen 2019[3] 30301358 China Medium Explanatory	PLWD Individual 30 min., 3x/week 6 months Supervision: 1:1 with trained Master's level RN	PLWD Routine care	Nursing Home RCT Clusters: NA N=60	Type: 100% AD Severity: mild-moderate (mean MMSE=18) Diagnosis: ISCDRHP-10th edition Age diagnosed: NR	N=60 82 years 72% female Race: NR Education: NR	NR	NR	NR	NR	NR	6 months	QoL: NR Function: EdFED, Time autonomous eating (min.) Mobility: NR BPSD: NR AE: NR Services: NR Other: Eating metrics	NR
Huang 2019[4] 31743998 China Medium Explanatory	PLWD Group Tai Chi 20 min., 3x/week 10 months Supervision: professional therapists in LTC	PLWD Routine care	Nursing Homes (3) RCT Clusters: NA N=80	Type: NR Severity: mild (mean MMSE=21) Diagnosis: DSM-IV Age diagnosed: NR	N=80 82 years 68% female Race: NR Education: 72 months	NR	NR	NR	NR	NR	5 months, 10 months	QoL: NR Function: Barthel Mobility: NR BPSD: NPI, GDS AE: AE, falls Services: NR Other: cognitive	NR
Lamb 2018[8] 29769247 UK Low Explanatory Petrou 2019[22] Lamb 2018[8]	PLWD Group sessions in gym: moderate-high intensity aerobic (cycling) & strength exercises (dumb bells) + UC 1-1.5 hours, 2x/week 4 months; then advised home exercise Supervision: PT and assistant	Mostly PLWD Individual Usual care (activity advice, prescriptions for symptoms; counseling for IC)	Community: Groups in gym; Individual at home. RCT Clusters: NA N=494	Type: NR Severity: mild-moderate (mean MMSE=22) Diagnosis: DSM-IV Age diagnosed: NR	N=494 77 years 39% female 97% white More race: no Education: NR	NR	N=459 69 years 77% female Race: NR Education: NR Relation: 78% spouse	NR	NA	NA	6 months, 12 months	QoL: EQ-5D-3L, QOL-AD Function: BADLS Mobility: NR BPSD: NPI AE: AE, SAE (fall, hospitalization, fracture, death) Services: health service use Other: ADAS-cog	QoL: EQ-5D-3L Burden: ZBI
Bossers 2016[10] 27321604 Medium Netherlands Explanatory Bossers, 2015[23], Bossers 2014 [24]	PLWD Group 1. Aerobic (walking) plus strength training 30 min, 4x/week (2 weeks strength, 2 walking) 9 weeks (total 36) 2. Aerobic (walking) 30 min, 4x/week 9 weeks	PLWD Group Social activity 4x/week 9 weeks	Nursing Homes; Psycho-geriatric RCT Clusters: NA N=118	Type: AD, VD, mixed AD-VD, NR Severity: mild 22%, moderate 53%, severe 25% (of n=105) Diagnosis: Chart diagnosis Age diagnosed: NR	N=118 86 years 26% female Race: NR More race: no Education: mean NR; 60% ≤ high school	NR	NR	NR	NA	NA	9 weeks	QoL: NR Function: Katz ADL, E-ADL, PPT-7 Mobility: NR BPSD: NR AE: NR Services: NR Other: NR	NR

Author, year **PMID** **Country** **RoB** **Type**	**Intervention:** **Intervention target** **Mode** **Components** **Frequency** **Duration** **Delivery/supervision**	**Comparison:** **Target** **Mode** **Components** **Frequency** **Duration** **Delivery**	**Setting** **Design** **Clusters** **N randomized**	**PLWD** **Dementia characteristics** **Type(s)** **Severity** **Diagnostic Criteria** **Age diagnosed**	**PLWD** **N** **Age (mean)** **Female %** **Race (% majority)** **Detailed Race** **Education (mean years)**	**PLWD** **SES** **Prior Disability** **Household Characteristics** **Health Insurance**	**Informal Caregiver** **N** **Age (mean)** **Female %** **Race (% majority)** **Education (mean years)** **Relationship**	**Informal Caregiver (IC)** **Duration** **Live with PLWD** **IC paid** **Health status** **Dementia family history** **Employment** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing**	**PLWD Outcomes** **Quality of Life** **Daily function** **Mobility** **BPSD** **Adverse events** **Services** **Other**	**Informal Caregiver Outcomes**
	Supervision: Trained RA (HMS student)												
Hoffman 2016[12] 26682695 Denmark Low Explanatory Sobol 2016[25] Hoffman 2013[26]	PLWD Group Supervised exercise [strength 1st 4 weeks; aerobic x 16 weeks (bike ergometer, cross trainer, treadmill)] 60 min, 3x/week 16 weeks Supervision: PT	PLWD Usual care Individual As needed (access to memory clinic staff)	NR (PLWD all community-dwelling) Cluster: NA N=200	100% probable AD Severity: mild (MMSE > 19) Diagnosis: NINCDS-ADRDA Diagnosis age: NR	N=200 71 years 44% female Race: NR More race: NA Education: NR	NR	N=NR, assume 200 (inclusion criterion) All: NR	Live together: 72% Other: NR	NA	NA	16 weeks	QoL: EQ-5D-5L Function: ADCS-ADL Mobility: NR BPSD: NPI-12, HAM-D AE: AE, SAE Services: NR Other: ADAS-Cog, MMSE, adherence	NR (ICG proxy for NPI-12, ADCS-ADL and 1 EQ-5D)
Toots 2016[13] 26782852 Sweden Medium Explanatory Sondell 2018[27] Toots 2018[28] Toots 2017[29] Bostrom 2016[30]	PLWD Groups at RC facilities Individualized high-intensity functional (weight-bearing) exercise (HIFE): leg strength, balance, mobility 5 x 45 min per 2 weeks 4 months (40 sessions) Supervision: 2 PTs	PLWD Seated group activity per OT Frequency: NR Duration: NR Supervision: OT or OTA	16 residential care facilities (9 NH units, 10 dementia units Cluster RCT Clusters: 36 N=186	86% AD, VD, or mixed AD-VD Severity: mild-moderate (mean MMSE=15) Diagnosis: DSM-IV-TR Age diagnosed: NR	N=186 85 years 76% female Race: NR More race: NA Education: NR	NR	NA	NA	NA	NA	4 months, 7 months	QoL: NR Function: Barthel ADL, FIM Mobility: BBS BPSD: NR AE: collected/NR (except 1 death) Services: NR Other: adherence	NR
Telenius 2015[14] 26630910 Norway Medium Explanatory	PLWD Group Individualized high-intensity functional (weight-bearing) exercise (HIFE): 50-60 min, 2x/week 12 weeks Supervision: 1 PT per 3 PLWD	PLWD Group Seated activity (game, music, read, stretch) 50-60 min, 2x/week 12 weeks Supervision: OT or nurse	18 NHs RCT Block randomized (6-12 PLWD/site) N=170	NR Severity: Mild-moderate (CDR 1 or 2) Diagnosis: NR Age diagnosed: NR	N=170 87 years 74% female Race: NR More race: NA Education: NR	NR	NA	NA	NA	NA	12 weeks, 6 months	QoL: QUALID Function: Barthel ADL Mobility: BBS BPSD: NPI, CSD AE: AE Services: NR Other: MMSE, attendance, CST,6-meter walk	NR
Pitkala 2013[16] 23589097 Finland Medium Explanatory Roitto 2018[31] Ohman 2016[32] Ohman 2016[33] Pertilla 2016[34] Pitkala 2011[35]	PLWD 1. Individual tailored home-based exercise (various) 1 hour, 2x/week 12 weeks 2. Pre-determined group exercise (balance strength, endurance, executive function) 1 hour, 2x/week 12 weeks Supervision: PT; ICG participation optional	PLWD Usual care plus nutrition & exercise advice per study nurses	Home (individual), adult day care centers (group) RCT Clusters: NA N=210	100% AD 67% moderate-severe Diagnosis: NINCDS-ADRDA Age diagnosed: NR	N=210 (dyads) 78 years 39% female 100% white More race: NA Education: mean NR; 41% 8-12 years; 38% < 8 years	NR	N=210 76 years 61% female 100% white Education: mean NR; 54% 8-12 years; 26% < 8 years Relation: 100% spouse	Duration: NR Live together: 100% Paid: NR Health: count of medications, Charlson Index Family history: NR Employed: NR Training: NR	NA	NA	6 months (12 months=high RoB)	QoL: NR Function: FIM Mobility: SPPB BPSD: NR AE: falls, fractures, hospitalizations Services: health & social service use, costs Other: Adherence	NR

Author, year PMID Country RoB Type	Intervention: Intervention target Mode Components Frequency Duration Delivery/supervision	Comparison: Target Mode Components Frequency Duration Delivery	Setting Design Clusters N randomized	PLWD Dementia characteristics Type(s) Severity Diagnostic Criteria Age diagnosed	PLWD N Age (mean) Female % Race (% majority) Detailed Race Education (mean years)	PLWD SES Prior Disability Household Characteristics Health Insurance	Informal Caregiver N Age (mean) Female % Race (% majority) Education (mean years) Relationship	Informal Caregiver (IC) Duration Live with PLWD IC paid Health status Dementia family history Employment IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing	PLWD Outcomes Quality of Life Daily function Mobility BPSD Adverse events Services Other	Informal Caregiver Outcomes
Hauer 2012[17] 22211512 Germany Medium Explanatory [36]	PLWD Group Progressive resistance & lower extremity functional training (walk, stair climb, sit to stand)) 2 hours, 2x/week 3 months Supervision: “a qualified instructor”	PLWD Group Low-intensity activity (stretch, hand weights, seated ball games, etc.) 1 hour, 2x/week 3 months Supervisor: Yes but NR	Outpatient geriatric rehabilitation RCT Clusters: NA N=122	Type: 50% AD, 34% VD, 16% other AD/VD Severity: mean MMSE 22 (mild) Diagnosis: NINCDS-ADRDA or NINDS-AIREN, CERAD, TMT Diagnosis age: NR	N=122 83 years 74% female Race: NR More race: NA Education: 11 years	84% community-dwelling Other: NR	NR	NR	NA	NA	3 months, 6 months	QoL: NR Function: NR Mobility: TUG, POMA, modified PAQE, modified SPPB (SPPB NR) AE: AE (text) Services: NR Other: strength (lab metrics), adherence	NR
Eggermont 2009[20] 18926856 Netherlands Medium Explanatory	PLWD Group (by living unit): Hand movement program (fingers, pinch ball, handle rubber ring) 30 min, 5x/week 6 weeks Supervision: RT or Master students	PLWD Group Stories read by RT followed by conversation 30 min, 5x/week 6 weeks Supervision: RT or student	NHs (10 psychogeriatric units) Cluster RCT Clusters: 10 N=66	Type: uncertain Severity: mean MMSE=16 Diagnosis: DSM-IV Age diagnosed: NR	N=66 85 years Female%: NR Race: NR Education: NR but “NSD”	NR	NA	NA	NA	NA	6 weeks, 12 weeks	QoL: NR Function: NR Mobility: NR BPSD: GDS, SCL-90 (anxiety) AE: NR Services: NR Other: cognition, actigraphy	NR

* High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: AD=Alzheimer’s Disease; ADAS-Cog= Alzheimer’s Disease Assessment Scale, cognitive subscale; ADCS-ADL= Alzheimer’s Disease Cooperative Study-Activities of Daily Living; ADL=Activities of Daily Living; AE=adverse events; BADLS=Bristol Activities of Daily Living Scale; BBS=Berg Balance Scale; BPSD=Behavioral and Psychiatric Symptoms of Dementia; CERAD=Consortium to Establish a Registry for Alzheimer’s Disease; char=characteristics; CSD=Cornell Scale for Depression; CST=Chair Stand Test; DSM=Diagnostic and Statistical Manual of Mental Disorders; E-ADL=Erlangen-ADL scale; EdFED=Edinburgh Feeding Evaluation in Dementia; EQ-5D-5L=EuroQol 5 dimension-5 level; EQ-5D-3L=EuroQol 5 dimension-3 level; ET=exercise therapist; FC=formal caregiver; FIM=Functional Independence Measure; FINALEX=Finnish Alzheimer’s Disease Exercise Trial; GDS=Geriatric Depression Scale; GHQ=Global Health Questionnaire; Govt.=Government; HAM-D=Hamilton Depression Rating Scale; HIFE=high-intensity functional exercise; HMS=Human Movement Science; IC=informal caregiver; ISCDRHP=International Statistical Classification of Diseases and Related Health Problems; LTC=long term care; MMSE=Mine Mental State Exam; N=number; NA=not applicable; NH=nursing home; NINDS-AIREN= National Institute of Neurological Disorders and Stroke and Association Internationale pour la Recherché et l'Enseignement en Neurosciences; NINCDS-ADRDA=National Institute of Neurological and Communicative Diseases and Stroke/Alzheimer's Disease and Related Disorders Association; NPI=Neuropsychiatric Inventory; NR=Not Reported; OT=occupational therapist; OTA=occupational therapy assistant; PAQE=Physical Activity Questionnaire for the Elderly; PMID=PubMed Identification Number; POMA=Performance Oriented Motor Assessment; PPT-7=7-item Physical Performance Test; PT=physical therapist/physiotherapist; PLWD=Persons with Dementia; QoL=Quality of Life; QOL-AD=Quality of Life in Alzheimer’s Disease; QUALID=Quality of Life in Late-stage Dementia Scale; RA=Research Assistant; RCT=Randomized controlled trial; RT=Recreational Therapist; SAE=serious adverse events; SCL-90=Symptom Checklist; SPPB=Short Physical Performance Battery; TMT=Trail Making Test; TUG=Timed Up and Go; VD=vascular dementia; wk=week; yrs=years; ZBI=Zarit Burden Interview

Appendix Table D.3. PWD outcomes summary low and medium risk of bias studies: exercise

Study (PMID) Comparison RoB Category	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Chen 2019[3] 30301358 China Medium Explanatory	EdFED (proxy) Mean (SD) Time of autonomous eating (minutes) Mean (SD) 6 months	Change from baseline Change from baseline	-0.63 (0.8) 2.13 (3.5)	-0.10 (0.5) 0.29 (0.4)	<0.05 <0.05
Huang 2019[4] 31743998 Tai Chi vs. Usual Care Medium Explanatory	Barthel ADL GDS NPI 10 months	Mean (SD) Mean (SD) Mean (SD)	94.1 (11.6) 2.4 (1.0) 6.4 (4.8)	92.6 (13.3) 5.4 (1.9) 10.2 (5.7)	NR <0.05 <0.05

Study (PMID) **Comparison** **RoB** **Category**	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Lamb 2018[8] (29769247) Group Exercise (aerobic + strength training) vs. Usual Care Low Explanatory	QOL-AD (self-report) Mean (SD) EQ-5D-3L (self-report) Mean (SD) BADLS (proxy) Mean (SD) NPI (proxy) Median (IQR) 6 months, 12 months	Adjusted mean difference (CI) 0.7(-0.2, 1.7) Adjusted mean difference (CI) -0.002 (-0.04, 0.04) Adjusted mean difference (CI) 0.3 (-1.7, 1.2) Adjusted median difference (CI) −2.1 (−4.8, 0.7)	12 months 38.4 (5.8) 0.81 (0.22) 17.0 (10.2) 12 (4 to 23)	12 months 39.1 (5.7) 0.82 (0.25) 15.9 (9.7) 9 (3 to 20)	0.13 0.93 0.70 0.14
Bossers 2016[10] (27321604) Group (walking + strength training) vs. Walking vs. Social Activity Medium Explanatory	Katz ADL (proxy) Between group mean change from baseline E-ADL (RA) Between group mean change from baseline PPT-7 (RA) Between group mean change from baseline 9 weeks	Combined vs social -2.79 Walking vs social -0.99 Combined vs social -3.83 Walking vs social -2.92 Combined vs social -3.38 Walking vs social -1.66	NR	NR	0.01 0.97 <0.001 0.01 0.003 0.29
Hoffman 2016[12] (26682695) Group Exercise (aerobic + initial strength training) vs. Usual Care Low Explanatory	EQ-5D-3L (self-report) Mean (SD) ADCS-ADL (proxy) Mean (SD) NPI-12 (proxy) Mean (SD) HAM-D: Depression Mean (SD) 16 weeks	Mean difference (CI) -0.1 (-0.02, 0.04) Mean difference (CI) -0.1 (-1.8,1.5) Mean difference (CI) -3.5 (-5.8, -1.3) Mean difference (CI) -0.1 (-0.7, 0.5)	0.92 (0.11) 64.4 (9.4) 8.8 (8.5) 1.7 (2.5)	0.92 (0.09) 62.7 (10.4) 11.4 (11.0) 1.8 (2.3	0.40 0.88 0.002 0.79
Toots 2016[13] (26782852) HIFE (leg strength, balance, mobility) vs. seated group activities Medium Explanatory	Barthel ADL Mean (SE) FIM Mean (SE) BBS Mean (SE) 4 month, 7 months	Mean difference (CI) 0.57 (-0.30, 1.43) Mean difference (CI) 0.78 (-2.21, 3.77) Mean difference (CI) -0.02 (-2.53, 2.49)	-1.56 (0.32) -6.77 (1.09) -2.08 (0.91)	-2.12 (0.32) -7.55 (1.08) -2.05 (0.90)	0.20 0.61 0.98
Telenius 2015[14] (26630910) HIFE (strength + balance) vs. seated group activity Medium Explanatory	QUALID Between group difference Barthel ADL Between group difference Berg Balance Scale Mean change from baseline NPI Mean (CI) CSD Between group difference 3 months, 6 months	-0.9 points 1.0 points NR Between group difference -1.6 Between group difference 0.2 points	NR NR +2.7 points 4.8 (3.8, 5.8) NR	NR NR -1.4 points 6.4 (5.1, 7.7) NR	NR NR 0.031 0.059 NR
Pitkala 2013[16] 23589097 Medium (6 months) Explanatory	FIM Within-group mean change from baseline 6 months FIM Between-group change from baseline 6 months Adverse events: 12 months Falls Incidence rate (95% CI) Fractures (any) Incidence rate (95% CI) Hospitalizations Incidence rate (95% CI)	NR NR NR NR NR	Home exercise: -6.5 (-4.4, -8.6) Group exercise: -8.9 (-6.7, -11.2) Home: 1.35 (1.07, 1.67) Group: 1.86 (1.51, 2.26) Home: 0.06 (0.02, 0.17) Group: 0.09 (0.03, 0.21) Home: 0.47 (0.31, 0.68) Group: 0.54 (0.37, 077)	-11.8 (-9.7, -14.0) UC: 3.07 (2.63, 3.57) UC: 0.07 (0.02, 0.18) UC: 0.65 (0.46, 0.90) UC: $34,121 ($24,599, $43,681)	Mixed-effect model p=0.003. Home exercise vs. UC: p=0.001 Group exercise vs UC: p=0.07 p=0.005 p=0.88 p=0.63

Study (PMID) Comparison RoB Category	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
	Health service costs (24 months): Adjusted mean (95% CI) per dyad per year, US dollars	NR	Home exercise: $25,112 ($17,642, $32,581) Group exercise: $22,066 ($15,931, $28,199)		Home vs. UC: p=0.13 Group vs. UC: p=0.03
Hauer 2012[17] (22211512) Group resistance & functional training vs low intensity motor activity Medium Explanatory	TUG Mean percent change from baseline (SD) POMA Mean percent change from baseline (SD) Modified PAQE Mean percent change from baseline (SD) 3 months, 6 months	Effect size 0.07 Effect size 0.15 Effect size 0.002	-11.2 (28.1) 22.2 (28.4) 134.5 (274.5)	-1.4 (26.3) 0.8 (23.5) 101.1 (178.6)	0.009 <0.001 0.64
Eggermont 2009[20] (18926856) Group hand movement program vs. read aloud control Medium Explanatory	GDS Change in group mean from baseline SCL-90 Change in group mean from baseline 12 weeks, 6 months	NR NR	-1.56 -2.61	-0.17 -0.69	NR NR

Abbreviations: ADCS-ADL= Alzheimer's Disease Cooperative Study-Activities of Daily Living; ADL=Activities of Daily Living; AE= adverse events; BADLS= Bristol Activities of Daily Living Scale; BBS=Berg Balance Scale; CSD=Cornell Scale for Depression; E-ADL=Erlangen-ADL (instrumental ADLs); EdFED=Edinburgh Feeding Evaluation in Dementia;EQ-5D-3L=EuroQol 5 dimension-3 level; EQ-5D-5L=EuroQol 5 dimension-5 level; FIM=Functional Independence Measure; GDS= Geriatric Depression Scale; HAM-D=Hamilton Depression Rating Scale; HIFE=high-intensity functional exercise; N=number; NPI = Neuropsychiatric Inventory (10 items); NPI-12= Neuropsychiatric Inventory-12 items; NR=not reported; PAQE=Physical Activity Questionnaire for the Elderly; PPT-7=7-item Physical Performance Test; POMA=Performance Oriented Motor Assessment (gait and balance); PMID=PubMed Identification Number; QOL-AD=Quality of Life in Alzheimer's Disease; QUALID= quality of life in late-stage dementia scale; SAE=serious adverse event; SCL-90=Symptom Checklist-90; SD=standard deviation; SPPB=Short Physical Performance Battery; TUG=Timed Up and Go; UC=usual care; vs=versus

Appendix Table D.4. Summary of strength of evidence for PLWD outcomes: exercise

Outcome Comparison	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Quality of Life: Group exercise vs usual care (2) or seated group activity (1)	3-12 months	3 RCTs[8, 12, 14] (1 NH) n=864	No significant difference in Quality of Life (QOL-AD, EQ-5D-5L, EQ-5D-3L or QUALID) for group exercise compared with usual care or seated group activity.	Low	Inconsistent	Direct	Imprecise	Insufficient
Daily function: Group exercise vs usual care (3) or home exercise (1)	4-12 months	3 RCTs[8, 12, 16] (0 NH) n=904	Inconsistent findings. Two RCTs found no significant difference in daily functioning (BADLS, ADCS-ADL) for PLWD for group exercise compared with usual care. One RCT found benefits of group exercise vs usual care and for home exercise vs usual care on the FIM at 6 months.	Low	Inconsistent	Direct	Imprecise	Insufficient
Daily function: Group exercise vs seated group activity (3)	3-7 months	3 RCTs[10, 13, 14] (3 NH) n=474	Inconsistent findings. Two RCTs found no significant difference in daily functioning (Barthel ADL) for group exercise compared with seated group activity. One RCT found benefits of combined group exercise vs social activity, and for walking vs. social activity on daily functioning [Katz ADL, E-ADL, PPT-7 (combined only)] at 9 weeks.	Medium	Inconsistent	Direct	Imprecise	Insufficient
Daily function: Tai Chi vs usual care	10 months	1 RCT[4] (NH) n=80	No significant difference in daily functioning (Barthel ADL) for Tai Chi compared with usual care.	Medium	Unknown	Direct	Imprecise	Insufficient
Daily function: Eating assistance needed. Supervised 1:1 hand exercise program vs. usual care	6 months	1 RCT[3] (NH) n=60	Statistically significant reduction (< 1 point) in feeding assistance needed (EdFED) with individual hand exercise program vs. usual care over 6 months.	Medium	Unknown	Direct	Imprecise	Insufficient
Daily function: Time of autonomous eating (min.) Supervised 1:1 hand exercise program vs. usual care	6 months	1 RCT[3] (NH) n=60	Statistically significant improvement in minutes of autonomous eating per meal with individual hand exercise program vs. usual care over 6 months.	Medium	Unknown	Direct	Imprecise	Insufficient
Balance: HIFE (strength + balance) vs. seated group activity	3-7 months	2 RCTs[13, 14] (2 NH) n=356	Inconsistent findings. One RCT found no significant difference in balance (BBS) between HIFE compared with seated group activity at 3 months, but beneficial effect at 6 months. One RCT found a	Medium	Inconsistent	Direct	Imprecise	Insufficient

Outcome Comparison	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
			beneficial of HIFE vs. seated group activities at 4 months but not 7 months.					
Neuropsychiatric symptoms: Tai Chi vs usual care	10 months	1 RCT[4] (NH) n=80	Statistically significant improvement in NPI with group Tai Chi vs. usual care over 10 months but not at 5 months.	Medium	Unknown	Direct	Imprecise	Insufficient
Neuropsychiatric symptoms: Group exercise vs usual care (2) or seated group activity (1)	3-12 months	3 RCTs[8, 12, 14] (1 NH) n=864	Inconsistent findings. Two RCTs found no significant difference in neuropsychiatric symptoms (NPI) with group exercise vs. usual care (1 NH), and one RCT reported a benefit of exercise vs. usual care on the NPI-12 at 4 months.	Low	Inconsistent	Direct	Imprecise	Insufficient
Depression: Tai Chi vs usual care	10 months	1 RCT[4] (NH) n=80	Statistically significant improvement in GDS with group Tai Chi vs. usual care over 10 months but not at 5 months.	Medium	Unknown	Direct	Imprecise	Insufficient
Depression: Group exercise vs usual care (1) or seated group activity (2)	3-6 months	3 RCTs[12, 14, 20] (2 NH) n=436	No significant difference in depression (HAM-D, CSD, GDS) for group exercise compared with usual care or seated group activity.	Medium	Inconsistent	Direct	Imprecise	Insufficient
Anxiety: Group hand movement program vs. attention control	3 months	1 RCT[20] (NH) n=66	No significant difference in anxiety (SCL-90) with a group hand movement program vs. attention control over 3 months.	Medium	Unknown	Direct	Imprecise	Insufficient

Abbreviations: ADCS-ADL=Alzheimer's Disease Cooperative Study-Activities of Daily Living; ADL=Activities of Daily Living; BADLS=Bristol Activities of Daily Living Scale; BBS=Berg Balance Scale; CSD=Cornell Scale for Depression; E-ADL=Erlangen-ADL scale; EdFED=Edinburgh Feeding Evaluation in Dementia; EQ-5D-5L=EuroQol 5 dimension-5 level; EQ-5D-3L=EuroQol 5 dimension-3 level; FIM=Functional Independence Measure; GDS=Geriatric Depression Scale; HAM-D=Hamilton Depression Rating Scale; HIFE=high-intensity functional exercise; N=number; NH=nursing home; NPI=Neuropsychiatric Inventory; PPT-7=7-item Physical Performance Test; PLWD=Persons with Dementia; QoL=Quality of Life; QOL-AD=Quality of Life in Alzheimer's Disease; QUALID=Quality of Life in Late-stage Dementia Scale; RCT=Randomized controlled trial; SCL-90=Symptom Checklist

Evidence Map: Exercise

Appendix Table Exercise D.5. Characteristics of evidence map studies: exercise

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Enette 2020[37] (31921371) France Small sample	I1. Continuous aerobic training (cycling) 30 minutes 2x/week 9 weeks I2. Interval aerobic cycling 30 minutes 2x/week 9 weeks	Interactive information sessions: supervised and structured. Multiple-choice questionnaires that PLWD discussed afterward	Memory clinic of a university hospital RCT 54 PLWD from NH or home	Mild to moderate AD diagnosed according to DSM-IV and MMSE ≥ 16.	N=54 (3 groups) Mean age: 78 years Female: 61% % majority race: no Education: 7-10 years	NR	NR	NR	NR	NR	10 weeks	QoL-AD, 6 meter walk, cognitive, blood tests	NR
Fleiner 2020[1] 32039852 Germany High RoB	PLWD Small group exercise (strength and	Social stimulation program (table games per OT) 120 min./week	3 acute dementia care wards of a psychiatric	PLWD with ICD-10 diagnosis of dementia (AD, VD, mixed, LBD, PD).	N=70 Mean age: 80 years Female: 47% % majority race: no Education: 13 years	NR	NA	NR	All RNs Other: NR	NA	2 weeks	NR	NPI

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	endurance) 20 minutes 4x/day 3 days/week 2 weeks	2 weeks	hospital RCT 70 PLWD	Mean MMSE=18. Able to do TUG.									
Lee, 2020[38] (31347294) Korea Small sample	Fumanet exercise program 1 hour/week 8 weeks	Non-equivalent control group	Community-based Quasi-experimental (segregated by day at center) N=45	Persons with mild dementia (CDR 0.5 to 1). Not visually impaired. Able to ambulate with or without assistance. Age 45 or older. Other exclusions	N=45 (22 exercise, 23 control) Age: Y Sex: Y Education: Y Race & majority: N	Dementia diagnosis: Y	NA	NA	NR	Training: Y	8 weeks	Cognitive function, gait, depression	NA
Liu 2020[2] (32084347) Taiwan High RoB	Isotonic strength training (weight machines) 2 sets of 12 5 days/week 4 weeks	Aerobic exercise (stationary cycling) 30 minutes 5 days/week 4 weeks	PLWDs Veterans NH RCT 80 PLWDs	MMSE 15-26 Other: NR	N=69 analyzed Mean age: 86 years Female: 16% % majority race: no Education: no	NR	NR	NR	NR	NR	4 weeks	Barthel Index, GDS, cognitive, blood test	NR
Sanders 2020[39] (32192537) Netherlands Pilot	Outdoor walking and lower limb strength training: 12 weeks low-intensity, then 12 weeks high-intensity training 3x/week 24 weeks	Flexibility exercises and recreational activities 3x/week 24 weeks	Recruited from daycare or residential care RCT 91 PLWDs	Dementia diagnosis per physician using DSM-IV; MMSE score >10 (mild-to-moderate dementia)	N=69 Mean age: 82 years Female: 62% % majority race: no Education: yes (3 levels)	None	NA	None	NA	NA	12 weeks 24 weeks 6MWS, leg strength and STROOP (6 weeks 18 weeks 36 weeks)	6MWT (6-minute walk test) SPPB (Short Physical Performance Battery) Cognitive	NA
Brett 2019[40] (30912690) Australia Small sample	I1. 45-minute exercise program 1x per week I2. 15-minute exercise program 3x per week	Usual care activities (routine group activities)	2 nursing homes RCT N=60	PLWD living in nursing home, able to participate in intervention. Stratified by able to walk (71%) vs. participated sitting	Reported N=55 (17 Group 1, 19 Group 2, 19 usual care) Mean age: 85 Female: 66% Race % majority: Y Education: N	N of comorbidities: Y	NA	NA	NR	Length of service: Y	12 weeks	Falls, Timed Up & Go, Sit to Stand, Gait speed, Functional reach	NA
Karssemeijer 2019[5] (31409559) Netherlands High RoB	I1. Exergame training I2. Aerobic training Both: 3x/week 12 weeks	Active control 12 weeks	Community centers RCT N=115 (92 completed)	Diagnosed with VD, AD or mixed dementia, MMSE ≥ 17, age ≥ 60 years. Additional criteria applied	N=115 (38 exergame, 38 aerobic, 39 controls) Mean age: 79 Female: 54% Education: N Race & majority: N	Living situation: Y	NA	NA	NR	NR	12 weeks	Frailty, adherence	NA
Nyman 2019[41] (31819385)	Group Tai Chi 45 min plus discussion	Usual care	Community-dwelling dyads	Diagnosis of dementia per MD (VD, AD, mixed,	N=85 (70 complete data) Mean age: 78 years	NR	N=85 Mean age: 71 years	Living with PLWD: 87%	NA	NA	6 months	Berg Balance, Timed Up &	IC: TUG, other

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
UK Pilot	Weekly 20 weeks		(PLWD and IC). Classes in church halls N=85	other), Mini Addenbrooke's Cognitive Exam ≥ 10, willing to attend Tai Chi class, able to do standing, other exclusions	Female: 40% Education: N Race & majority: N Time since diagnosis: Y		Female: 79% Other: NR					Go, falls, cognitive	
Todri 2019[42] (None) Spain Pilot	Global Postural Reeducation 30-40 minutes 2x/week 6 months (total 48 sessions)	Conventional exercises (proprioceptive, equilibrium, aerobic/walking) 30-40 minutes 2x/week 6 months	PLWDs were recruited from nursing homes , 2 countries 174 PLWD	Dementia (mild to moderate) per NINCDS-ADRDA criteria	N=135 analyzed Mean age: 81 years Female: 66% % majority race: no Education: "Medium"	NR	NA	NR	NR	NR	2 weeks	Qol-AD GDS Barthel Index, NPI Tinetti Scale, MMSE	NR
Henskens 2018[6] (29750023) Netherlands High RoB	I1. [Exercise (strength + walking) + ADL training] I2. ADL training only I3. Exercise only All: 3x/week 6 months	Social control	11 Nursing homes 4 group RCT Cluster: 11 N=87	Dementia (AD, VD, Mixed, Unknown) per DSM-IV, living in NH, age ≥ 65 yrs., MMSE 1-24, complete 6-minute walk test	N=87 (66 completed) Age: Y Sex: Y Race: N Education: Y	NR	NA	NA	NR	NR	3 months, 6 months	QoL, function (created composite)	NA
Ho 2018[7] (30496547) Hong Kong High RoB	I1: Dance movement therapy I2. Exercise Both: 2x/week 12 weeks	Waitlist	Outpatient RCT PLWD N=204	Dementia per DSM-IV or neurocognitive disorder (DSM V), CDR 0.5 to 1, age ≥ 65 years. Other exclusion criteria	N=204 (166 completed)	NR	NA	NA	NR	NR	3, 6, and 12 months	Depression, mood, daily function, cortisol	NA
Liu, 2018[43] (29969916) Hong Kong/ China Pilot	Simplified Tai-chi program to improve motor skills 16 weeks	Social activities	Community-dwelling PLWD; four community health centers RCT	PLWD aged 60 or older with Montreal Cognitive Assessment score <=20; capable of exercise; caregiver able to exercise	N=26 (13 intervention/, 2 centers; 13 controls/2 centers) Age: Y Sex: Y %majority race: N Education: Y	Prior disability: Y Household Characteristics: Y	N=11 exercise group 13 control group Age: Y Sex: Y Education: Y Relation to PLWD: Y	Duration: Y	NR	NR	16 weeks	Motor performance	
Chen 2017[9] (27879982) Taiwan High RoB	Resistance-band exercise program 3x/week x 6 mo., then 9 mo. per DVD	Usual daily activities	Nursing homes Cluster RCT (8 NH) N=150 PLWD	Wheelchair-bound PLWD, lived in nursing home 3 months, dementia per diagnosis or MMSE (cutpoint by education level)	N=127 completed (65 intervention, 62 controls) Age: Y Sex: Y % majority race: N Education: Y	100% wheelchair-bound Other: NR	NR	NR	NR	NR	3, 6, 9, 12 and 15 months	Depression, behavioral problems (BRS)	NR
Dawson, 2017[44] (28252473)	Moderate-Intensity Home-	Continuation of current levels of	Community-based	Dementia unspecified	N=13 intervention group	NR	NA	NA	NR	NR	12 weeks	Measurements of walking	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
USA Small sample	Based Exercise Program	activity Randomized control trial	RCT PLWD		10 control group Age: Y Sex: Y % majority race: N Education: Y							and balance Assessment of cognition	
De Souto, 2017[45] (28542742) France Pilot	Multicomponent training: coordination, balance, muscle-strengthening & aerobic	Structured social activity	Nursing Homes RCT cluster PLWD	Dementia unspecified	N=47 PLWD (4 nursing homes) exercise; 50 PLWD (3 nursing homes) social activity Age: Y Sex: Y % majority race: N Education: Y	NR	NA	NA	NR	NR	24 weeks	MMSE Physical performance evaluation	NA
Hamilton, 2017[46] (27692024) Australia Small sample	Home-based exercise program	Structured, individually tailored exercise program	Home-based RCT	PLWD diagnosed with mild to moderate dementia	N=33 completed the study; 9 did not Ae: Y Sex: Y % majority race: N Education: Y	NR	NA	NA	NR	NR	6 months	Psychological assessment Physical assessment fall risk Adherence	NA
Henwood, 2017[47] (28473006) Australia Small sample	Aquatic exercise for 2x/week 12 weeks	Usual care	Non-RCT: Facility PLWD allocated by ability to transport to swimming facility N=56	PLWD living in residential care facility, moderate to severe dementia	N=56 (analyzed 46; 23 each group) Age: Y Sex: Y % majority race: N Education: N	NR	NA	NA	NR	NR	12 weeks	Assessment of physical condition, balance and physical functions	NA
Lam, 2017[48] (28094873) Hong Kong Small sample	Whole–body vibration plus routine day activity program 2x/week 9 weeks	Routine day activity program 2x/week 9 weeks	PLWD with mild or moderate dementia, recruited from 2 day-care centers RCT	PLWD aged 65 or older with MMSE 10-22; ability to stand; living in the community	N=54 (27 intervention, 27 control) Age: Y Sex: Y % majority race: N Education: N	NR	NA	NA	NR	NR	9 weeks	Ability to stand; balance; quality of life; balance confidence	NA
Morris 2017[49] (28187125) USA Pilot	Supervised aerobic exercise program: 150 minutes per week for 26 weeks	Non-aerobic stretching and toning	Community-based RCT PLWD	PLWD with probable AD; age 55 or older; sedentary; community dwelling, supportive caregiver; other exclusion criteria	N=76 Age: yes Sex: yes % majority race: no Education: no	NR	NR	NR	NA	NA	26 weeks	Functional ability and depression	NA
Padala, 2017[50] (28655135) US	Home-based Wii-Fit interactive	Walking program	Community-based RCT	PLWD 60 years and older diagnosed with AD;	N=15 exercise group 15 control group	Comorbidities: yes Medications: yes	NR	NR	NA	NA	8 weeks, 16 weeks	Balance	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Pilot	video-game-led physical exercise program, 8 weeks		N=30	MMSE score >=18 with fear of falling; exclusion criteria applied	Age: yes Sex: yes % majority race: yes Education: yes								
Cancela 2016[11] (26087884) Spain High RoB	Exercise (stationary cycling) 15 minutes/day 15 months	Sedentary recreational activities	Institutional residential care RCT N=189	PLWD age ≥ 65 yrs., dementia per DSM-IV, able to stand and walk 30 meters without assistance, resident of facility	N=114 completed Age: Y Sex: Y % majority race: N Education: Y	Comorbidities: Y Other: NR	NR	NR	NR	NR	15 months	Neuropsychiatric symptoms, cognition, Katz ADL, mobility, depression	NA
Burge, 2016[51] (27831462) Switzerland & Belgium Pilot	Group physical exercise 20 sessions 4 weeks	Social visits 20 sessions 4 weeks	5 Hospitals, acute psychiatric wards RCT PLWD	Moderate to severe dementia, on acute psychiatric ward	N=270 Age: yes Sex: no % majority race: no Education: no	NR	NA	NA	NA	NA	4 weeks	Barthel ADL, FIM, depression & behavior	NA
Venturelli 2016[52] (27540967) Italy Small sample	I1:Aerobic exercise and cognitive training I2:aerobic exercise only I3: cognitive training only	No training	Nursing home PLWD Control trial	PLWD diagnosed with dementia, MMSE between 10 and 15; PLWD screened for physical limitations	N=80 (20 each group) Age: yes Sex: yes % majority race: no Education: no	Prior disability	NA	NA	NR	NR	3 months	Cortisol level; level of cognitive function; neuropsychological symptoms	NA
Bosser, 2015[23] (25648055) Netherlands High RoB	I1: Combined aerobic and strength training: 36 individualized sessions over 9 weeks I2: Aerobic only: participated in four walking sessions per week, 9 weeks	Four social visits each week	Nursing homes RCT PLWD	Mild-severe vascular dementia	N=123 Age: yes Sex: yes % majority race: no Education: yes	NR	NA	NA	NA	NA	18 weeks	MMSE 6-minute walk test, the 30-second sit-to-stand test	NA
Holthoff, 2015[53] (25884637) Germany Pilot	Home-based exercise; lower body on a movement trainer with computer control 12 weeks	Usual care Monthly clinical visits and a counselling including specific advice how to change inactive habits and increase the exercise	Community-based RCT PLWD	PLWD with mild to moderate AD per NINCDS-ADRA criteria, age 55 or older and their family caregivers; PLWD evaluated for other conditions that would rule out AD	N=30 Age: yes Sex: yes % majority race: Education:	Age at diagnosis	NR	NR	NR	NR	12 weeks	ADL; Neuro-psychiatric symptoms; Executive function, language ability; Motor skills; Caregiver	NA

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
												burden; MMSE	
Yang 2015[15] (26556080) China High RoB	Moderate aerobic exercise (cycling) 3x/week 3 months	Health education	Outpatient RCT PLWD	Mild AD (criteria NR) or vascular dementia, age 65-80 years, MMSE 10-24; other exclusion criteria	N=50 Age: Y Sex: Y % majority race: N Education: Y	NR	NR	NR	NR	NR	3 months	QoL, cognition, neuro-psychiatric symptoms	NA
Yu, 2015[54] (24652914) US Pilot	Cycling as exercise	Single group	Community-based Single group Pilot study	Older adults, mild to moderate AD; MMSE 12-24; CDR 1-3; able to perform exercises, qualified family caregivers	N=26 Age: Y Sex: Y % majority race: Y Education: Y	NR	N=26 Age: Y Sex: Y % majority race: Y Education: Y Relation to PLWD: N	NR	NR	Training: Y	6 months	Cognitive function; ADL; BPSD; caregiver distress	Caregiver distress decreased from baseline
Bosser 2014[24] (24844772) Netherlands Pilot	Evaluation of a combined aerobic and strength training program for institutionalized PLWD; studied effects on cognitive and physical function	Non-randomized pilot study; comparison of training program and social group visit program	PLWD from a single nursing home	Diagnosis of dementia; age 70 or older; not wheelchair bound; able to walk	N=18 PLWD exercise group 18 PLWD control group Age: Y Sex: Y Race: N Education: N	NR	NR	NA	NA	NR	6 weeks	Cognitive function tests Physical function tests	NA
Suttanon, 2013[55] (23117349) Australia Pilot	Individual tailored home-based exercise program; balance, strengthening and walking exercise	Home-based education program	Community-based RCT PLWD	PLWD assessed with mild to moderate AD	N=40 Age: yes Sex: yes % majority race: no Education: no	Prior disability: Y	NA	NA	NA	NA	6 months		Exercise arm PLWD dropped out due to inability of home caregivers to maintain the program
Canonici, 2012[56] (22994617) Brazil Small sample	Evaluation of a motor intervention program for PLWD wit AD to promote functionality and reduce caregiver burden	Motor intervention compared to control group	NR	PLWD diagnosed with mild to moderate AD; CDR of 1 to 2	N=16 PLWD, 16 FC exercise arm 11 PLWD, 11 FC control arm Age: Y Sex: Y Race: N Education: Y	NR	NA	NA	NR	NR	6 months	Measurements of physical function, cognition and caregiver burden	NA
Nascimento, 2012[57] (22499405)	Supervised exercise program, including	PLWD who did not participate in the exercise program	Community Non-RCT: assigned by willingness	Community-based PLWD diagnosed with mild to moderate dementia	N=20 (10exercise; 10 controls) Age: N Sex: N	NR	NA	NA	NA	NA	6 months	Neuropsychiatric, ADL	NA

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Brazil Small sample	aerobic activity, strength, motor coordination, balance 6 months		to follow the exercise program	and using MMSE; exclusion criteria for other health conditions	% majority race: N Education: N								
Vreugdenhil, 2012[58] (21564154) Australia Small sample	Home-based exercise program	Usual care	Community-based RCT	PLWD diagnosed with AD	N=80 Age: Y Sex: Y % majority race: N Education: N	NR	NR	NR	NA	NA	4 months	Cognitive function; physical function; ADL; depression; global function	Caregiver burden
Fan 2011[18] (21385519) Taiwan High RoB	Yoga training program 3 x 1 hour/week 12 weeks	Usual activities	Long term care facilities Quasi-experimental N=68	Age 60 or older, living in LTC, mild dementia per DSM-IV and MMSE 18-23, no recent exercise	N=68 (33 yoga, 35 usual activities); reported 59 Mean age: 75 Female: 59% Education: ≤ 9 yrs Race & majority: N	SES: N Disability: N Household: NA Marital status: Y N comorbidities: Y Length of residence: N Insurance: NA	NA	NA	NR	NR	12 weeks	Mobility (6 m. walk), balance, strength, depression (CSDD), behavior (BRS)	NR
Roach 2011[19] (21937893) USA High RoB	I1: activity-specific exercise group I2. Supervised walking group 5x/week 16 weeks	Social conversation group	Long term care sites (7) RCT PLWD N=105	Residence in long term care, AD per NINCDS-ADRDA, able to walk, dependent in ≥ 1 ADL	N=82 completed Age: Y Sex: N % majority race: N Education: N	Length of stay: Y Other: N	NA	NA	NR	NR	16 weeks?	Walking, transferring, bed mobility	NR
Stella, 2011[59] (21915483) Brazil Small sample	Individual exercise (flexibility, strength, and agility)& functional balance exercise) 60 minutes three times per week.	Motor intervention compared to PLWD who did not receive the intervention	Community-based RCT PLWD	mild or moderate state of probable AD	N=16 PLWD exercise group 16 PLWD control group Age: Y Sex: Y % majority race: N Education: Y	NR	Age: Y Sex: Y % majority race: N Education: Y Relation to PLWD: N	Duration: Y	NA	NA	6 months	Neuropsychiatric inventory; Caregiver burden and stress	Reduction of caregiver stress
Venturelli, 2011[60] (21852281) Italy Small sample	Group exercise, 30 minutes of moderate walking exercise 4 times a week	Daily organized activities like bingo, patchwork sewing, and music therapy	Nursing homes RCT PLWD	PLWD diagnosed with AD, MMSE <=15 and absence of mobility limitations	N=12 PLWD, 12 caregivers walking group 12 PLWD, 12 caregivers control group Age: yes Sex: no % majority race: no Education: no	NR	Age: Y Sex: Y Relation to PLWD: Y	NR	NA	NA	6 months	Reduction of Functional, cognitive and physical decline	NR

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Steinberg, 2009[61] (19089875) US Pilot	Home-based exercise intervention program: Aerobic fitness, strength, balance & flexibility training	Home safety assessment	Community-based RCT PLWD	PLWD diagnosed with probable AD, MMSE score >=10; community-residing; ambulatory, with caregiver	N=14 exercise group 13 control group Age: yes Sex: yes % majority race: yes Education: no	NR	NR	NR	NA	NA	12 weeks	Functional performance, cognitive functioning, neuropsychiatric symptoms, caregiver burden and quality of life:	NA
Kwak, 2008[62] (18050054) Korea Small sample	Individual home-based exercise 30–60 minutes per day, 2–3 times per week for 12 months	Control: NR	Community-based RCT	Women with AD,, age >60; living with relative, MMSE 10-26; able to exercise	N=30 (15 exercise, 15 controls) Age: yes Sex: yes % majority race: yes Education: no	NR	Not clear –it appears the IC were all women, but it also appears the PLWD were all women	NR	NA	NA	12 months	Cognition. cardio-vascular health, and physical condition	NR
Williams, 2008[63] (17959874) US Small sample	I1: Group exercise (walking plus strength training, balance, and flexibility) I2: Supervised walking	Social conversation	Nursing home RCT	PLWD diagnosed with AD and symptoms of depression	N=116 Age: yes Sex: yes (overall) % majority race: yes (NR by group) Education: no	NR	NA	NA	Education: Y	Training: Y	16 weeks	Observed Affect Scale (OAS), Alzheimer Mood Scale, Dementia Mood Assessment	NA
Rolland 2007[21] (17302650) France High RoB	Group exercise (walk, strength, balance, flexibility) 2x/week 12 months	Routine medical care	Nursing homes (5) RCT	Mild to severe AD	N=134 Age: Y Sex: Y % majority race: N Education: N	Disability: Hearing and visual impairment Other: NR	NA	NA	NR	NR	12 months	Function, Katz ADL, depression, Neuropsychiatric Inventory	NA
Stevens, 2006[64] (16594879) Australia Pilot	Individually prescribed exercise program of 20 to 30 minutes 3x per weeks	Two groups: 1. no intervention 2. social visit of equal length to exercise program	Nursing home-based RCT	PLWD assessed with mild to moderate dementia; MMSE score <9 and <23; not all PLWD assessed for MMSE	N=24 exercise, 21 social visit, 30 control Age: Y Sex: Y % majority race: N Education: N	NR	NA	NA	NA	NA	12 weeks	Assessment of physical and psychiatric problems, dependence on nursing care	NA
Van de Winkel 2004[65] (15137556) Belgium Small sample	Music-based exercises	Social conversation	RCT Institutionalized	PLWD with MMSE score lower than 24; able to respond to verbal and visual commands; capable of responding to music	N=15 PLWD exercise group 10 PLWD control group Age: N Sex: N % majority race: N Education: N	NR	NA	NA	NA	NA	3 months	Measures of cognition; need for help; aggressiveness; depression; level of activity	NA

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Toulotte, 2003[66] (12540351) France Small sample	Exercise: chair-assisted or standing supervised exercise 1 hour, 2x/week 16 weeks	Usual daily routine	Home and institutionalized PLWD Crossover RCT	Demented elderly people with a history of falling	N=20 Age: yes Sex: yes % majority race: no Education: no	NR	NA	NA	NA	NA	16 weeks	Walking, mobility, flexibility and static balance	NA

Abbreviations: AD=Alzheimer's Disease; ADL=Activities of Daily Living; AE=adverse events; BADL=Bristol Activities of Daily Living Scale; BBS=Berg Balance Scale; CDR=Clinical Dementia Rating; BPSD=Behavioral and Psychological Syndrome of Dementia; CSD=Cornell Scale for Depression; CST=Chair Stand Test; E-ADL=Erlangen-ADL (instrumental ADLs); EQ-5D-3L=Euroqol 5 dimension-3 level; EQ-5D-5L=Euroqol 5 dimension-5 level; FIM=Functional Independence Measure; FINALEX=Finnish Alzheimer's Disease Exercise Trial; GDS=Geriatric Depression Scale; GHQ=Global Health Questionnaire; HIFE=high-intensity functional exercise; IC=informal caregiver; MMSE=Mini Mental State Exam; N=number; NINCDS-ADRDA=National Institute of Neurological and Communicative Diseases and Stroke/Alzheimer's Disease and Related Disorders Association; NPI=Neuropsychiatric Inventory (10 items); NPI-12=Neuropsychiatric Inventory-12 items (with sleep and appetite); NR=Not Reported; PAQE=Physical Activity Questionnaire for the Elderly; PPT-7=7-item Physical Performance Test; POMA=Performance Oriented Motor Assessment (gait and balance); PMID=PubMed Identification Number; PLWD=Persons with Dementia; QUALID=quality of life in late-stage dementia scale; RCT=Randomized controlled trial; ROB=risk of bias; SAE=serious adverse event; SCL-90=Symptom Checklist-90; SD=standard deviation SES=socioeconomic status; SPPB=Short Physical Performance Battery; TMT=Trail Making Test; TUG=Timed Up and Go; UC=usual care; vs=versus

Music Intervention

Appendix Table D.6. Risk of bias assessment: music intervention

Study (PMID)	**Outcome Timing**	**Attrition Bias** **Attrition %**	**Selection Bias**	**Detection Bias**	**Performance Bias**	**Reporting Bias**	**Fidelity Bias**	**Funder**	**Overall Rating**
Ugur, 2019[67] (30497077)	3 months	Medium 14%	Low	Medium	High	Low	High	University	High
Cheung, 2018[68] (30235949)	6 weeks	Low 6 weeks: 19.39% 12 weeks: 24.84%	Low	Low	Moderate	Low	High	No funding	Medium
Ho, 2018[69] (29468887)	8 weeks	Low 0%	Medium	High	High	Low	Low	The Tung Wah Groups of Hospitals	High
Kwak 2018[70] (29871544)	14 weeks	Low 0%	Low	Medium	Medium	Low	Moderate	Nonprofit, University, Government	Medium
Pongan, 2017[71] ((28922159)	12 weeks & 20 weeks	Low 20%	Medium	Low	Medium	Low	High	Nonprofit, Government	High
Wang, 2017[72] (26443002)	24 weeks	Medium 13.37%	High	Medium	High	Low	High	Unclear	High
Sarkamo, 2014[73] (24009169)	3 months	Low 3 months: 5.61% 9 months (6months follow up post intervention): 16.85%	Low	Low	High	Low	High	Nonprofit, Government	Medium
Vink, 2013[74] (23280604)	4 months	Low 18%	Medium	Medium	Medium	Low	High	Nonprofit	High
Sung, 2012[75] (21823174)	6 weeks	Low 8.33%	Low	Medium	High	Low	High	Government	Medium

Study (PMID)	**Outcome Timing**	**Attrition Bias Attrition %**	**Selection Bias**	**Detection Bias**	**Performance Bias**	**Reporting Bias**	**Fidelity Bias**	**Funder**	**Overall Rating**
Ugur, 2019[67] (30497077)	3 months	Medium 14%	Low	Medium	High	Low	High	University	High
Lin, 2011[76] (20672256) #2	6 weeks	Low 6 weeks: 3.84% 10 weeks: 3.84%	Low	Medium	High	Low	High	NR	Medium
Chu, 2014[77] (23639952)		Low	Low	Medium	Medium	Low	Low	The Taipei Medical University Hospital	Medium
Raglio, 2008[78] (18525288)	16 weeks 20 weeks post intervention	Low 3.38%	Medium	Low	High	Low	High	NR	High
Ledger, 2007[79] (17558584)	1 Year	High 25%	High	X	X	X	X	No funding	High

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: NR=Not Reported; PMID=PubMed Identification Number; #2=Companion

Appendix Table D.7. Characteristics of included studies: music intervention

Study (PMID) **Country** **RoB*** **Type**	**Intervention** **Intervention Focus** **Theoretical Model** **Delivery Person** **Intervention Target Recipient** **Mode** **Components** **Frequency** **Duration**	**Comparison** **Target** **Mode** **Components** **Frequency** **Duration**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics** **Dementia Types** **Dementia Severity** **Diagnostic Criteria** **Age of Diagnosis**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Cheung 2018[80] (30235949) Hong Kong Medium Explanatory	PLWD met 30 mins, twice a week for six weeks to receive music intervention that involved listening to their preferred music and moving their limbs and trunk. The first author facilitated the intervention.	(1) Music Listening: PLWD in this group listened to their preferred music (2) Social activity: chatted casually, twice a week for six weeks.	Residential care facilities RCT multisite 165 PLWD	Any type of dementia with moderate severity according to Global Deterioration Scale (stage 5 or 6)	N=165 82.27 years 75.8% Female 54.5% had no formal education	NR	NA	NA	NA	NA	6 weeks 12 weeks	Agitation: CMIA-Nursing home version (Chinese version)	NA
Cheung 2018[68] (27819483) Taiwan Medium Explanatory	PLWD met 30 mins, twice a week for six weeks to receive music intervention that involved listening to their preferred music and moving their limbs and trunk. The first author facilitated the intervention.	(1) Music Listening: PLWD in this group listened to their preferred music (2) Social activity: chatted casually, twice a week for six weeks	Residential care facilities RCT multisite 165 PLWD	Any type of dementia with moderate severity according to Global Deterioration Scale (stage 5 or 6)	N=165 82.27 years 75.8% Female 54.5% had no formal education	NR	NA	NA	NA	NA	6 weeks 12 weeks	Anxiety: The Chinese RAID Depressive symptoms: GDS	NA
Kwak 2018[70] (29871544) USA Low Explanatory	Music & memory: In addition to treatment as usual, personalized music playlists delivered on digital music players over a 6-week period followed by 2-week washout period & 6 weeks of treatment as usual only	Condition 2: 6 weeks of treatment as usual only followed by 2-week washout period and then music and memory for 6 weeks	Nursing homes RCT (Crossover) 59 PLWD	Alzheimer's disease or other dementia	N=59 86.9 years 77.96% Female 93% White Education: No	NR	NA	NA	NA	NA	14 weeks	Agitation: CMAI Dementia-related cognitive-behavioral issues: NPI-NH Medication use: Standardize record form	NA

Study (PMID) **Country** **RoB*** **Type**	**Intervention** **Intervention Focus** **Theoretical Model** **Delivery Person** **Intervention Target** **Recipient** **Mode** **Components** **Frequency** **Duration**	**Comparison** **Target** **Mode** **Components** **Frequency** **Duration**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics** **Dementia Types** **Dementia Severity** **Diagnostic Criteria** **Age of Diagnosis**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Sarkamo, 2014 [73] (24009169) Finland Medium Explanatory # 2 Sarkamo, 2016[81] (26519435)	Group Music: (1) Singing coaching group: In a group of 10, PLWD participated in primarily singing familiar songs coupled occasionally with vocal exercises and rhythmic movements led by a trained music teacher once a week for 10 weeks (2) Listening coaching group: In a group of 10, led by a therapist, PLWD primarily listened to songs from CD and discussed about the emotions, thoughts, and memories, once a week for 10 weeks	Usual care: PLWD continued with their normal everyday activities and hobbies without & were not given any additional activities throughout the follow-up.	Day activity centers & inpatient centers RCT 89 Dyads (59 family members & 30 nurses)	All types of dementia (diagnosis made by a geriatrician or a primary care Physician) Mild to moderate (CDR)	N=84 Age: 89.6 years 71.42% Female 54.5% had no formal education	NR	59 IC (family members) randomized; No details provided on how many completed or their demographic details	NR	30 nurses randomized No details provided on how many completed and their demographic details	NR	10 weeks 9 months	PLWD Mood & QoL: CBS & QOL-AD Psychological well-being of CGs: GHQ and ZBI	NA
Sung 2012[75] (21823174) Taiwan Medium Explanatory	Group music: PLWD received 30-min music intervention using percussion instruments with familiar music in a group setting, delivered by trained research assistants in midafternoon twice weekly for 6weeks,	PLWD in the control group received usual care and did not attend the group music interventions.	Residential care facility RCT 60 PLWD	Any type of dementia with mild to severe severity (the Short Portable Mental Status Questionnaire)	N=55 Average age 81.37 years for the control group and 97.5 years for the control group 65.8% Female 76.2% had no formal education	NR	NA	NA	NA	NA	6 weeks	Anxiety: RAID Agitation: CMAI	NA
Lin 2011[76] (20672256) Taiwan Medium Explanatory 2 [77] (23639952)	PLWD received a total of twelve 30-min group music intervention sessions, conducted twice a week for six consecutive weeks by the researcher who underwent training	PLWD in control group continued to engage in their normal Daily activities.	Nursing facilities RCT multisite 104	All dementia types (DSM-IV-TR) with mild-severe severity (C-MMSE-<24)	N=100 82 years 53% Female 100% Chinese Education Mean NR	NR	NA	NA	NA	NA	6 weeks 10 weeks	Agitation: Chinese Version of the Cohen-Mansfield Agitation Inventory (C-CMAI). Depression: C-CSDD	NA

* High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: char=characteristics; FC=formal caregiver; IC=informal caregiver; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RoB=Risk of Bias; RS=Reporting Status; C-CMAI=The Chinese Version of the Cohen-Mansfield Agitation Inventory; C-CSDD=The Chinese version of Cornell Scale for Depression; GDS=Geriatric Depression Scale; RAID=The Rating Anxiety in Dementia; CBS=the Cornell-Brown Scale for Quality of Life; QOL-AD=the Quality of Life in Alzheimer's Disease; QOL=Quality of Life; GHQ=The General Health Questionnaire; ZBI=Zarit Burden Interview; RoB=Risk of Bias; NPI-NH=the Neuropsychiatric Inventory–Nursing Home Version; CDR=Clinical Dementia Rating; CG=Caregiver; RCT=Randomized controlled trial; MMSE=Mini-Mental State Exam

Appendix Table D.8. PLWD outcomes summary low and medium risk of bias studies: music Intervention

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Cheung, 2018[68] (27819483) Music with movement vs. music listening and social activity Medium Explanatory	Adjusted Mean Difference (95% CI) Anxiety (RAID- Chinese version) 6 weeks Depressive symptoms (GDS) 6 weeks	No useable outcome reported No useable outcome reported			
Cheung, 2018[80](30235949) Music with movement vs. music listening and social activity Medium Explanatory	Adjusted Mean Difference (95% CI) Agitation (CMAI-NH) 6 weeks	Group x time interaction do not favor intervention F(df)=1.22 (4, 324)			0.303
Sarkamo, 2014[73] (24009169) Music vs. usual care Medium Explanatory	Quality of life ((QOL-AD) – administered in an interview format 3 months Adjusted Mean Difference (95% CI) Mood (CBS) – administered in an interview format	Group x time interaction favors intervention F(df)=12.9 (1, 81) Group x time interaction favors intervention F(df)=4.6 (1, 62)			p=.001 p=.036
Sung, 2012[75] (21823174) Group music vs. usual care Medium Explanatory	Adjusted Mean Difference (95% CI) Agitation (CMAI) 6 weeks Adjusted Mean Difference (95% CI) Anxiety (RAID) 6 weeks	Group x time interaction do not favor intervention F(df)=0.33 (1, 51) The outcome favors intervention: Mean difference (95% CI): 3.77 (1.25 to 6.3)			0.95 p=0.004
Lin, 2011[76] (20672256) Group music vs. usual care Medium Explanatory #2 Chu, 2014[77] (23639952)	Adjusted Mean Difference (95% CI) Agitated behavior (C-CMAI). 6 weeks Adjusted Mean Difference (95% CI) Depression (C-CSDD) 6 weeks	The outcome favors music intervention Adjusted Mean Difference (95% CI): -0.47 (-0.74 to -0.19) --------------------------			<0.001 <.001

Abbreviations: CBS=Caregiver Burden Scale; CMAI=Cohen Mansfield Agitation Inventory; CSDD=Cornell Scale for Depression in Dementia; GDS=Geriatric Depression Scale; NR=Not Reported; PMID=PubMed Identification Number; QoL-AD=Quality of life of the person with dementia; RAID=the Rating Anxiety in Dementia Scale

Appendix Table D.9. Summary of strength of evidence for PLWD outcomes: music intervention

Outcome Comparison	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Agitation Group music vs. Usual care	6 weeks	2 RCT (n=155)	Inconsistent finding. One study reported significant reduction of agitation (C-CMAI) in the music group compared to usual care group, another reported no significant difference in the reduction of agitation scores (& CMAI) between two groups.	Moderate	Inconsistent	Direct	Imprecise	Insufficient
Agitation Music with movement vs. music listening & social activity	6 weeks	1 RCT (n=165)	No sig difference between groups in terms of reducing agitation measured using CMAI-NH.	Moderate	Unknown	Direct	Imprecise	Insufficient
Depression Group music vs usual care	6 weeks	1 RCT (100) Companion study (Lin,2011)	Significant difference between groups in the change in depression (C-CSDD) level from baseline to posttest	Moderate	Unknown	Direct	Imprecise	Insufficient
Anxiety Music with movement vs. music listening & social activity	6 weeks	1 RCT (n=165)	Results showed that the Music with movement did not differ from ML and SA in changing the symptoms of anxiety measured using RAID.	Moderate	Unknown	Direct	Imprecise	Insufficient
Group music vs. usual care Mood	3 months	1 RCT (n=84)	A significant effect of music on mood (CBS) was observed in the music group. Music was effective in temporarily improving mood.	Moderate	unknown	Direct	Imprecise	Insufficient

Outcome Comparison	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Group music vs. usual care Quality of Life	3 months	1 RCT (n=84)	Result was inconsistent. There was a long-term specific effect in the self-report total scores. However, statistical significance could not be established with caregiver-report QOL-AD scores. Music listening than singing, showed long term effect.	Moderate	Inconsistent	Direct	Imprecise	Insufficient

Abbreviations: CBS=Caregiver Burden Scale; CMAI=Cohen Mansfield Agitation Inventory; CSDD=Cornell Scale for Depression in Dementia; GDS=Geriatric Depression Scale; NR=Not Reported; PMID=PubMed Identification Number; QoL-AD=Quality of life of the person with dementia; RAID=the Rating Anxiety in Dementia Scale

Evidence Map: Music Intervention

Appendix Table D.10. Characteristics of evidence map studies: music intervention

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Weise 2020[82] Germany Pilot	Individualized music program: Participants listened to personally-relevant music playlists for 30 minutes every other day for four weeks	Wait-list control	NH Residents RCT 20 PLWD	Clinical diagnosis of dementia (mild to severe) and no severe hearing problems	N=20 Mean age: 85 years % Female: 80 % majority race: no Education: no	None	NA	None	NA	NA	4 weeks	CMAI	NA
Ihara 2019[83] (30460747) US Quasi-experimental	MUSIC & MEMORY program: an individualized music listening system where individuals are given an iPod programmed with their personalized playlist	Participated in daily planned activities, such as exercises and games.	Residents of community-based adult day health centers Quasi-experimental 51 PLWD	Diagnosis of dementia and MMSE score of ≤24	N=51 Mean age: 82 years % Female: 67 % majority race: no Education: no	None	NA	None	NA	NA	During the intervention 6 weeks	CMAI CSDD video recording of Behavioral observations	NA

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Park, 2019[84] (31533443) US Pilot	Chair yoga: Practiced Hatha yoga (breathing, physical posture & guided relaxation), in a chair or standing and using a chair as support twice-weekly 45-minute sessions for 12 weeks	Music: Attended music sessions twice-weekly 45-minute sessions for 12 weeks facilitated by music therapy. Chair-based exercise: Attended 45-min gentle exercise session twice weekly for 12 weeks	Community setting RCT (Cluster) 31 PLWD	All types of dementia Any stage of severity	N=31 Age: 84.3 Sex: Yes % majority race: Yes Education: No	PLWD Household Characteristics: Yes PLWD Detailed Race Information: Yes	NA	NA	NA	NA	12 weeks	Psychological symptoms: HADS Behavioral problems: CMAI-SF QoL; sleep problems; Epworth Sleepiness Scale	NA
Ugur, 2019[67] (30497077) Turkey High RoB	Music Therapy: PLWD listened to instrumental classical Turkish music, 3 sessions per week in the mornings in their own rooms for 12 weeks	**Control: MT was not provided for the participants in the control**	Nursing homes RCT 70 PLWD	Non-specified Mild -severe	**N=60** **Age: 82.91 years** **Sex: Yes** **% majority race: No** **Education: Yes**	**NR**	**N=60** **Age: Yes** **Sex: No** **% majority race: No** **Education: Yes**	**Health status: Yes**	**NA**	**NA**	**12 weeks**	CBS & ADLS	**Caregiver burden: CBS**
Ho, 2018[69] (29468887) Hong Kong High RoB	Music Intervention: 16 half-hour sessions of music intervention with multi-sensory components over eight weeks	**Control: Received standard care**	Elderly residential home RCT 73	Moderate dementia (non-specified)	**N=73** **Age: 85.3 years** **Sex: Yes** **% majority race: Yes** **Education: Yes**	**NR**	**NA**	**NA**	**NA**	**NA**	**8 weeks**	Behavioral and psychological symptoms: The NPI (Chinese version) Subjective mood: VAMS	**NA**

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Giovagnoli 2017[85] (29550981) Italy Small sample	Active music therapy (AMT) and neuro-education (NE): involving a regulatory action of sound stimulating non-verbal communication. AMT lasted 2 45 minutes group sessions per week for 12 weeks. NE also 12 weeks	cognitive training lasted 2 45 minutes group sessions per week for 12 weeks	Recruited from a center RCT 50 PLWD	Mild to moderate dementia or AD with a MMSE score >15	N=50 Age: 74 years Sex: Yes % majority race: no Education: Yes	NR	NA	NA	NA	NA	12 weeks 24 weeks	Word Fluency on phonemic cue Attentive Matrices Trail Making Test A/B Weigl Sorting Test Short Story test	
Pongan, 2017[71] (28922159) France High RoB	Choral singing: participated in 12 weekly two-hour singing sessions	Painting: participated in 12 weekly two-hour painting sessions	Community setting RCT 65 PLWD	Probable AD with mild severity	N=59 Age: Yes Sex: Yes % majority race: No Education: Yes	NR	NA	NA	NA	NA	12 weeks	Chronic pain: NRS, SVS & BPI Anxiety: STAI Depression: GDS Quality of life: EQ-5D	NA
Wang, 2017[72] (26443002) Taiwan High RoB	Music: received Kagayashiki music care (KMC) twice per week for 24 weeks.	Usual care: provided with activities as usual	Long-term care facility Quasi 172 PLWD	Any type of dementia Mild - severe	N=147 Age: Yes Sex: Yes % majority race: No Education: Yes	NR	NA	NA	NA	NA	24 weeks	Behavior problem: CAPE-BRS Depression: CSD	NA
Narme, 2014[86] (23969994) France (<25 in each arm)	Music Intervention: Listened to Classical instrumental; familiar songs from the 1950–80s, 1 hour twice a week for 4 weeks	Cooking: Participants engaged in cooking activities	Nursing home RCT 48 PLWD	Moderate or severe Alzheimer's type or mixed dementia	N=37 Age: Yes Sex: Yes % majority race: No Education: Yes	NR	NA	NA	NA	NA	4 weeks	Emotional state: Interview Mood: STAI-A, CMAI & NPI FC distress: Distress scale of NPI	NA

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Ridder, 2013[87] (23621805) Norway Pilot	Individual music therapy: Individual music therapy was given biweekly over a period of six weeks, altogether 12 sessions	Control: Received Standard Care (for some includes group sing-along sessions as usual)	Nursing home RCT(Crossover) 42 PLWD	Moderate to severe dementia	N=42 Age: Yes Sex: Yes % majority race: No Education: No	NR	NA	NA	NA	NA	6 weeks	CMAI-NH; the ADRQL; & psychotropic medication	NA
Sakamoto, 2013[88] (23298693) Japan Small sample	Music therapy - Passive OR interactive: Each intervention was performed for 30 min once a week for 10 weeks (10 sessions in total). Passive: participants passively listened to the selected music via a CD player. Interactive: participants not only listened to the selected music via a CD player but also participated in interactive activities (e.g., clapping, singing, & dancing) guided by a music facilitator	Control- No music: participant spent time with one caregiver in their own room as usual, without any music intervention	Nursing home RCT 39 PLWD	Severe Alzheimer's Type dementia	N=39 Age: Yes Sex: Yes % majority race: Yes Education: No	NR	NA	NA	NA	NA	10 weeks	BPSD changes: BEHAVE-AD	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Vink, 2013[74] (23280604) Netherlands High RoB	Music therapy: Each music therapy intervention lasted for 40 min and was provided twice weekly, by a formally trained music therapist with at least 5 years working experience.	General recreational day activities: 40 minutes of general daily recreational activities	Nursing homes RCT 94 PLWD	Any type of dementia with mild to very severe severity	N=77 Age: Yes Sex: Yes % majority race: No Education: No	NR	NA	NA	NA	NA	4 months	CMAI	NA
Ceccato, 2012[89] Italy Small sample	The Sound Training for Attention & Memory in Dementia (STAM-Dem): Music employed as stimulus. Followed the STAM-Dem for 2 weekly sessions of 45 minutes for 12 weeks (in addition to standard care).	Standard care: Continued with the normal ‘‘standard care’’ provided	RCT 51 PLWD	NR	N=50 Age: Yes Sex: Yes % majority race: No Education: No	NR	NA	NA	NA	NA	12 weeks	Cognitive function: MPI, MPD Mood: GDS Aggressive behavior: CMAI Functional status: ADL	NA
McHugh, 2012[90] USA Pilot study	Music therapy - vocal re-creative music therapy (VMT): residents participated in 25 mins of music session just before their mid-day meal, 4 times a week for 3 weeks.	Control wait-list group: Unclear	Care facility RCT 15 PLWD	Moderate to severe dementia (primarily AD)	N=15 Age: Yes Sex: Yes % majority race: No Education: No	NR	NA	NA	NA	NA	3weeks	Nutritional intake: Care-tracker by Ingenix	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Chang et. al, 2010[91] (20492038) Small sample (<25 in each arm)	Music(background) was administered over the institution's internal broadcast network during the second week of the study over the lunchtime (11:00–12:00).	No music (time series)	Institution housing ITS 47 PLWD	AD, vascular and other dementia Mild	N=41 Age: 81.68 years Sex: Yes % majority race: No Education: Yes	NR	NA	NA	NA	NA	8 weeks	Dementia-related problem behavior: CMAI (Chinese version)	NA
Cooke, 2010[92] (20603300) Australia Small sample #2 Cooke, 2010[93] (20635236)	Live music: Participated in a 30 mins of musician-led familiar song singing (with guitar accompaniment) and 10 mins of pre-recorded instrumental music for active listening, three times a week for eight weeks,	Reading: Engaged in a range of reading/ social activities including reading local news stories, short stories, telling jokes & undertaking quiz activities.	Aged care facility RCT(crossover) 47 PLWD	Early to mid-stage dementia or probable dementia	N=47 Age: Yes Sex: Yes % majority race: No Education: Yes	NR	NA	NA	NA	NA	8 Weeks	DQOL; GDS; #2 CMAI-SF; RAID;	NA
Han, 2010[94] (21252549) Singapore (<25 in each arm)	Music therapy and activity program: Attended a weekly group MAP conducted by a qualified music therapist and occupational therapist for once a week for 8 weeks.	Waitlist	Outpatient dementia clinic Non-RCT 45 PLWD	Alzheimer's disease or vascular dementia with moderate severity	N=43 Age: Yes Sex: Yes % majority race: No Education: No	NR	NA	NA	NA	NA	8 weeks	Mood & disruptive behavioral: RMPCP & AES	**NA**

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Raglio 2010[78] (20735342) Italy Pilot	Music therapy: received three cycles of 12 sessions each, three times a week. Each session involved a group of three patients and lasted 30 minutes	Standard care (i.e. educational and entertainment activities such as reading a newspaper, performing physical activities, etc.).	Nursing home RCT 60 PLWD	AD diagnosis based on DSM-IV and MMSE between 18 and 30	N=60 Age: Yes Sex: Yes % majority race: No Education: No	NR	NA	NA	NA	NA	4 weeks 8 weeks	MMSE Barthel index NPI	NA
Sung 2010[95] (20492050) Taiwan Quasi-experimental	30-minute music listening intervention based on personal preferences delivered by trained nursing staff, twice a week for six weeks.	Standard care without music	Long term care facility RCT 60 PLWD	Clinical diagnosis of dementia and moderate to severe cognitive decline with GDS score between 4 and 6	N=52 Age: Yes Sex: Yes % majority race: Yes Education: Yes	NR	NA	NA	NA	NA	6 weeks	RAID	NA
Guetin, 2009[96] (19628939) France (<25 in each arm)	Music therapy: Participated in weekly sessions of individual, receptive music therapy	Reading: Participated under the same conditions in reading sessions.	Nursing homes RCT 30 PLWD	AD with no specified severity	N=30 Age: Yes Sex: Yes % majority race: No Education: Yes	Household Characteristics: Yes Age of Diagnosis: Yes Rest: No	NA	NA	NA	NA	16 weeks	Anxiety: the Hamilton Scale Depression: GDS	NA
Choi, 2008[97] South Korea Pilot	Group music: received 50 minutes of music intervention (singing songs, analysis of libretto, making musical instruments, song writing & playing instruments) 3 times per week for 5 consecutive weeks.	Usual care: received usual care, and did not participate in any structured therapeutic programs during the study period.	Special dementia care unit Non-RCT 20 PLWD	AD, vascular and other type	N=20 Age=74.9 years Sex: No % majority race: No Education: No	NR	NA	NA	NA	NA	5 weeks	Depression: GDS Quality of life: GQoL Behavioral disturbances: NPI-Q	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Raglio, 2008 [78] (18525288) Italy High RoB	Music Therapy: received 3 cycles of 10 MT sessions (30 min/session) over 16 weeks	Control: received educational support or entertainment activities.	Nursing home RCT 59 PLWD	Mild Alzheimer type or vascular or mixed dementia	N=59 Age: Yes Sex: Yes % majority race: No Education: Yes	NR	NA	NA	NA	NA	16 weeks	BPSD	NA
Ledger, 2007[79] (17558584) Australia High RoB	Group music therapy: Received weekly music therapy for	Standard care: Received standard nursing home care	Nursing home Non-RCT 60 PLWD	Mild or moderate or moderately severe Alzheimer's type	N=45 Age: 71-100 years Sex: Yes % majority race: No Education: No	NR	NA	NA	NA	NA	42 weeks	Agitation; CMAI	NA
Holmes, 2006[98] (16805928) UK Pilot	Music Therapy: Participants listened to either live or prerecorded music for 30 mins	Silence: 30 mins of silence	Residential-care or nursing-home facility RCT 32 PLWD	Moderate or severe dementia with apathy	N=32 Age: Yes Sex: No % majority race: No Education=No	NR	NA	NA	NA	NA	Unclear	Engagement: DCM	NA
Sung, 2006[99] (16765849) Taiwan Small sample	Group music with movement intervention: received 30-min group music with movement intervention in the afternoon twice a week over a 4-week period by a nursing researcher and two research assistants trained in music intervention	Control: Received usual care without intervention	Residential care facility RCT 36 PLWD	Moderate to severe dementia	N=36 Age: Yes Sex: Yes % majority race: No Education: Yes	NR	NA	NA	NA	NA	4 weeks	CMAI; & RAID	NA
Svansdottir, 2006[100] (16618375) Iceland Small sample	Music therapy: received 18 sessions of music therapy, each lasting 30 minutes, three times a week for 6 weeks	Usual care: had no change of care.	Nursing homes and psychogeriatric wards. RCT 46 PLWD	Moderate or severe AD	N=47 Age: Yes Sex: No % majority race: No Education: No	NR	NA	NA	NA	NA	6 weeks	Behavioral & psychological symptoms: BEHAVE-AD	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Gerdner, 2000[101] (10798453) Australia (<25 in each arm)	G1-Individualized music: Received individualized music for 6 weeks followed by a 2-week=“washout” period and 6 weeks of classical”relaxation” music.	G2-Classical "relaxation" music: Received classical relaxation music for 6 weeks followed by a 2-week“washout” period and 6 weeks of individualized music	Long term care facility RCT (crossover) 45 PLWD	Mild to severe dementia	N=39 Age: Yes Sex: Yes % majority race: Yes Education: No	PLWD Detailed Race Information: Yes	NA	NA	NA	NA	6 weeks	Agitation: MCMAI	NA
Groene, 1993[102] USA (<25 in each arm)	Mostly Music therapy: Each participant received one session per day for 7 days (five sessions of music followed by two sessions of reading)	Mostly reading session: Each participant received one session per day for 7 days (five sessions of reading followed by two sessions of music)	Health care facility RCT 30 PLWD	Late moderate to severe stages of Alzheimer’s disease	N=30 Age: Yes Sex: Yes % majority race: No Education: No	NR	NA	NA	NA	NA	7 days	Wandering Behaviour: researcher and nursing staff recorded the wandering behavior of each participant	NA
Lord, 1993[103] (8483655) USA (<25 in each arm)	(1) Music: given six 30-min. music sessions during which music of the "Big Bands" of the 1920s and 1930s was played each week (2) Puzzle exercise: were given puzzle exercises during their activity sessions	Control: received no special treatment, but instead was involved in the usual recreational activities of drawing, painting, and watching television.	Nursing care facility RCT 60 PLWD	Alzheimer disease	N=60 Age: Yes Sex: Yes % majority race: No Education: No	NR	NA	NA	NA	NA	6 months	Social interaction, mood & Mental state: Researcher generated questionnaire	NA

Abbreviations: ADLS=Activities of Daily Living Scale; ADRQL=The Alzheimer's Disease-Related Quality of Life; AES=the Apparent Emotion Scale; BEHAVE-AD=The Behavioral Pathology in Alzheimer’s Disease; BPI=The Brief Pain Inventory; BPSD=Behavioral and Psychological Syndrome of Dementia; CAPE-BRS- The Elderly Behavior Rating Scale; CBS=Caregiver Burden Scale; CDR=Clinical Dementia Rating; CMAI=Cohen Mansfield Agitation Inventory; CSDD=Cornell Scale for Depression in Dementia; DCM=Dementia care mapping; DQOL=Dementia Quality of Life; EM=Evidence Map; DSM-1V=Diagnostic and Statistical Manual of Mental Disorders, 4th Edition; EQ-5D=The EuroQol-5 dimensions; GQoL=Geriatric Quality of Life; FC=Formal caregiver; GDS=Geriatric Depression Scale; GDS=Global Deterioration Scale; HADS=the Hospital Anxiety and Depression Scale; IC=Informal caregiver; ICEA-D=the Inventory to Assess Communication, Emotional Expression and Activity in Dementia; MMSE=Mini-mental state examination; N=number; NA=Not Applicable; NIA=National Institute on Aging; NPI=Neuropsychiatric Inventory; NR=Not Reported; PPI & MPD= Immediate and Deferred Prose Memory test; PLWD=Persons with Dementia; RoB=Risk of Bias; RA=Research Assistant; RAID=the Rating Anxiety in Dementia Scale; RCT=Randomized controlled trial; RMBCP=the Revised Memory and Behavioral Problems Checklist; STAI-I=The State-Trait Anxiety Inventory for Adults; VAMS=The Visual Analog Mood Scale; ZBI=Zarit Burden Interview

Reminiscence Therapy

Appendix Table D.11. Risk of bias assessment: reminiscence therapy

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Li 2019[104] (31645180)	12 weeks 24 weeks	Low 5.6%	Low	Low	Medium	Low	Medium	Government	Medium
Lok 2019[105] (30246408)	8 weeks	Medium 15.5%	Medium	High	High	Medium	X	NR	High
Lin 2018[106](28881430)	10 week 22 weeks	Low 10 weeks: 2.6% 22 weeks: 9.3%	High	High	Low	Low	X	Government	High
Amieva 2016[107] (26572551)	3 months 24 months	Medium 3 months: 10.8% High 24 months: 30.3%	Low	Low	Low	Medium	Medium	Government	Medium (3 months) High (24 months)
Duru Asiret 2016[108] (26251112)	12 weeks	Low 6%	High	X	X	X	X	NR	High
Van Bogaert 2016[109] (27511740)	9 weeks	Medium 16.7%	Medium	Low	High	Low	X	Foundation, Government	High
Wu 2016[110] (25965388)	6 weeks	Low 2.8%	Low	High	Low	Low	X	Government	High
O'Shea 2014[111] (24633858)	2 years	Medium 17%	Low	Low	High	Low	X	Government	High
Seranni Azcurra 2012[112] (23429813)	3 months 6 months	Low 3.7%	Medium	Low	Low	High	X	NR	High
Woods 2012[113] (23211271)	3 months 10 months	Medium 3 months: 19.1% High 10 months: 28.3%	Low	Low	Low	Medium	Medium	Government	Medium (3 months) High (10 months)
Hsieh 2010[114] (NA)	3 months	High 33.3~~3~~%	X	X	X	X	X	Government	High
Wang 2007[115] (17503545)	8 weeks	Medium NR	Medium	Low	Medium	Low	Medium	Government	Medium
Lai 2004[116] (15190995)	6 weeks 12 weeks	Medium 15%	Medium	Low	Low	High	X	NR	High
Camberg 1999[117] (10203120)	4 weeks	Low 0%	Medium	High	Low	Low	X	NR	High

X indicates that domain was not assessed due to high risk of bias.
Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

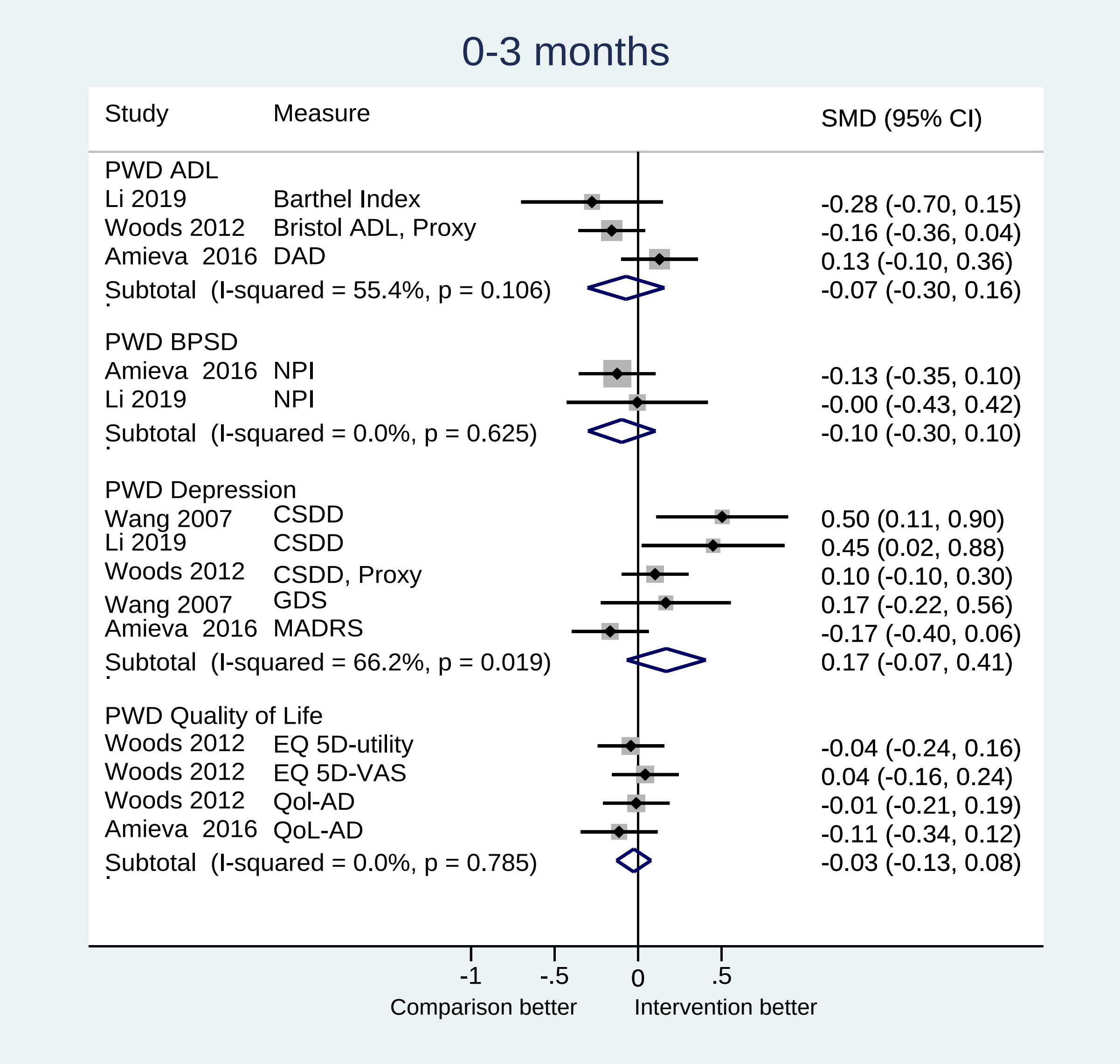
Appendix Table D.12. Characteristics of included studies: reminiscence therapy

Study (PMID) **Country** **RoB*** **Type**	**Intervention** **Intervention Focus** **Theoretical Model** **Delivery Person** **Intervention Target Recipient** **Mode** **Components** **Frequency** **Duration**	**Comparison** **Target** **Mode** **Components** **Frequency** **Duration**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics** **Dementia Types** **Dementia Severity** **Diagnostic Criteria** **Age of Diagnosis**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Li 2019[104] (31645180) China Medium Explanatory	Group reminiscence therapy in an antique setting; 30 to 45-minute sessions, 2 sessions/week for 12 weeks	Usual care	Geriatric hospital RCT, single site 90 PLWD	Diagnosis of AD based on NINCDS-ADRDA criteria; Mild-to-moderate stage of dementia based on CDR score of 1 or 2	N=90 83 years 45% Female Race NR 90.5% Primary education and above	NR	NA	NA	NA	NA	12 weeks 24 weeks	ADAS-Cog NPI CSDD Barthel index	NPI-Caregiver Distress
Amieva 2016[107] (26572551) France Medium Explanatory	Group reminiscence therapy; 90-minute weekly sessions for 3 months and monthly maintenance sessions for 21 months	Usual care	Memory centers or geriatric day care units RCT; multisite 326 PLWD	Mild to moderate AD diagnosis based on NINCDS-ADRDA criteria, MMSE from 16 to 26, and GDS score of 2 to 5	N=326 79 years 60% Female Race NR 49% Secondary education and above	NR	N=326 Age: NR Sex: NR Race: NR Education: NR Relation to PLWD: NR	NR	NA	NA	3 months 24 months	ADAS-Cog NPI DAD Apathy Inventory MADRS QOL-AD RUD Lite	ZBI
Woods 2012 (23211271)[113] UK Medium Explanatory Woods 2009[118] (19642992) Woods 2016[119] (27093052)	Group reminiscence therapy for PLWD-informal caregiver dyads; 2-hour weekly sessions for 12 weeks, with monthly maintenance for 7 months	Usual care	Community-based setting RCT; multisite 488 PLWD-informal caregiver dyads	Mild to moderate dementia (any type) based on DSM-IV criteria and CDR	N=488 76 years 50% Female 95% White Education: NR	NR	N=488 70 years 67% Female 95% White Education NR 71% Spouse	NR	NA	NA	3 months 10 months	QoL-AD AMIE CSDD RAID Bristol Activities of Daily Living EQ-5-D Resource Utilization	GHQ QCPR HADS RSS EQ5-D
Wang 2007[115] (17503545) Medium Taiwan Explanatory Wang 2009[120] (18930560)	Group reminiscence therapy; 60-minute session one time/week for 8 weeks	Usual care	Elderly care facilities RCT; multisite 102 PLWD	Mild to severe dementia, CDR score of 1 to 3	N=102 79 years 51% Female Race NR 5.2 years education	SES: yes	NA	NA	NA	NA	8 weeks	MMSE GDS-SF CSDD	NR

* High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: char=characteristics; FC=formal caregiver; IC=informal caregiver; N=number; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status; ; N=number; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RS=Reporting Status; SES=socioeconomic status; MMSE=Mini-Mental State Exam; ADAS-Cog=The Alzheimer's Disease Assessment Scale-Cognitive Subscale; NPI=Neuropsychiatric Inventory; CSDD=Cornell Scale for Depression in Dementia; DAD=Disablement Assessment for Dementia; MADRS=(Montgomery-Asberg Depression Rating Scale; QoL-AD=Quality of Life - Alzheimer’s Disease scale; RUD=resource utilization; GHQ-28=General Health Questionnaire-28 item version; QoL-AD=Quality of life of the person with dementia; AMI(E)=of the autobiographical memory interview; QCPR=the quality of carer– patient relationships; HADS=the Hospital Anxiety and Depression Scale; RAID=the Rating Anxiety in Dementia Scale; RSS=Relocation Stress Syndrome; EQ-5D=the European Quality of Life-5 Dimensions; GDS-SF=Geriatric Depression Scale Short Form. ; ZBI=Zarit Burden Interview; NINCDS/ADRDA=National Institute of Neurological and Communicative Disorders and Stroke/ Alzheimer's Disease and Related Disorders Association; RCT=Randomized controlled trial; CDR=Clinical Dementia Rating; CSDD=Cornell Scale for Depression in Dementia; ZBI=Zarit Burden Interview.

Figure D.1. PLWD outcomes summary low and medium risk of bias studies: activities of daily living, BPSD, depression, and quality of life at 3 months



Appendix Table D.13. PLWD outcomes summary low and medium risk of bias studies: reminiscence therapy

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Li 2019[104] (31645180) Reminiscence Therapy vs. Usual Care Medium Explanatory	Barthel Index Mean (SD) 6 months	No difference between groups.	55.47 (18.96)	57.07 (17.89)	NR
Li 2019[104] (31645180) Reminiscence Therapy vs. Usual Care Medium Explanatory	NPI Mean (SD) 6 months	No difference between groups.	22.21 (10.63)	25.57 (12.45)	NR
Li 2019[104] (31645180) Reminiscence Therapy vs. Usual Care Medium Explanatory	CSDD Mean (SD) 6 months	Favors intervention.	0.84 (1.41)	2.48 (2.41)	NR
Amieva 2016 (26572551) Reminiscence Therapy vs. Usual Care Medium Explanatory	Apathy Inventory Mean (SD) 3 months	NA	11.8 (13.1)	10.4 (11.8)	0.69
Amieva 2016[107] (26572551) Reminiscence Therapy vs. Usual Care Medium Explanatory	AGGIR Mean (SD) 3 months	NA	7.1 (8.7)	6.63 (7.5)	0.49
Amieva 2016[107] (26572551) Reminiscence Therapy vs. Usual Care Medium Explanatory	RUD-Lite Mean (SD) 3 months	NA	2230.1 (3301.8)	2259.3 (3078.3)	0.89
Woods 2012[113] (23211271) Reminiscence Therapy vs. Usual Care Medium Explanatory	RAID (Proxy) Mean (SD) 3 months	Pooled Mean Difference (95% CI) 1.2 (–0.0364, 2.807)	8.44 (6.92)	7.87 (6.45)	NR
Woods 2012[113] (23211271) Reminiscence Therapy vs. Usual Care Medium Explanatory	QCPR Mean (SD) 3 months	Pooled Mean Difference (95% CI) 0.99 (–1.460, 2.424)	57.89 (6.52)	57.37 (6.71)	NR

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; QCPR=the quality of carer– patient relationships;; RAID=Rating for Anxiety in Dementia; RUD=resource utilization; GAGGIR: Grille d'Autonomie Gérontologique-Groupes Iso-Ressources (standardized dependency scale in France)

Appendix Table D.14. Caregiver outcomes summary low and medium risk of bias studies: reminiscence therapy

Study (PMID) Comparison Caregiver Type RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Li 2019[104] (31645180) Reminiscence Therapy vs. Usual Care Medium Explanatory	NPI-Caregiver Distress Mean (SD) 3 months, 6 months	No difference between groups.	3 months: 12.19 (5.1) 6 months: 10.02 (4.5)	3 months: 12.36 (4.51) 6 months: 11.43 (4.69)	NR
Amieva 2016[107] (26572551) Reminiscence Therapy vs. Usual Care Medium Explanatory	ZBI Mean (SD) 3 months	NA	31.65 (27.5)	30.05 (25.6)	0.70
Woods 2012[113] (23211271) Reminiscence Therapy vs. Usual Care Medium Explanatory	GHQ-28 Mean (SD) 3 months	Pooled Mean Difference (95% CI) 0.021 (–0.080, 0.122)	22.67 (11.8)	22.9 (10.37	NR

Study (PMID) Comparison Caregiver Type RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Woods 2012[113] (23211271) Reminiscence Therapy vs. Usual Care Medium Explanatory	EQ 5D-utility Mean (SD) 3 months	Pooled Mean Difference (95% CI) 0.01 (–0.031, 0.051)	0.76 (0.23)	0.75 (0.23	NR
Woods 2012[113] (23211271) Reminiscence Therapy vs. Usual Care Medium Explanatory	EQ 5D-VAS Mean (SD) 3 months	Pooled Mean Difference (95% CI) -0.96 (–5.06, 3.13)	71.59 (20.17)	70.99 (19.23)	NR
Woods 2012[113] (23211271) Reminiscence Therapy vs. Usual Care Medium Explanatory	RSS Mean (SD) 3 months	Pooled Mean Difference (95% CI) 0.98 (–7.65, 2.716)	22.81 (10.48)	21.14 (10.21)	NR
Woods 2012[113] (23211271) Reminiscence Therapy vs. Usual Care Medium Explanatory	QCPR Mean (SD) 3 months	Pooled Mean Difference (95% CI) 0.82 (–3.114, 0.128)	52.45 (9.01)	53.43 (8.74)	NR
Woods 2012[113] (23211271) Reminiscence Therapy vs. Usual Care Medium Explanatory	HADS-Anxiety Mean (SD) 3 months	Pooled Mean Difference (95% CI) 0.35 (–0.391, 1.083)	6.61 (4.33)	5.91 (4.18)	NR
Woods 2012[113] (23211271) Reminiscence Therapy vs. Usual Care Medium Explanatory	HADS-Depression Mean (SD) 3 months	Pooled Mean Difference (95% CI) 0.11 (–0.494, 0.708)	4.4 (3.19)	3.99 (3.09)	NR

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; HADS=Hasegawa dementia scale revised; QCPR=Quality of Caregiver and Patient Relationship; EQ-5D=EuroQoL 5D scale; ZBI=Zarit Burden Interview

Appendix Table D.15. Summary of strength of evidence for PLWD outcomes: reminiscence therapy

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Reminiscence Therapy vs. Usual Care Activities of Daily Living	3 months	3 RCTs (n=802)	No difference between groups.	Moderate	Consistent	Direct	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care BPSD	3 months	2 RCTs (n=416)	No difference between groups.	Moderate	Consistent	Direct	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care Depression	2 to 3 months	4 RCTs (n=1,006)	No difference between groups.	Moderate	Consistent	Indirect	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care Quality of Life	3 months	2 RCTs (n=814)	No difference between groups.	Moderate	Consistent	Direct	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care Anxiety	3 months	1 RCT (n=488)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care PLWD-Caregiver Relationship	3 months	1 RCT (n=488)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care Apathy	3 months	1 RCT (n=326)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care Dependency	3 months	1 RCT (n=326)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient

Abbreviations: RCT=Randomized controlled trial; PLWD=Persons with Dementia

Appendix Table D.16. Summary of strength of evidence for caregiver outcomes: reminiscence therapy

Comparison Caregiver Type Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Reminiscence Therapy vs. Usual Care Caregiver Burden	3 months	1 RCT (n=326)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care Caregiver Distress	3 months 6 months	1 RCT (n=90)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care Mental Health	3 months	1 RCT (n=488)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care Quality of Life	3 months	1 RCT (n=488)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care Stress	3 months	1 RCT (n=488)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care Anxiety	3 months	1 RCT (n=488)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care Depression	3 months	1 RCT (n=488)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Reminiscence Therapy vs. Usual Care PLWD-Caregiver Relationship	3 months	1 RCT (n=488)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient

Abbreviations: n=number RCT=Randomized controlled trial; PLWD=Persons with Dementia

Evidence Map: Reminiscence Therapy

Appendix Table D.17. Characteristics of evidence map studies: reminiscence therapy

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)s	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Ching-Ten, 2020[121] Taiwan Small sample	Group reminiscence therapy 1 hour per week for 8 weeks	Usual care	Nursing Home Quasi-experimental 24 PLWD	Veterans with mild dementia	N=24 Age: yes Sex: yes % majority race: no Education: yes	NR	NA	NA	NA	NA	3 months	GDS Meaning of life scale	NA
Lok 2019[105] (30246408) Turkey High RoB	Group reminiscence therapy; 60-minute sessions once/week for 8 weeks	Usual care	Nursing home RCT; single site 60 PLWD	AD diagnosis based on IWG-2 criteria, MMSE 13 to 24, CSDD > 8	N=60 Age: no Sex: yes % majority race: no Education: yes	NR	NA	NA	NA	NA	8 weeks	MMSE CSDD QOL-AD	NA
Manav 2019[122] (30612511) Turkey Pilot Study	Reminiscence therapy with internet-based videos; 60 minutes a week for 3 months	Unstructured casual conversations; 25-30 minutes once a week for 3 months	Elderly care and rehabilitation centers RCT; multisite	Mild AD (DSM-V); MMSE 18 to 24	N=32 Age: yes Sex: yes % majority race: no Education: yes	SES: yes	NA	NA	NA	NA	3 months	MMSE Apathy Rating Scale	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)s	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Martinez 2019[123] (31453826) US Pilot Study	Online cognitive tasks with positive memory recall; 40 tasks taking 5 minutes to complete	Standard reminders without positive reinforcement	Outpatient memory clinic RCT; single site 22 PLWD	Mild AD; MMSE 18 or higher	N=22 Age: yes Sex: yes % majority race: yes Education: no	NR	NA	NA	NA	NA	3 months	Rosenberg Self-Esteem Scale MMSE GDS	NA
Laird 2018[124] (30206053) UK Pilot Study	Home-based personalized reminiscence using iPad app; 19 weeks	NR	Community-based (intervention at home) Quasi experimental 60 PLWD-informal caregiver dyads	Early to moderate dementia	N=60 Age: yes Sex: yes % majority race: no Education: no	NR	N=50 Age: yes Sex: yes % majority race: no Education: no Relation to PLWD: no	Living with PLWD: yes	NA	NA	19 weeks	Mutuality Scale QCPR WHO-5	Mutuality Scale QCPR WHO-5
Lin 2018[106] (28881430) Taiwan High RoB	Reminiscence therapy; 50-minute sessions once/week for 10 weeks	Usual care	Long-term care facilities Quasi experimental; multi-site	Dementia with agitation MMSE<17 for non-high school graduates MMSE<24 for high school graduates	N=75 Age: yes Sex: yes % majority race: no Education: yes	NR	NA	NA	NA	NA	12 weeks 24 weeks	MMSE QoL-AD	NA
Duru Asiret 2016[108] (26251112) Turkey High RoB	Group reminiscence therapy; 30 to 25-minute sessions for 12 weeks	Group conversations. 20 to 25 minutes per week for 12 weeks	Quasi experimental; single site 62 PLWD	Mild to moderate AD; MMSE from 10 to 24	N=62 Age: yes Sex: yes % majority race: no Education: yes	NR	NA	NA	NA	NA	3 months	ADL Observation Form MMSE GDS	NA
Van Bogaert 2016[109] (27511740) Belgium High RoB	Individual reminiscence therapy based on SolCos model; 2 times/week for 8 weeks	Usual care	RCT; multisite	Major neurocognitive disorder (DSM-V); MMSE 10 to 24	N=72 Age: yes Sex: yes % majority race: no Education: no	NR	NA	NA	NA	NA	8 weeks	CSDD MMSE NPI	NA
Wu 2016[110] (25965388) Taiwan High RoB	Spiritual reminiscence therapy group therapy; 6 weeks	Usual care	Medical center RCT; single site 103 PLWD	Mild to moderate AD 21 <MMSE<24 for mild 13<MMSE<20 for moderate	N=103 Age: yes Sex: yes % majority race: no Education: yes	NR	NA	NA	NA	NA	6 weeks	Heath Hope Index Life Satisfaction Scale Spirituality Index of Well-being MMSE	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)s	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Gonzalez 2015[125] (25765779) Spain Sample Size	Group reminiscence therapy; 10 weekly 60-minute sessions	Wait-list control	Nursing home Quasi experimental 42 PLWD	AD (DSM-IV); MMSE less than 23; GDS 3 to 4	N=42 Age: yes Sex: yes % majority race: no Education: no	NR	NA	NA	NA	NA	10 weeks	MMSE CES-D RSES PWB	NA
Lalanee 2015[126] (25122521) France Sample Size	Autobiographical cognitive training reminiscence; 6 sessions	Cognitive training program	Health institutions RCT; multisite 33 PLWD	Mild to moderate AD (MMSE>18)	N=33 Age: yes Sex: no % majority race: no Education: yes	NR	NA	NA	NA	NA	6 weeks 8 weeks	Semi autographical Memory Episodic memory GDS	NA
O'Shea 2014[111] (24633858) High RoB	Staff training to incorporate reminiscence into general care	Usual care activities	Nursing home Cluster RCT 18 units	PLWD with AD, and no significant sensory impairment or acute physical illness	N=304 Age: Y Sex: Y Race: Y Education: N	Prior disability	NA	NA	NR	NR	2 years	QOL-AD CMAI-AD CSDD	MZBI nurse MZBI heath care assistant
Nakamae 2014[127] (NA) Japan Pilot Study	Six activity sessions (making rice balls) with reminiscence therapy; one session/week	Eating rice balls	Long-term care facilities RCT; multisite 36 PLWD	AD and vascular dementia; MMSE 23 or lower	N=36 Age: yes Sex: no % majority race: no Education: yes	NR	NA	NA	NA	NA	6 weeks	CSDD MOSES MMSE Vitality Index	NA
Subramaniam 2014[128] (24063317) Wales Pilot Study	Individual life review sessions and co-creating a life story book; 12 sessions	Person life story book created by relatives	Care homes RCT; multisite 23 PLWD	Mild to moderate dementia diagnosis (DSM criteria)	N=24 Age: yes Sex: yes % majority race: no Education: no	NR	N=24 Age: yes Sex: yes % majority race: no Education: no Relation to PLWD: yes	NR	N=68 Age: yes Sex: yes % majority race: no Education: yes	Length of services: yes	12 weeks 18 weeks	QOL-AD AMI-E GDS (Residential) QCPR	FC: ADQ
Van Bogaret 2013[129] (23583001) Belgium Pilot Study	Individual thematically-based reminiscence therapy; 4 weeks with two 45 min sessions/week	No intervention	Psychiatric day care, inpatient, and long-term care facilities RCT; 82 PLWD	AD based on NINCDS-ADRDA	N=82 Age: yes Sex: yes % majority race: no Education: no	NR	NA	NA	NA	NA	4 weeks	MMSE FAB NPI GDS-30 CSDD	NA
Seranni Azcurra 2012[112] (23429813) Argentina High RoB	Life-story reminiscence; biweekly sessions for 1 hour over 12 weeks	Unstructured social contact; biweekly sessions for 1 hour over 12 weeks	Nursing home RCT; multisite	AD (DSM-IV); Folstein Minimental Exam above 10	N=90 Age: yes Sex: yes % majority race: no Education: yes	NR	NA	NA	N=NR Age: no Sex: no % majority race: no Education: no Relation to PLWD: no	NR	12 weeks 6 months	SRQol SES WIB ADL	ZBI

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)s	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Hsieh 2010[114](NA) Taiwan High RoB	Group reminiscence therapy; 12 sessions 40 to 50 minutes per week	No intervention	Nursing homes RCT; multisite 61 PLWD	Mild to moderate dementia (DSM-IV)	N=61 Age: yes Sex: yes % majority race: no Education: yes	NR	NA	NA	NA	NA	12 weeks	CDR GDS Apathy Evaluation Scale NPI	NA
Baillon 2004[130] (15481068) UK Sample Size	Reminiscence therapy; 3 one-on-one sessions, 40 minutes/ session	Snoezelen; 3 one-on-one sessions, 40 minutes/ session	Crossover RCT; 20 PLWD	Dementia diagnosis with BPSD	N=20 Age: yes Sex: yes % majority race: no Education: no	NR	NA	NA	NA	NA	4 weeks	Agitation Behavior Mapping Instrument Interact Scale	NA
Lai 2004[116] (15190995) China High RoB	Life-story reminiscence; weekly 30-minute session for 6 weeks	Friendly discussions; 30-minute sessions for 6 weeks	Nursing homes RCT; multisite 101 PLWD	Dementia diagnosis (DSM-IV)	N=101 Age: yes Sex: yes % majority race: no Education: no	NR	NA	NA	NA	NA	6 weeks 12 weeks	SES WIB MMSE	NA
Politis 2004[131] (15481065) US Pilot Studies	Kit-based activity intervention to reduce apathy; 30-minute sessions for 4 weeks	One-on-one meetings with activity therapist	Long-term care facility for PLWD RCT; single site 37 PLWD	Dementia diagnosis (DSM-IV) with apathy and a GDS score of 3 to 5	N=37 Age: yes Sex: yes % majority race: no Education: yes	NR	NA	NA	NA	NA	4 weeks	NPI-Apathy NPI ADRQRL CRAI	NA
Camberg 1999[117] (10203120) US High RoB	Stimulated presence continuous play memory audio recordings	Usual care	Nursing homes RCT; multisite 54 PLWD	ARDR with agitation	N=54 Age: yes Sex: yes % majority race: yes Education: no	NR	NA	NA	NA	NA	12 weeks	Observed Agitation Scale Agitation VAS PARS WVAS FACE	NA

Abbreviations: char=characteristics; EM=Evidence Map; FC=formal caregiver; IC=informal caregiver; N=number; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RS=Reporting Status; SES=socioeconomic status; MMSE=Mini-Mental State Exam; QoL-AD=Quality of life of the person with dementia; CSDD=Cornell Scale for Depression in Dementia; GDS=Geriatric Depression Scale; QCPR=the quality of carer– patient relationships; WHO-5=The World health organization-Five Well-Being Index; ADL=Activities of Daily Living; NPI=Neuropsychiatric Inventory; DSM-IV=Diagnostic and Statistical Manual for Mental Disorders, Fourth Edition; ; BPSD=Behavioral and psychological symptoms of dementia; QCPR=Quality of Caregiver and Patient Relationship; MOSES=Multidimensional Observation Scale for Elderly Subjects; ZBI=Zarit Burden Interview

Cognitive Rehabilitation

Appendix Table D.18. Risk of bias assessment: cognitive rehabilitation

Author, year PMID	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funding	Overall Rating
Chen 2020[132] (No PMID)	1 month	Low (reported no attrition)	High	X	X	X	X	Not reported	High

Author, year PMID	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funding	Overall Rating
Clare 2019[133] 30724405	9 months	Low 10%	Low	Low	High	Low	Medium	Government	Medium
Voigt-Radloff 2017[134] 28335810	16 week	Low 13%	Low	Medium	Medium	Low	Low	Foundation (Government-funded)	Low
Voigt-Radloff 2017[134] 28335810	26 week	Low 15%	Low	Medium	Medium	Low	Low	Foundation (Government-funded)	Low
Amieva 2016[107] 26572551	3 months	Low 10%	Low	Low	Medium	Low	Medium	Government, Foundation	Low
Amieva 2016[107] 26572551	24 months	Medium 28%	Low	Low	Medium	Low	Medium	Government, Foundation	Medium
Kumar 2014[135] 24982692	5 weeks	High: attrition NR	Low	High	High	Low	Medium	Government	High
Wu 2014[136] 24444172	6 months	High: 56%	X	X	X	X	X	Government	High

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Appendix Table D.19. Characteristics of analytic set studies: cognitive rehabilitation

Author, year PMID Country RoB* Type Funder	Target Intervention Group vs not Components Frequency Duration	Target Comparison Group vs not Components Frequency Duration	Setting Design Clusters N randomized	PLWD Dementia characteristics Type(s) Severity Diagnostic Criteria Age diagnosed	PLWD Age (mean) Female % Race (% majority) Detailed Race Education (mean years)	PLWD SES Prior Disability Household Characteristics Health Insurance	Informal Caregiver N Age (mean) Female % Race (% majority) Education (mean years) Relation to PLWD	Informal Caregiver Duration Live with PLWD IC paid Health Dementia family history Employed Training	Outcome Timing	PLWD Outcomes Quality of Life Daily function BPSD Adverse events Services Other	Informal Caregiver Outcome
Clare 2019[133] 30724405 UK Medium Explanatory Government Clare 2019[137]	PLWD Individual goal-oriented cognitive rehabilitation 1 hour/week (10 sessions in 3 months) plus 4 maintenance sessions over 6 months. 9 months Directed by trained OT or RN	Usual care	Home-based intervention by therapist RCT N=475	Types: 60% AD, vascular, mixed per ICD-10 code. Early-stage mild-moderate dementia (mean MMSE 24, enrolled MSSE ≥ 18); stable dementia medication acceptable	N=475 Mean age: 79 years 48% female 96% white race Education: 13 years	Married: 70%	N=474 Mean age: 69 yrs Female: 70% 96% white race Education: 14 years Relation: 70% spouse/partner	NR	3 months and 9 months post intervention	QoL: DEMQOL Function: NR BPSD: HADS AE: SAE Services: NR Other: Self-rated goal attainment (COPM), self-efficacy (GSES)	Stress, Quality of life
Voigt-Radloff 2017[134] 28335810 Germany, Netherlands Low Explanatory Government, Foundation ~~REDALI-DEM~~ Voight-Radloff 2011[138]	PLWD Individual Errorless Learning (feed-forward instructions) at home 9 x 1-hour task-training sessions 8 weeks	PLWD Individual Trial & Error learning at home 9 x 1-hour task-training sessions 8 weeks	Home (community) RCT Cluster: NA N=161	Type: AD or mixed Severity: mild- moderate (MMSE 14-24), with available ICG Diagnosis: NR Diagnosis age: 1.9 years prior	N=161 77 years 57% female Race: NR More race: NA Education: 98% ≥ 9 years	SES: NR Disability: NR Household: NA Insurance: NR (Germany)	N=NR (161) Mean age: 63 Female: 36% Race: NR Education: NR Relation: NR	Duration: 25 months Live together: 67% Paid: NR Health: NR Family history: NR Employed: NR Training: NR	16 weeks, 26 weeks	QoL: QOL-AD Function: IDDD BPSD: NPI-12, AE: NR Services: NR Other: Task performance videos, cognitive, satisfaction	NR

Author, year **PMID** **Country** **RoB*** **Type** **Funder**	**Target Intervention Group vs not** **Components** **Frequency** **Duration**	**Target Comparison Group vs not** **Components** **Frequency** **Duration**	**Setting** **Design** **Clusters** **N randomized**	**PLWD Dementia characteristics** **Type(s)** **Severity** **Diagnostic Criteria** **Age diagnosed**	**PLWD** **Age (mean)** **Female %** **Race (% majority)** **Detailed Race** **Education (mean years)**	**PLWD** **SES** **Prior Disability** **Household Characteristics** **Health Insurance**	**Informal Caregiver** **N** **Age (mean)** **Female %** **Race (% majority)** **Education (mean years)** **Relation to PLWD**	**Informal Caregiver** **Duration** **Live with PLWD** **IC paid** **Health** **Dementia family history** **Employed** **Training**	**Outcome Timing**	**PLWD Outcomes** **Quality of Life** **Daily function** **BPSD** **Adverse events** **Services** **Other**	**Informal Caregiver Outcome**
Amieva 2016[107] 26572551 France Medium Explanatory Government, Foundation ETNA3	PLWD (+ ICG support group): 1. Group cognitive rehabilitation 2. Group reminiscence 3. Individually-tailored cognitive rehabilitation (with psychologist + weekly call to ICG) All: 1.5 hours/week x 3 months, then once every 6 weeks x 21 months (24 months total) Supervision: psychologist or related	PLWD (+ ICG support group): Individual Usual care (+ ICG support group 1x/week x 3 months, then once every 6 weeks x 21 months).	Outpatient (small groups or individual). RCT Clusters: NA N=653	Type: NR Severity: mild-moderate (mean MMSE=22) Diagnosis: NINCDS-ADRDA Age diagnosed: NR 88% anti-dementia drugs	78 years 60% female Race: NR More race: NR Education: 49% secondary school or higher	SES: NR Disability: NR Household: NR Insurance: NR (France)	N=NR Mean age: NR Female: NR Race: NR Education: NR Relation: NR	Duration: NR Live together: NR Paid: NR Health: NR Family history: NR Employed: NR Training: NR	3, -24 months	QoL: QOL-AD Function: DAD, GAGGIR BPSD: NPI AE: NR (survival rate reported) Services: RUD Lite, rate of institutionalization Other: ADAS-cog, MMSE, % without severe dementia	Apathy, ZBI

Abbreviations: ADL=Activities of Daily Living; AE=adverse events; CDR=Clinical Dementia Rating; COPM=Canadian Occupational Performance Measure; DAD=Disablement Assessment for Dementia; DEMQOL=Dementia-specific health-related quality of life; GAGGIR: Grille d'Autonomie Gérontologique-Groupes Iso-Ressources (standardized dependency scale in France); GSES=Generalized Self-Efficacy Scale; HADS=Hospital Anxiety and Depression Scale; IC=informal caregiver; IDDD=Interview for Deterioration in Daily Living Activities; MMSE=Mini Mental State Exam; N=number; NPI=Neuropsychiatric Inventory; PMID=PubMed Identification Number; OT: occupational therapist; PLWD=Persons with Dementia; RN=Registered Nurse; RoB=Risk of Bias; SES=socioeconomic status; UC=usual care; ZBI=Zarit Burden Interview; QoL-AD: Quality of Life in Alzheimer's Disease scale; E=Apathy Evaluation; NR=NR; ADAS-Cog=Alzheimer's Disease Assessment Scale – Cognition RUD=resource utilization; BPSD=Behavioral and psychological symptoms of dementia

Appendix Table D.20. PLWD outcomes summary low and medium risk of bias studies: cognitive rehabilitation

Study (PMID) **Comparison** **RoB** **Category*** **Type**	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Clare 2019[133] (30724405) Individual cognitive rehabilitation vs Usual care Medium Explanatory	DEMQOL Mean (SD)	Mean difference (95% CI) 1.08 (-0.6, 2.8)	92.36 (12.0)	92.25 (12.8)	0.22
	HADS depression Mean (SD)	Mean difference (95% CI) 0.12 (-0.4, 0.6)	4.19 (3.2)	3.83 (2.8)	0.61
	HADS anxiety Mean (SD)	Mean difference (95% CI) 0.26 (-0.3, 0.8)	5.63 (3.8)	4.88 (3.4)	0.33
	Self-rated goal attainment (COPM, 0-10; 2 point change=clinically significant) Mean (SD) 9 months	Mean difference (95% CI) 1.7 (1.4, 2.1)	6.05 (2.2)	4.22 (2.0)	<0.001
Amieva 2016[107] (26572551) Individual cognitive rehabilitation vs Usual care Medium Explanatory	QOL-AD Mean (SD)	NR	29.05 (9.2)	28.83 (9.5)	0.94
	DAD (ADLs) Mean (SD)	NR	27.04 (11.9)	25.38 (13.4)	0.39
	GAGGIR (dependency) Mean (SD)	NR	12.73 (11.6)	15.21 (11.5)	0.025
	NPI Mean (SD) 24 months	NR	34.44 (32.8)	39.31 (32.3)	0.081
Voigt-Radloff 2017[134] (28335810) Individual: Errorless Learning (feed-forward instructions) vs Trial & Error Learning Low Explanatory	IDDD (ADL performance) Mean (SD)	Difference (CI) 1.4 (-2.1, 4.8)	22.3 (10.2)	23.6 (10.1)	NR
	NPI Mean (SD)	Difference (CI) 0.6 (-1.5, 2.7)	8.0 (5.4)	8.6 (6.5)	NR
	Task performance rating video (A) Mean (SD) (1=worst, 7=best)	Difference (CI) 0.3 (-0.5, 0.8)	3.8 (1.8)	4.0 (1.7)	NR
	Task performance rating video (B) Mean (SD) (1=worst, 7=best) 26 weeks	Difference (CI) -0.2 (-0.9, 0.5)	4.1 (2.0)	3.9 (1.9)	NR

Abbreviations: PMID=PubMed Identification Number ADL=Activities of Daily Living; CI=Confidence Interval; COPM=Canadian Occupational Performance Measure; DAD=Disablement Assessment for Dementia; DEMQOL=Dementia-specific health-related quality of life; GAGGIR: Grille d'Autonomie Gérontologique-Groupes Iso-Ressources (standardized dependency scale in France); HADS=Hospital Anxiety and Depression Scale; IDDD=Interview for Deterioration in Daily Living Activities; NPI=Neuropsychiatric Inventory; NR=Not Reported; PMID=PubMed Identification Number; QoL-AD: Quality of Life in Alzheimer's Disease scale; RoB=Risk of Bias; SD=Standard Deviation; vs=versus

Appendix Table D.21. Summary of strength of evidence for PLWD outcomes: cognitive rehabilitation

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Individual cognitive rehabilitation vs Usual care Quality of Life	9 months	1 RCT[133] (n=475)	No significant difference between groups	Medium	Unknown	Direct	Imprecise	Insufficient
Individual cognitive rehabilitation vs Usual care Quality of Life	24 months	1 RCT[107] (n=311)	No significant difference between groups	Medium	Unknown	Direct	Imprecise	Insufficient
Individual cognitive rehabilitation vs usual care Daily function	24 months	1 RCT[107] (n=311)	No significant difference between groups	Medium	Unknown	Direct	Imprecise	Insufficient
Individual cognitive rehabilitation vs usual care Self-rated goal attainment	9 months	1 RCT[133] (n=475)	Statistically but not clinically significant benefit of individual cognitive rehabilitation compared with usual care on function assessed as self-rated goal attainment	Medium	Unknown	Direct	Imprecise	Insufficient
Errorless Learning (feed-forward instructions) vs Trial & Error Learning Daily function	6 months	1 RCT[134] (n=161) 6 months	No difference between groups	Low	Unknown	Direct	Imprecise	Insufficient
Individual cognitive rehabilitation vs usual care Dependency	24 months	1 RCT[107] (n=311)	Less dependency (slower functional decline) with cognitive rehabilitation over 24 months	Medium	Unknown	Direct	Imprecise	Insufficient
Individual cognitive rehabilitation vs usual care Neuropsychiatric symptoms	24 months	1 RCT[107] (n=311)	No difference between groups	Medium	Unknown	Direct	Imprecise	Insufficient
Errorless Learning (feed-forward instructions) vs Trial & Error Learning Neuropsychiatric symptoms	6 months	1 RCT[134] (n=161)	No difference between groups	Low	Unknown	Direct	Imprecise	Insufficient
Individual cognitive rehabilitation vs usual care Depression	9 months	1 RCT[133] (n=475)	No difference between groups	Medium	Unknown	Direct	Imprecise	Insufficient
Individual cognitive rehabilitation vs usual care Anxiety	9 months	1 RCT[133] (n=475)	No difference between groups	Medium	Unknown	Direct	Imprecise	Insufficient

Evidence Map: ~~Reminiscence Therapy~~ Cognitive Rehabilitation

Appendix Table D.22. Characteristics of evidence map studies: cognitive rehabilitation

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics N Age (mean) Sex (% female) Race (% majority) Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Mbakile-Mahlanza 2020[139] (31762434) Australia Small sample	Montessori-based activities for PLWD implemented by family members 30 minutes 2x/week 2 weeks	Reading a newspaper with family member 30 minutes 2x/week 2 weeks	Nine~~9~~ Nursing Homes. Cluster crossover RCT; 1-week ~~break~~ between groups (6-week study). N=20 PLWD and 20 ICG	Chart diagnosis of dementia, ≥ 3 months in NH, family willing to visit at least 2x/week & attend 3-hr. training. Dementia severity: unable to determine	N=20 Age: NR Sex: NR Other: NR	NR	N=20 Mean age: 64 yrs. Female: 85% Race: NR Education: secondary or higher=68% Relation: 50% offspring	Duration: 5 yrs. Not living with PLWD: 100% (70% IC lived with family) Employed: 48% (45% retired)	NA	NA	2 weeks x 2 (after each group)	Affect, engagement	IC: quality of relationship, mutuality, mood, mastery, Carer-QoL
Chen 2020[132] (No PMID) China High RoB	Montessori-method of sensory stimulation and feeding training (re-identify food and utensils, use utensils). Details: NR 1 month	Observation and timely correction by staff, if needed	Hospital. Retrospective (randomized retrospective data); PLWD with complete records, orally fed, informed consent. Not RCT	Clinical diagnosis of AD or VD. Mild to severe (54% moderate, 40% severe)	N=85 Mean age: 71 yrs. Female: 46% Education: 43% junior high or above	NR	NA	NA	NR	NR	1 month	EdFED, EBS, eating time, MMSE	NR
Yuen 2019[140] (no PMID) Hong Kong Small sample	DementiAbility: Montessori-based cognitive rehabilitation 6 sessions, 45 minutes each	Structured social activities	Nursing home RCT N=46 PLWD	Dementia diagnosis	N=46 Age: yes Sex: yes Race: no (Hong Kong) Education: no	NR	NR	NR	NA	NA		Agitation; Global deterioration scale	NA
Silva 2017[141] (28124633) Portugal Small sample Silva 2017[142]	Use of a sense-cam as a cognitive intervention	Memo-taking; Diary	RCT Community-based or integrated in day-care center	PLWD with a diagnosis of probable AD; <6 months since diagnosis; MMSE 15-26; other inclusion criteria applied	N=51 (17 sense-cam, 17 memo-writing, 17 diary) Age: N Sex: N Race % majority: N Education: Y	NR	NA	NA	NR	NR	6 weeks	Depression,; functional capacity; quality of life	NA

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **N** **Age (mean)** **Sex (% female)** **Race (% majority)** **Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Tanaka 2017[143] (27612310) Japan Small sample	5-dimension cognitive rehabilitation: 1. Group (1 hour) 2. Individual (20 min.) Both: 2x/week for 12 weeks	Control	One NH RCT N=60	Resident of one geriatric health facility, MMSE 5-23; dementia AD, VD, mixed, other; and completed this rehabilitation program	N=60 (reported 43: 13 group, 20 individual, 20 control) 21 regular care) Age: Y Sex: Y Race: NR Education: N	SES: NR Disability: NR Household: NR Insurance: NR (Japan)	NR	NR	NR	NR	12 weeks	Cognition, mood, QOL (Japan), GDS, communication	NR
Tsuchiya 2016[144] (27303064) Japan Small sample	Brain-Activating Rehabilitation 1 hour 3 times weekly plus standard cognitive rehabilitation	Standard cognitive rehabilitation	Hospital daycare RCT N=48	Diagnosed dementia CDR rating 0.5-3	N=201 Age: Y Sex: Y Race: N Education: N	NR	NA	NA	NA	NA	Post intervention (NR)	MOSES	NA
Seyun Kim 2015[145] (25729212) ~~South~~ Korea Small sample	Cognitive training in the performance of everyday activities	Unstructured conversation and watch health-related videos	RCT PLWD recruited from a day care center	PLWD diagnosed with possible or probable AD; MMSE ≥ 18	N=43 (22 intervention, 21 control) Age: Y Sex: Y % majority race: N Education: Y	NR	NA	NA	NR	NR	8 weeks	Task performance; satisfaction; quality of life; mental status; memory	NA
Kumar 2014[135] (24982692) India High RoB	Novel occupational therapy program + usual care 5 weeks	Usual care	Outpatient Unblinded RCT	Adults with mild (most) to moderate dementia, MMSE 11-23	n=77 (attrition NR) Age: Y Sex: Y Race: N Education: Y	SES: NR Disability: NR Household: NR Insurance: NR	NA	NA	NA	NA	5 weeks	Standard OT assessment, WHO-QOL-BREF	NR
Thivierge 2014[146] (23871120) Canada Small sample Brunelle-Hamann 2015[147]	Cognitive rehabilitation of instrumental ADL activities	Delayed training	Mix of community and nursing home adults. 6 months RCT crossover	PLWD diagnosed with AD; mean MMSE=22; Additional criteria applied	N=20 (reported 17) Age: Y Sex: Y % majority race: N Education: Y	NR	NA	NA	NR	NR	6 months	ADL/IADL, NPI, memory, QOL	caregiver burden
Wu 2014[136] (24444172) Taiwan High RoB Wu 2013[148]	Individualized Montessori-based eating activities with spaced retrieval 24 sessions over 8 weeks; number of sessions adjusted per PLWD's recall	1. Standardized Montessori-based eating activities 24 sessions over 8 weeks 2. N~~n~~o treatment ~~control~~	Four Veteran's homes ~~RCT~~ 3-group quasi-experimental N=90	Dementia diagnosis	N=205 (reported 90) Age: Y Sex: Y Race: N Education: Y	NR	NA	NA	NA	NA	1, 3, 6 months	Edinburgh Feeding Evaluation in Dementia (Chinese)	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics N Age (mean) Sex (% female) Race (% majority) Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Van der Ploeg 2013[149] (23237211) Australia Small sample	One-to-one Montessori-based activities 30 min, 2x/week 2 weeks	Non-personalized activities	Nine residential facilities. RCT crossover after 2 weeks	Adults diagnosed with dementia, agitated behavior & resident for > 3 months	N=44 Age: Y Sex: Y % majority race: N Education: N	Lost English fluency: Y	NA	NA	NR	NR	Two periods of 4 weeks	Agitated behavior; engagement; apathy, affect	NA
Kurz 2012[150] (21986341) Germany Pilot	CORDIAL 12 individual weekly sessions. Combined 4 established strategies adopted from neurorehabilitation & psychotherapy	Standard care	Home-based RCT N=201 PLWD	Mild AD MMSE >21	N=201 Age: Y Sex: Y Race: N Education: Y	NR	N=201 Age: Y Sex: Y Race: N Education: N Relation to PLWD: Y	NR	NA	NA	3, 9 months	B-ADL AFIB DEMQOL GDS NPI	ZBI BDI WMSRLM TMT ZUF-8
Lin 2011[151] (20054841) Taiwan Small sample	Use of a Montessori method to increase eating ability ½ hour, 3x/week 8 weeks	Routine activities	RCT crossover with 2-week washout. Randomized by care unit, 2 dementia care facilities	PLWD diagnosed with dementia; EdFED score of >=2 and MMSE 10-23	N=29 Age Y Sex: Y Race majority: N Education: Y (not by group)	Religion: Y (not by group)	NA	NA	NR	NR	8 week intervention with 2 week washout between	Edinburgh Feeding evaluation, Verbal assistance, Physical assistance, nutrition	NA
Clare 2010[152] (20808145) UK Small sample	Individualized cognitive rehabilitation	1. R~~r~~elaxation therapy ~~group~~ 2. N~~n~~o treatment	Community-based RCT	PLWD with diagnosis of AD, early stage, with MMSE>=18 Screened for exclusion criteria	N=69 (23 cognitive rehabilitation, 24 relaxation, 22 no treatment) Age: Y Sex: Y Race % majority: N Education: N	Prior disability: Y	NR	Living with PLWD: Y	NR	NR	8 week intervention period; 6 month follow-up	Quality of life, anxiety, depression, memory functioning, verbal fluency	Stress level, anxiety, physical health, social relationships, environment
Lam 2010[153] (19582757) Hong Kong Pilot	Individualized functional skills training for affective disturbances and functional skills	General occupational therapy program	Community and residential center based RCT	PLWD diagnosed with mild or moderate dementia; Screening criteria applied	N=74 (37 skills training, 37 control) Age: Y Sex: Y Race % majority: N Education: Y	NR	NA	NA	NR	NR	8 week, 3 months, 6 months	MMSE Motor skills Depression Apathy	NA
Lin 2010[154] (20054841) Taiwan Small sample ~~Lacks usable outcomes~~	1. Spaced retrieval activities 3x/week, 8 weeks 2. Montessori-based activities 3x/week, 8 weeks	Routine activity	Nursing homes (3) RCT Clusters: 3 n=85	Adults with chart diagnosis of dementia, lived in 1 of 3 NH, scored ≥ 2 on EdFED, MMSE 10-23	N=85 (32 spaced retrieval, 29 Montessori, 24 control) Age: Y Sex: Y Race: N Education: N	SES: NR Disability: NR Household: NA Insurance: NR (Taiwan) More race: NR	NA	NA	NR	NR	8 weeks	Eating ability & feeding assistance required (multiple)	NR

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **N** **Age (mean)** **Sex (% female)** **Race (% majority)** **Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Loewenstein 2004[155] (15249277) US Small sample	Cognitive rehabilitation program focused on memory and functional performance	Mental stimulation program, using computer games	Setting NR (assume community due to mean MMSE=24) RCT	PLWD diagnosed with probable or possible AD (DSM-IV), all on stable cholinesterase inhibitor	N=44 (25 cognitive rehabilitation, 19 mental stimulation) Age: Y Sex: Y Race: NR Language: Y Education: Y	NR	NR	NR	NA	NA	12 weeks	Performance on trained skills; memory/recall; ability to perform tasks	NA
Beck 2002[156] (12131234) US Small sample	ADL and psychosocial activity combinations (3 groups) 1. Combined psychosocial & ADL intervention 2. ADLs 3. psycho-social	2 control groups: 1. attention control 2. usual care	Nursing home (7 sites) RCT (5 groups total in each center) Randomized 179; reported 127	PLWD diagnosed with dementia MMSE <=20 Screened for exclusion criteria	N=179 (reported 129): 28 ADL, 29 psycho-social activity, 22 combined, 29 attention control, 19 no intervention. Age: Y Sex: Y Race % majority: Y Education: N	% widowed: Y	NA	NA	Education: Y	Training: Y	12-week intervention period One- and two-month follow-up post intervention	Disruptive behavior scores	NA
Quayhagen 1995[157] 7761291 USA Small sample ~~Lacks usable outcomes~~	Active cognitive stimulation training (dyadic remediation program)	1. Passive activity 2. Waitlist	Community (intervention in home by ICG) n=95 eligible	AD, living at home with caregiver	N=78 completed (25 intervention, 28 passive activity, 25 control) Age: Y Sex: Y Race: Y Education: Y	NR ~~(no PLWD characteristics reported)~~	N=78~~NR~~ Age: Y Sex: Y Race: N Education: Y	NR	NA	NA	9 months	Memory & Behavior Problems Checklist, multiple cognitive	NR
Tappen 1994[158] (8184127) USA Small sample	1. Skill training in performance of basic daily activities	1. Traditional situational approach 2. regular care	RCT Nursing home; random selection from entire NH population	PLWD diagnosed with dementia; exclusion criteria applied	N=63 (21 treatment, 21 situational, 21 regular care) Age: Y Sex: Y % majority race: N Education: N	NR	NA	NA	NR	NR	20 weeks	Self-maintenance; skills performance; goal attainment	NA

Abbreviations: AD=Alzheimer's Disease; ADL=Activities of Daily Living; EBS=Eating Behavior Scale; EdFED=Edinburgh Feeding Evaluation in Dementia; FC=formal caregiver; GDS=Geriatric Depression Scale; IC=informal caregiver; MMSE=Mini Mental State Exam; N=number; N=no; NA=Not applicable; NH=nursing home; NR=Not Reported; PMID=PubMed Identification Number; OT=occupational therapist; RoB=risk of bias; UC=usual care; VD=vascular dementia; Y=yes; **PLWD**=Persons with Dementia; RCT=Randomized controlled trial; IGC=Informal Caregiver; IADL=Instrumental Activities of Daily Living; QoL=Quality of Life; RCT=Randomized controlled trial

Cognitive Training

Appendix Table D.23. Risk of bias assessment: cognitive training

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Tseng 2019[159] (30970666)	6 months	Medium	High	X	X	X	X	NR	High
Kallio 2018[160] (29345724) Finland Medium Explanatory	3 months 9 months	Low 3 months: 0% High 9 months: 20.4%	Low	Low	Low	Medium	Medium	Foundation	Medium (3 months) High (9 months)
Amieva 2016[107] (26572551)	3 months 24 months	Medium 3 months: 9.9% High 24 months: 28.1%	Low	Low	Low	Medium	Medium	Government	Medium (3 months) High (24 months)
Cavallo 2016[161] (27600448)	3 months 6 months	Low 5%	Low	Medium	Low	Medium	Medium	NR	Medium
Giuli 2016[162] (26952713)	10 weeks	Low 5.9%	Low	High	Medium	Medium	X	Government	High
Hsu 2016[163] (27878873)	6 weeks	Low 2%	Medium	Low	Medium	Low	Medium	NR	Medium
Kao 2016[164] (27307717)	6 weeks 10 weeks 18 weeks 30 weeks	Low 6%	Medium	Low	Medium	Medium	Medium	Government	Medium

X indicates that domain was not assessed due to high risk of bias.
Abbreviations: NR=Not Reported PMID=PubMed Identification Number

Appendix Table D.24. Characteristics of included studies: cognitive training

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Kallio 2018[160] (29345724) Finland Medium Explanatory Kallio 2017(NA)[165]	Group or individual paper-and-pencil cognitive training focused on executive function; 2 times/week, 45 minutes/session for 12 weeks	Usual care	Adult day care RCT; single site 147 PLWD	AD or other dementia, very mild to moderate; CDR 0.5 to 2	N=147 83 years 72% Female Race NR 46% Education < 8 years	Household Characteristics: yes	NA	NA	NA	NA	3 months	ADAS-Cog 15-D HRQoL	NA
Amieva 2016[107] (26572551) France Medium Explanatory	Group cognitive training program focused on ADL and tasks involving memory,	Usual care	Memory centers or geriatric day care units RCT; multisite 324 PLWD	Mild to moderate AD diagnosis based on NINCDS-ADRDA criteria, MMSE from 16 to	N=324 79 years 58% Female Race NR 52% Secondary education and	NR	N=324 Age: NR Sex: NR Race: NR Education: NR	NR	NA	NA	3 months	ADAS-Cog NPI DAD Apathy Inventory MADRS	ZBI

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	attention, language, or executive function; 90-minute weekly sessions for 3 months and monthly maintenance sessions for 21 months			26, and GDS score of 2 to 5	above		Relation to PLWD: NR					QOL-AD AGGIR RUD-Lite	
Cavallo 2016[161] (27600448) Italy Medium Explanatory	Structured rehabilitative cognitive training software aimed at memory, attention, executive function, and language; three 30 minutes sessions /week for 12 weeks	Using computer to read newspaper or play games; three 30 minutes sessions /week for 12 weeks	Assisted health residence RCT; single site 80 PLWD	Early-stage AD; NINCDS-ADRDA criteria	N=80 76 years 64% Female Race NR 8 years	NR	NA	NA	NA	NA	3 months 6 months	HADS-Depression HADS-Anxiety RMBT	NA
Hsu 2016[163] (27878873) Taiwan Medium Explanatory	Individual spatial retrieval training ; 5 times/week, 40 min/session, for 6 weeks	Usual care	Nursing centers and dementia units of Veterans Homes RCT; multisite 97 PLWD	Dementia with hyperphagia behaviors(all severities, vascular and brain injury excluded) with at least 3 points on the DHBS	N=97 82 years 28% Female Race NR 41% Secondary or higher	NR	NA	NA	NA	NA	6 weeks	DHBS Food Intake	NA
Kao 2016[164] (27307717) Taiwan Medium Explanatory	Spatial retrieval training with Montessori activities during recall; 5 times/week, 40 min/session, for 6 weeks	Usual care	Dementia special care units RCT; multisite 100 PLWD	Dementia with hyperphagia behaviors(all severities, vascular and brain injury excluded) with at least 3 points on hyperphagia scale	N=100 82 years 28% Female Race NR 44% High school or higher	NR	NA	NA	N=NR Age NR Sex NR Race NR Education NR	NR	6 weeks 10 weeks 18 weeks 30 weeks	Hyperphagic behavior Pica Behavior Change in Eating Habit Short Meal Frequency	Caregiver Distress to Hyperphagic Behavior

* High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: char=characteristics; FC=formal caregiver; IC=informal caregiver; N=number; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status; HADS=Hospital Anxiety and Depression Scale; NR=Not reported; NINCDS/ADRDA=National Institute of Neurological and Communicative Disorders and Stroke/ Alzheimer's Disease and Related Disorders Association; ADAS-cog=Alzheimer’s Disease Assessment Scale, cognitive subsection; NPI=Neuropsychiatric Inventory; DAD=Disability Assessment for Dementia; MADRS=Montgomery-Asberg Depression Rating Scale; QoL-AD: Quality of Life in Alzheimer’s Disease scale; RUD=resource utilization; ZBI=Zarit Burden Interview;

Appendix Table D.25. PLWD outcomes summary low and medium risk of bias studies: cognitive training

Study (PMID) **Comparison** **RoB** **Category***	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Kallio 2018[160] (29345724) Cognitive Training vs. Usual Care Medium Explanatory	15-D HRQoL Mean Change from Baseline (95% CI) 3 months	NR	-0.04 (-0.058, -0.021)	-0.04 (-0.056, -0.018)	p=0.82
Amieva 2016[107] (26572551) Cognitive Training vs. Usual Care Medium Explanatory	NPI Mean (SD) 3 months	NR	25.34 (28.8)	23.29 (28.4)	p=0.22
Amieva 2016[107] (26572551) Cognitive Training vs. Usual Care Medium Explanatory	DAD Mean (SD) 3 months	NR	27.54 (9.2)	26.94 (9.6)	p=0.62
Amieva 2016[107] (26572551) Cognitive Training vs. Usual Care Medium Explanatory	Apathy Inventory Mean (SD) 3 months	NR	10.26 (11.7)	10.4 (11.8)	p=0.97
Amieva 2016[107] (26572551) Cognitive Training vs. Usual Care Medium Explanatory	AGGIR Mean (SD) 3 months	NR	7.0 (7.9)	6.63 (7.5)	p=0.67
Amieva 2016[107] (26572551) Cognitive Training vs. Usual Care Medium Explanatory	MADRS Mean (SD) 3 months	NR	10.65 (9.9)	8.82 (9.1)	p=0.06
Amieva 2016[107] (26572551) Cognitive Training vs. Usual Care Medium Explanatory	QOL-AD Mean (SD) 3 months	NR	31.99 (8.0)	33.28 (7.7)	p=0.22
Amieva 2016[107] (26572551) Cognitive Training vs. Usual Care Medium Explanatory	RUD-Lite Mean (SD) 3 months	NR	2559.3 (3078.3)	2199.8(3002.2)	p=0.50
Cavallo 2016[161] (27600448) Cognitive Training vs. Attention Control Medium Explanatory	HADS-Anxiety Mean (SD) 3 months, 6 months	No difference between groups at either time point	3 months: 7.65 (2.41) 6 months: NR	3 months: 7.57 (1.33) 6 months: NR	NR
Cavallo 2016[161] (27600448) Cognitive Training vs. Attention Control Medium Explanatory	HADS-Depression Mean (SD) 3 months, 6 months	No difference between groups at either time point	3 months: 6.42 (2.21) 6 months: NR	3 months: 6.35 (2.21) 6 months: NR	NR
Hsu 2016[163] (27878873) Cognitive Training vs. Usual Care Medium Explanatory	DHBS Mean Change from Baseline (SD) 6 weeks	NR	-0.88 (2.48)	1.04 (1.98)	p<0.001
Hsu 2016[163] (27878873) Cognitive Training vs. Usual Care Medium Explanatory	Average Food Intake (g) Mean Change from Baseline (SD) 6 weeks	NR	-38.63 (145.51)	18.28 (127.34)	p=0.046
Kao 2016[164] (27307717) Cognitive Training vs. Usual Care Medium Explanatory	Hyperphagic Behavior Group x Time p-value 6 weeks, 10 weeks, 18 weeks, 30 weeks	NR	NR	NR	All time points p<0.05
Kao 2016[164] (27307717) Cognitive Training vs. Usual Care Medium Explanatory	Pica Behavior Group X Time p-value 6 weeks, 10 weeks, 18 weeks, 30 weeks	NR	NR	NR	6 weeks, 10 weeks, 18 weeks: p<0.05 30 weeks: p=0.092

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Kao 2016[164] (27307717) Cognitive Training vs. Usual Care Medium Explanatory	Change in Eating Habit Group X Time p-value 6 weeks, 10 weeks, 18 weeks, 30 weeks	NR	NR	NR	6 weeks, 10 weeks, 18 weeks: p>0.05 30 weeks: p=0.037
Kao 2016[164] (27307717) Cognitive Training vs. Usual Care Medium Explanatory	Short Meal Frequency Group X Time p-value 6 weeks, 10 weeks, 18 weeks, 30 weeks	NR	NR	NR	All time points p<0.05

*Explanatory studies are listed first, followed by pragmatic studies.
Abbreviations: NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number

Appendix Table D.26. Caregiver outcomes summary low and medium risk of bias studies: cognitive training

Study (PMID) Comparison Caregiver Type RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Amieva 2016[107] (26572551) Cognitive Training vs. Usual Care Medium Explanatory	ZBI Mean (SD) 3 months	NR	30.31 (25.9)	30.05 (25.6)	0.88
Kao 2016[164] (27307717) Cognitive Training vs. Usual Care Medium Explanatory	Caregiver Distress to Hyperphagic Behavior Group X Time p-value 6 weeks, 10 weeks, 18 weeks, 30 weeks	NR	NR	NR	6 weeks: p=0.004 10 weeks, 18 weeks, 30 weeks: p>0.05

*Explanatory studies are listed first, followed by pragmatic studies.
Abbreviations: NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; ZBI=Zarit Burden Interview

Appendix Table D.27. Summary of strength of evidence for PLWD outcomes: cognitive training

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Cognitive Training vs. Usual Care Quality of Life	3 months	2 RCTs (n=471)	No benefit.	Moderate	Consistent	Direct	Imprecise	Insufficient
Cognitive Training vs. Usual Care or Attention Control Depression	3 to 6 months	2 RCTs (n=404)	No benefit.	Moderate	Consistent	Direct	Imprecise	Insufficient
Cognitive Training vs. Usual Care Hyperphagia Behavior	6 to 30 weeks	2 RCTs (n=197)	Benefit favoring intervention.	Moderate	Consistent	Direct	Imprecise	Insufficient
Cognitive Training vs. Usual Care Food Intake	6 weeks	1 RCT (n=97)	Benefit favoring intervention.	Moderate	Unknown	Direct	Imprecise	Insufficient
Cognitive Training vs. Usual Care Short meal frequency	6 to 30 weeks	1 RCT (n=100)	Benefit favoring intervention at all time-points.	Moderate	Unknown	Direct	Imprecise	Insufficient
Cognitive Training vs. Usual Care Pica behavior	6 to 30 weeks	1 RCT (n=100)	Benefit favoring intervention post-intervention, but not sustained 6-months post-intervention.	Moderate	Unknown	Direct	Imprecise	Insufficient
Cognitive Training vs. Usual Care Change in eating habits	6 to 30 weeks	1 RCT (n=100)	No benefit.	Moderate	Unknown	Direct	Imprecise	Insufficient
Cognitive Training vs. Usual Care BPSD	3 months	1 RCT (n=324)	No benefit.	Moderate	Unknown	Direct	Imprecise	Insufficient
Cognitive Training vs. Usual Care Function/ADLs	3 months	1 RCT (n=324)	No benefit.	Moderate	Unknown	Direct	Imprecise	Insufficient
Cognitive Training vs. Usual Care Apathy	3 months	1 RCT (n=324)	No benefit.	Moderate	Unknown	Direct	Imprecise	Insufficient

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Cognitive Training vs. Usual Care Dependence	3 months	1 RCT (n=324)	No benefit.	Moderate	Unknown	Direct	Imprecise	Insufficient
Cognitive Training vs. Attention Control Anxiety	3 and 6 months	1 RCT (n=80)	No benefit.	Moderate	Unknown	Direct	Imprecise	Insufficient

Abbreviations: RCT=Randomized controlled trial; ADL=Activities of daily living; BPSD=Behavioral and psychological symptoms of dementia

Appendix Table D.28. Summary of strength of evidence for caregiver outcomes: cognitive training

Comparison Caregiver Type Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Cognitive Training vs. Usual Care Caregiver Distress Informal caregivers	3 months	1 RCT (n=324)	No benefit.	Moderate	Unknown	Direct	Imprecise	Insufficient
Cognitive Training vs. Usual Care Caregiver Distress, PLWD hyperphagic behavior Formal caregivers	6 to 30 weeks	1 RCT (n=NR)	No benefit.	Moderate	Unknown	Direct	Imprecise	Insufficient

Abbreviations: n=number; PLWD=Persons with Dementia; RCT=Randomized controlled trial

Evidence Map: Cognitive Training

Appendix Table D.29. Characteristics of evidence map studies: cognitive training

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Tseng 2019[159] (30970666) Taiwan High RoB	Smart Restored Learning exercise	No intervention	Veterans home Quasi-experimental . n=68	PLWD diagnosed with dementia, MMSE <25 and living in Veterans Home	N=68 (35 treatment, 33 control) Age: Y Sex: N Race % majority: N Education: Y	NR	NA	NA	NR	NR	6 months	MMSE Neuropsychiatric Inventory Frontal Assessment Battery	NA

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Giovagnoli 2017[166] (28577267) Italy Sample Size	Cognitive training	1. Music therapy or 2. neuro-education	One care center RCT single blind	PLWD with mild-moderate dementia or probable AD. Screened for additional criteria	N=50 (17 cognitive training, 17 music, 13 neuro-education Age: Y Sex: Y Race: N Education: Y	NR	NR	NR	NR	NR	3 months	Word fluency test Neuropsychological and behavioral assessments	NA
Venturelli 2016[52] (27540967) Italy Small sample	Cognitive training based on reality orientation method; 5 days/week for 1 hour before sunset for 3 months	Walking at moderate intensity; 5 days/week for 1 hour before sunset for 3 months	AD care units RCT 40 PLWD	AD with MMSE between 10 and 15 and neurobehavioral symptoms of SDS	N=40 Age: yes Sex: yes Race: no Education: no	NR	NA	NA	NA	NA	3 months	NPI ABS	NA
Chen, 2016[167] (27846102) Taiwan Small sample	Individualized learning therapy 30 minutes twice weekly for 3 months	Usual care	Nursing home Quasi-experimental, 2 homes	Dementia diagnosis, MMSE between 10 and 23	N=44 Age: yes Sex: yes Race: no Education: no	Marital status	NA	NA	NA	NA	12 weeks	Chinese NPI MMSE	NA
De Luca 2016[168] Italy Small sample	Combined standard cognitive training and web-based rehabilitation 24 sessions x 8 weeks	Standard treatment	Nursing home RCT	Diagnosis of mild to moderate cognitive decline MMSE 25 +/- 3.4); ability to perform training	N=20 (10 experimental 10 control) Age: Y Sex: Y Race: Y Education: Y	NR	NA	NA	NR	NR	8 weeks	MMSE Attention Verbal fluency ADL, ADL Behavioral, Depression	NA
Giuli 2016[162] (26952713) Italy High RoB	Comprehensive cognitive training	No intervention	Community based RCT	Three levels of cognitive impairment: healthy elderly, moderate cognitive impairment, mild to moderate AD; Aged 65 or older	N=321 (47 healthy experimental, 53 healthy control, 48 moderate decline experimental, 49 moderate decline control, 48 AD experimental, 47 AD control) Age: Y Sex: Y Race % majority: N Education: Y	NR	NA	NA	NR	NR	10 weeks	MMSE, Orientation, Memory, Attention, Verbal fluency, Depression, ADL, IADL, confidence in own cognition	NA

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Kawashima 2015[169] US Sample Size	Americanized SAIDO (working memory training program of basic arithmetic & language)	Usual care	Two nursing homes. Prospective non-randomized, by NH n=47 (39 reported)	PLWD diagnosed with dementia (DSM-IV)	N=n=47 (23 intervention, 24 controls) Age: Y Sex: Y Race % majority: N Education: N	NR	NA	NA	NR	NR	6 months	Cognitive scores, mood mental status	NA
Bergamaschi 2013[170] (23784727) Italy Sample Size	Repeated cycles of cognitive training x 1 year	Non-specific cognitive exercises	Day center RCT	PLWD diagnosed with mild to moderate AD; MMSE 18-24	N=32 (16 each group) Age: Y Sex: N Race % majority: N Education: Y	NR	NA	NA	NR	NR	1 year	MMSE Memory and recall Verbal fluency Depression ADL	NA
Mapelli 2013[171] (24052800) Italy Sample Size	Cognitive stimulation focused on memory, language, spatial and temporal orientation, attention and logic	Occupational therapy s placebo or no intervention	Nursing home RCT PLWD with AD, vascular and mixed dementia	PLWD diagnosed with AD, vascular and mixed dementia AD MMSE 19-24; vascular MMSE14-18	N=30 (10 each group) Age: Y Sex: N Race % majority: N Education: Y	NR	NA	NA	NR	NR	8 weeks	Cognition Behavior	NA
Tarraga 2006[172] (16820420) Spain Sample Size	Cognitive stimulation using an interactive multi-media tool plus psycho-stimulation and medication	Integrated psycho-stimulation and medication, or medication only	Community-based RCT PLWD diagnosed as having suspected AD	PLWD diagnosed with suspected AD >65 years old; at least 3 years education. MMMSE 18-24; GDS 3-4.	N=43 (15 experimental, 16 treatment control, 12 medication only control) Age: Y Sex: Y Race % majority: N Education: statistic only	NR	NA	NA	NR	NR	24 weeks	ADAS-Cog Additional tests of cognition, verbal fluency, recall, level of disability	NA
McGilton 2003[173] (12959805) Canada Sample Size	Training in way-finding in a new environment	No intervention	University geriatric care center RCT	PLWD with diagnosis of AD and moderate to severe cognitive decline. Able to ambulate and understand English	N=32 (17 treatment, 15 control) Age: Y Sex: Y Race % information: N Education: N	NR	NA	NA	NR	Training: Y	4 weeks training Re-evaluation at 1 week and 3 months post-test	Find dining room Agitation Spatial orientation	NA
Davis 2001[174] (11236819) US Sample Size	Training in face-name association, spaced retrieval	Mock placebo intervention	AD research center RCT	Diagnosis of probable AD	N=37 (19 intervention, 18 control) Age: Y	NR	NR	NR	NR	NR	10 weeks; Crossover at 5 weeks	MMSE Verbal and visual memory	NR

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
	and cognitive stimulation with ICGs		Crossover study		Sex: Y Race % majority: N Education: Y							Attention/concentration Word generation Motor speed Depression Quality of life	
Zarit 1982[175] (13238424) US Sample Size	1. Group didactic training (with imagery) 2. problem solving All groups with ICG	Wait list control	Community-based RCT n=35 PLWD	Community dwelling adults screened for cognitive impairment (Introduction states adults with	N=35 (14 didactic, 11 problem solving, 10 wait list Age: Y Sex: N Race % majority: N Education: Y	NR	Relation to PLWD: Y	NR	NA	NA	3.5 weeks	Recall trials Recognition trials	Burden Depression Memory problems Behavior problems Distress over problems

Abbreviations: char=characteristics; EM=Evidence Map; FC=formal caregiver; IC=informal caregiver; N=number; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RS=Reporting Status; SES=socioeconomic status; MMSE=Mini-mental State Examination; ADAS-cog=Alzheimer's Disease Assessment Scale; AD=Alzheimer's Disease; RCT=Randomized controlled trial; ADL=Activities of Daily Living; DSM-IV=Diagnostic and Statistical Manual for Mental Disorders, Fourth Edition; IADL=Instrumental; Activities of Daily Living; NPI=Neuropsychiatric Inventory

Cognitive Stimulation Therapy

Appendix Table D.30. Risk of bias assessment: cognitive stimulation therapy

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Lok, 2020 [176]	7 weeks	High 23.08%	Low	X	X	X	X	X	High
Lin, 2018[177] (28881430)	12 weeks 24 weeks	Medium 14.91%	Medium	High	High	Low	Low	Taiwanese government	High
Orgeta, 2015[178] (26292178) Orrell, 2017[179] (28350796)	13 weeks 26 weeks	Medium 23.31%	Low	Low	Moderate	Low	High	UK government	High
Orrell, 2014[180] (24676963)	12 weeks 24 weeks	Low 15.68%	Low	Low	High	Low	Moderate	UK government	Medium
Spector, 2003[181] (12948999) Knapp, 2006[182] (16738349)	8 weeks	Low 5.47%	Low	Low	Moderate	Low	Low	UK government	Low

X indicates that domain was not assessed due to high risk of bias.
Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Appendix Table D.31. Characteristics of included studies: cognitive stimulation therapy

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Orrell, 2014[180] (24676963) United Kingdom Medium Explanatory	Maintenance of CST after an initial 7-week program of CST. Program defined as group sessions focused on reality orientation and cognitive stimulation, led by trained facilitator; one 45-minute session for 24 weeks	Usual care after an initial 7-week program of CST	Care homes and community centers RCT Multisite 236 PLWD	DSM-IV criteria for dementia, mild to moderate dementia on Clinical Dementia Rating scale	N=236 Age 83 years 63.6% female Race NR Education NR	NR	NR	NR	NR	NR	12 weeks 24 weeks	Quality of life Neuropsychiatric symptoms Function	NR
Spector, 2003[181] (12948999) Knapp, 2006 (16738349) United Kingdom Low Explanatory	Group sessions focused on reality orientation and cognitive stimulation, facilitated by researcher; two 45-minute	Usual care, typically doing nothing, but sometimes including music, games, arts and crafts,	Residential homes and day care centers RCT Multisite 201 PLWD	DSM-IV criteria for dementia, MMSE between 10 and 24	N=201 Age 85.3 years 78.6% female Race NR Education NR	NR	NR	NR	NR	NR	8 weeks	Quality of life Function Depression Anxiety	NR

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	sessions for 7 weeks	and other activities											

* High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: char=characteristics; FC=formal caregiver; IC=informal caregiver; N=number; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status; CST=Cognitive Stimulation Therapy; NR=Not Reported; DSM-Iv=Diagnostic and Statistical Manual for Mental Disorders, Fourth Edition; RCT=Randomized controlled trial

Appendix Table D.32. PLWD outcomes summary low and medium risk of bias studies: cognitive stimulation therapy

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Orrell, 2014[180] (24676963) Explanatory	Quality of life, self-rated QoL-AD, DEMQOL 12 weeks	0.32 points (95% CI -0.88 to 1.52, QoL-AD) -0.86 points (95% CI -3.45 to 1.73, DEMQOL)	Cognitive stimulation maintenance therapy after initial cognitive stimulation	Usual care after withdrawal of cognitive stimulation	P=0.54 (QoL-AD) P=0.54 (DEMQOL)
Orrell, 2014[180] (24676963) Explanatory	Quality of life, caregiver-rated QoL-AD, DEMQOL 12 weeks	1.53 points (95% CI 0.37 to 2.69, QoL-AD) 3.24 points (95% CI 0.29 to 6.19, DEMQOL)	Cognitive stimulation maintenance therapy after initial cognitive stimulation	Usual care after withdrawal of cognitive stimulation	P=0.01 (QoL-AD) P=0.03 (DEMQOL)
Orrell, 2014[180] (24676963) Explanatory	Neuropsychiatric symptoms NPI 12 weeks	1.47 points (95% CI -1.59 to 4.53)	Cognitive stimulation maintenance therapy after initial cognitive stimulation	Usual care after withdrawal of cognitive stimulation	P=0.34
Orrell, 2014[180] (24676963) Explanatory	Function ADCS-ADL 12 weeks	2.64 points (95% CI 0.08 to 5.20)	Cognitive stimulation maintenance therapy after initial cognitive stimulation	Usual care after withdrawal of cognitive stimulation	P=0.04
Orrell, 2014[180] (24676963) Explanatory	Quality of life, self-rated QoL-AD, DEMQOL 24 weeks	1.78 points (95% CI -0.01 to 3.57, QoL-AD) 0.30 points (95% CI -3.45 to 1.73, DEMQOL)	Cognitive stimulation maintenance therapy after initial cognitive stimulation	Usual care after withdrawal of cognitive stimulation	P=0.03 (QoL-AD) P=0.87 (DEMQOL)
Orrell, 2014[180] (24676963) Explanatory	Quality of life, caregiver-rated QoL-AD, DEMQOL 24 weeks	0.07 points (95% CI -1.39 to 1.53, QoL-AD) 1.13 points (95% CI -2.24 to 4.51, DEMQOL)	Cognitive stimulation maintenance therapy after initial cognitive stimulation	Usual care after withdrawal of cognitive stimulation	P=0.95 (QoL-AD) P=0.50 (DEMQOL)
Orrell, 2014[180] (24676963) Explanatory	Neuropsychiatric symptoms NPI 24 weeks	1.58 points (95% CI -2.67 to 5.84)	Cognitive stimulation maintenance therapy after initial cognitive stimulation	Usual care after withdrawal of cognitive stimulation	P=0.53
Orrell, 2014[180] (24676963) Explanatory	Function ADCS-ADL 24 weeks	0.94 points (95% CI -2.04 to 3.92)	Cognitive stimulation maintenance therapy after initial cognitive stimulation	Usual care after withdrawal of cognitive stimulation	P=0.54
Spector, 2003[181] (12948999) Knapp, 2006[182]	Quality of life QoL-AD 8 weeks	1.64 points (95% CI 0.09 to 3.18)	Cognitive stimulation	Usual care	P=0.028

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
(16738349) Explanatory					
Spector, 2003[181] (12948999) Knapp, 2006[182] (16738349) Explanatory	Function HCS 8 weeks	2.3 points (95% CI -0.45 to 4.15)	Cognitive stimulation	Usual care	P=0.09
Spector, 2003[181] (12948999) Knapp, 2006[182] (16738349) Explanatory	Neuropsychiatric symptoms CAPE-BRS 8 weeks	0.40 points (95% CI -0.9 to 1.69 points)	Cognitive stimulation	Usual care	P=0.449
Spector, 2003[181] (12948999) Knapp, 2006[182] (16738349) Explanatory	Anxiety RAID 8 weeks	-1.30 points (95% CI -3.48 to 0.87)	Cognitive stimulation	Usual care	P=0.200
Spector, 2003[181] (12948999) Knapp, 2006[182] (16738349) Explanatory	Depression CSDD 8 weeks	0.12 points (95% CI 1.56 to 1.31)	Cognitive stimulation	Usual care	P=0.648

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; QoL-AD: Quality of Life in Alzheimer's Disease scale; HCS: Holden Communication Scale; CAPE-BRS: Clifton Assessment Procedures for the Elderly - Behaviour Rating Scale; RAID: Rating Anxiety in Dementia scale; CSDD: Cornell Scale for Depression in Dementia; DEMQOL: Dementia Quality of Life scale; NPI: Neuropsychiatric Inventory; ADCS-ADL: Alzheimer's Disease Cooperative Study – Activities of Daily Living scale

Appendix Table D.33 Summary of strength of evidence for PLWD outcomes: cognitive stimulation therapy

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
CS vs. Active control Quality of life	8 weeks	1 RCT (n=201)	Improvement in quality of life	Low	Unknown	Direct	Imprecise	Insufficient
CS vs. Active control Function	8 weeks	1 RCT (n=201)	No change in function	Low	Unknown	Direct	Imprecise	Insufficient
CS vs. Active control Neuropsychiatric symptoms	8 weeks	1 RCT (n=201)	No change in neuropsychiatric symptoms	Low	Unknown	Direct	Imprecise	Insufficient
CS vs. Active control Anxiety	8 weeks	1 RCT (n=201)	No change in anxiety	Low	Unknown	Direct	Imprecise	Insufficient
CS vs. Active control Depression	8 weeks	1 RCT (n=201)	No change in depression	Low	Unknown	Direct	Imprecise	Insufficient
CS maintenance therapy vs. Usual care after initial CS therapy Quality of life	24 weeks	1 RCT (n=236)	Improvement in quality of life	Moderate	Unknown	Direct	Imprecise	Insufficient
CS maintenance therapy vs. Usual care after initial CS therapy Neuropsychiatric symptoms	24 weeks	1 RCT (n=236)	Improvement in quality of life	Moderate	Unknown	Direct	Imprecise	Insufficient
CS maintenance therapy vs. Usual care after initial CS therapy Function	24 weeks	1 RCT (n=236)	Improvement in quality of life	Moderate	Unknown	Direct	Imprecise	Insufficient

Abbreviations: n=number; RCT=Randomized controlled trial; CS=Cognitive Stimulation

Evidence Map: Cognitive Stimulation Therapy

Appendix Table D.34. Characteristics of evidence map studies: cognitive stimulation therapy

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Lok, 2020 [176] Turkey High RoB	Cognitive stimulation therapy	Usual care	Hospital; single site 78 PLWD	MMSE between 13 and 24	N=60 Age NR Sex Race NR Education	Household characteristics	NR	NR	NR	NR	7 weeks	MMSE CAPS QoL-AD	NR
Cheung, 2019 [183] Hong Kong Small sample	Cognitive stimulating play intervention	Social activities	Community residents 30 PLWD	Dementia type NR	N=30 Age: yes Sex:yes Race: NR Education:yes	NR	NR	NR	NR	NR	8 weeks	MoCA FOME	
Lin, 2018[177] (28881430) Taiwan High RoB	Cognitive stimulation therapy	Reminiscence therapy; usual care	Long-term care institutions; multisite 105 PLWD	MMSE between 17 and 24, with agitation or depressive symptoms present	N=105 Age: no Sex:yes Race: NR Education: NR	Marital status	NR	NR	NR	NR	12 weeks 24 weeks	MMSE QoL-AD	NR
Capotosto, 2017[184] (27272538) Italy Small sample	Cognitive stimulation therapy	General activities	Residential homes; multisite 39 PLWD	Mild to moderate dementia	N=39 Mean age Mean education	NR	NR	NR	NR	NR	7 weeks	MMSE ADAS-Cog QoL-AD CSDD DAD NPI	NR
Wong, 2016[185] (29717527) Hong Kong Pilot	Cognitive stimulation therapy	No control group	Community and residential care units of major NGOs; multisite 30 PLWD	Clinical diagnosis of dementia, criteria unspecified	N=30 Mean age Race NR Sex Education	Living situation	Sex	NR	NR	NR	7 weeks	QoL-AD ADAS-Cog	NR
Orgeta, 2015[178] (26292178) Orrell, 2017[179] (28350796) United Kingdom High RoB	Carer-delivered individual cognitive stimulation therapy	Usual care	Unspecified community settings; multisite 356 PLWD	Dementia unspecified	N=356 Age NR Race Sex Education	Marital status Living situation	356 informal caregivers Sex Race	Marital status Living situation	NR	NR	26 weeks	ADAS-Cog QoL-AD DEMQOL NPI BADLs GDS-15 QCPR	QCPR EQ-5D HADS
Cove, 2014[186] (25525349) United Kingdom Small sample	Cognitive stimulation therapy plus carer training; cognitive	Waitlist control	Unspecified community settings; multisite 72 PLWD	DSM-IV diagnosis of mild to moderate dementia	N=72 Mean age Race/ethnicity Sex Education NR	Detailed race/ethnicity	NR	NR	NR		15 weeks	MMSE ADAS-Cog QoL-AD QCPR	QCPR

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	stimulation therapy alone												
Yamanaka, 2013[187] (23550665) Japan Pilot	Cognitive stimulation therapy	Usual care	Japanese residential and nursing homes; multisite 56 PLWD	Mild to moderate AD	N=56 Mean age Sex Education NR Race NR	NR	NR	NR	NR	NR	7 weeks	MMSE COGNISTAT QoL-AD EQ-5D Face scale for mood	NR
Niu, 2010[188] (20713437) China Small sample	Cognitive stimulation therapy	Communication exercise	Military sanatorium; single site 32 PLWD	Mild to moderate AD with marked neuropsychiatric symptoms	N=32 Mean age Sex Education	NR	NR	NR	NR	NR	10 weeks	MMSE NPI	NR
Matsuda, 2007[189] (17005066) Japan Small sample	Cognitive stimulation therapy plus donepezil	Donepezil alone	Outpatient neuropsychiatric clinic; single site 30 PLWD	DSM-IV diagnosis of dementia	N=30 NR	NR	NR	NR	NR	NR	1 year	MMSE	NR

Abbreviations: char=characteristics; EM=Evidence Map; FC=formal caregiver; IC=informal caregiver; N=number; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RS=Reporting Status; SES=socioeconomic status; MMSE=Mini Mental State Examination; CAPS=Coping and Adaptation Processing Scale; MoCA=Montreal Cognitive Assessment; FOME=Fuld Object Memory Evaluation; NPI=Neuropsychiatric Inventory; COGNISTAT=Neurobehavioral Cognitive Status Examination; QoL-AD: Quality of Life in Alzheimer's Disease scale; QCPR=Quality of Caregiver and Patient Relationship; DEMQOL=Dementia Quality of Life scale; BADLS=Bristol Activities of Daily Living Scale; GDS-15=Geriatric Depression Scale, 15 item; EQ-5D=EuroQoL 5D scale; HADS=Hospital Anxiety and Depression Scale; ADAS-Cog=Alzheimer's Disease Assessment Scale - Cognition; CSDD=Cornell Scale for Depression in Dementia; DAD=Disability Assessment for Dementia

Recreation Therapy

Appendix Table D.35. Risk of bias assessment: recreation therapy

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Pedrinolla, 2019[190] (31424399)	24 weeks	Low 6.75%	Low	Low	Moderate	Low	High	Foundations	Medium
Tse, 2018[191] (30255637)	8 weeks 12 weeks	High NR	X	X	X	X	X	Unfunded	High
Lin, 2015[192] (607203463)	24 weeks	High NR	X	X	X	X	X	NR	High
Van Haitsma, 2015[193] (24304555)	0 weeks	Low 7.69%	Moderate	Moderate	High	Low	Moderate	US state government, foundation	High
Low, 2013[194] (23315520)	13 weeks 26 weeks	Medium 13.82%	Low	Low	Moderate	Low	Low	Australian government	Medium
Kolanowski, 2011[195] (21649633)	Up to 3 weeks	Low 4.69%	Low	Medium	Low	Low	Low	National Institutes of Health	Low
Buettner, 2002[196] (11954670)	2 weeks 10 weeks	High NR	X	X	X	X	X	US state government	High
Hopman-Rock, 1999[197] (29403282)	24 weeks	High 31.3%	X	X	X	X	X	Foundations, health insurer	High

X indicates that domain was not assessed due to high risk of bias.
Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Appendix Table D.36. Characteristics of included studies: recreation therapy

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Pedrinolla, 2019[190] (31424399) Italy	Unstructured group interaction with enclosed natural environment including plants and flowers	Usual care in AD unit of a nursing home, including long corridor for walking plus recreation rooms	Nursing home Single site 163 PLWD	N=163 Probable AD diagnosis MMSE ≤ 15	N=163 Age 77 years 74.2% female Race NR Education NR	NR	NR	NR	NR	NR	24 weeks	Neuropsychiatric symptoms Function Antipsychotic dosage	NR
Low, 2013[194] (23315520) Australia Medium Explanatory	Individual, tailored humor therapy sessions for residents focused on humorous interactions; delivered by a nominated staff member who received one day of training; weekly therapy sessions for 9 to 12 weeks	Usual care, not otherwise specified	Nursing homes Cluster RCT Multisite 36 nursing homes 389 PLWD	N=389 Dementia type NR Mean Global Deterioration Scale 5.0	N=389 Age 84.5 years 64.1% female Race NR Education NR	NR	NR	NR	NR	NR	13 weeks 26 weeks	Depression Neuropsychiatric symptoms Social engagement Quality of life	NR
Kolanowski, 2011[195] (21649633) United States Low Explanatory	Individual recreational activities based on Need-driven Dementia-compromised Behavior model, tailored to residents based on either physical/cognitive function, personality as assessed through the Five Factor Model, or both;	Active control: same individual recreational activities targeted opposite to both physical/cognitive function and personality	Nursing homes Multisite 9 nursing homes 128 PLWD	N = 128 Dementia by DSM-IV criteria Mean MMSE 12.68 to 15.78	N = 128 Mean age 85.87 to 87.21 years Percent White 81.25% to 93.55% Mean years of education 11.64 to 13.87	NR	NR	NR	NR	NR	Up to 7 weeks	Agitation Affect Social engagement	NR

* High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.
Abbreviations: char=characteristics; FC=formal caregiver; IC=informal caregiver; N=number; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status; NR=NR; RCT=Randomized controlled trial

Appendix Table D.37. PLWD outcomes summary low and medium risk of bias studies: recreation therapy

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Pedrinolla, 2019[190] (31424399) Explanatory	Neuropsychiatric symptoms NPI 24 weeks	–31.8 points (95% CI –35.1 to –28.5)	Recreational therapy	Usual care	P < 0.001
Pedrinolla, 2019[190] (31424399) Explanatory	Antipsychotic use Quetiapine, mg/day 24 weeks	–150 mg/day (95% CI –175 to –120)	Recreational therapy	Usual care	P < 0.001
Pedrinolla, 2019[190] (31424399) Explanatory	Function Barthel Index 24 weeks	1.3 points (95% CI –1.9 to 4.4)	Recreational therapy	Usual care	Not significant; exact value NR
Low, 2013[194] (23315520) Explanatory	Neuropsychiatric symptoms NPI 13 weeks	0.05 points (95% CI -0.11 to 0.22)	Recreational therapy	Usual care	P=0.52
Low, 2013[194] (23315520) Explanatory	Depression CSDD 13 weeks	0.006 points (95% CI −0.19 to 0.20)	Recreational therapy	Usual care	P=0.95
Low, 2013[194] (23315520) Explanatory	Agitation CMAI 13 weeks	−0.04 points (95% CI −0.18 to 0.11)	Recreational therapy	Usual care	P=0.61
Low, 2013[194] (23315520) Explanatory	Function MOSES, withdrawal subscale 13 weeks	−0.046 points (95% CI −0.21 to 0.12)	Recreational therapy	Usual care	P=0.58
Low, 2013[194] (23315520) Explanatory	Quality of life DEMQoL 13 weeks	Self-rated: −0.10 points (95% CI −0.31 to 0.11) Proxy-rated: 0.07 points (95% CI −0.16 to 0.31)	Recreational therapy	Usual care	Self-rated: p=0.34 Proxy-rated: p=0.53
Low, 2013[194] (23315520) Explanatory	Neuropsychiatric symptoms NPI 26 weeks	-0.15 points (95% CI -0.34 to 0.04)	Recreational therapy	Usual care	P=0.13
Low, 2013[194] (23315520) Explanatory	Depression CSDD 26 weeks	0.046 points (95% CI −0.18 to 0.27)	Recreational therapy	Usual care	P=0.69
Low, 2013[194] (23315520) Explanatory	Agitation CMAI 26 weeks	0.17 points (95% CI 0.004 to 0.34)	Recreational therapy	Usual care	P=0.045
Low, 2013[194] (23315520) Explanatory	Function MOSES, withdrawal subscale 26 weeks	0.049 points (95% CI −0.13 to 0.22)	Recreational therapy	Usual care	P=0.59
Low, 2013[194] (23315520) Explanatory	Quality of life DEMQoL 26 weeks	Self-rated: 0.05 points (95% CI −0.18 to 0.28) Proxy-rated: -0.07 points (95% CI −0.28 to 0.13)	Recreational therapy	Usual care	Self-rated: p=0.67 Proxy-rated: p=0.48
Kolanowski, 2011[195] Explanatory	Agitation CMAI Up to 3 weeks	No difference between arms	Recreational therapy	Active control	p=0.607 personality tailoring alone p=0.339 function tailoring alone p=0.923 personality plus function tailoring

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: CMAI=Cohen-Mansfield Agitation Inventory; CSDD: Cornell Scale for Depression in Dementia; DEMQoL=Dementia Quality of Life Scale; MOSES=Multidimensional Observation Scale for Elderly Subjects; NPI= Neuropsychiatric Inventory; ARS = Affect Rating Scale; DMPT = Dementia Mood Picture Test; PDS = Passivity in Dementia Scale; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number

Appendix Table D.38. Summary of strength of evidence for PLWD outcomes: recreation therapy

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
RT vs. Usual care Neuropsychological symptoms	24-26 weeks	2 RCTs (n=552)	Reduction in neuropsychological symptoms	Medium	Inconsistent	Direct	Imprecise	Insufficient
RT vs. Usual care Depression	26 weeks	1 RCT (n=389)	Increase in depression symptoms	Medium	Unknown (single study)	Direct	Imprecise	Insufficient
RT vs. Usual care Agitation	Up to 13 weeks	2 RCT (n=517)	No change in agitation symptoms	Medium	Inconsistent	Direct	Imprecise	Insufficient
RT vs. Usual care Function, social	26 weeks	1 RCT (n=389)	No change in social function	Medium	Unknown (single study)	Direct	Imprecise	Insufficient
RT vs. Usual care Function, physical	24 weeks	1 RCT (n=163)	Improvement in physical function	Medium	Unknown (single study)	Direct	Imprecise	Insufficient
RT vs. Usual care Quality of life, self-rated	26 weeks	1 RCT (n=389)	Improvement in self-rated quality of life	Medium	Unknown (single study)	Direct	Imprecise	Insufficient
RT vs. Usual care Quality of life, proxy-rated	26 weeks	1 RCT (n=389)	Decline in proxy-rated quality of life	Medium	Unknown (single study)	Indirect	Imprecise	Insufficient
RT vs. Usual care Antipsychotic use	24 weeks	1 RCT (n=163)	Decrease in antipsychotic dosage	Medium	Unknown (single study)	Direct	Imprecise	Insufficient

Abbreviations: n=number; RT=Recreational Therapy; RCT=Randomized controlled trial

Evidence Map: Recreation Therapy

Appendix Table D.39. Characteristics of evidence map studies: recreation therapy

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Laksono, 2019[198] Indonesia Small sample	Chess game	NR	Community residents Single site 20 PLWD	NR	NR	NR	NR	NR	NR	NR	2 weeks	MoCA	NR
Lathifah, 2019[199] India Small sample	Dhakonan game	NR	Community residents Single site 20 PLWD	NR	NR	NR	NR	NR	NR	NR	0 weeks	GDS	NR
Tse, 2018[191] (30255637) Hong Kong High RoB	Play activity program	Reading sessions, unstructured group	Nursing homes Multisite 4 clusters 53 PLWD	N=53 MMSE between 10 and 25	N=53 Age Percent female Education Race NR	NR	NR	NR	NR	NR	8 weeks 12 weeks	Visual analog scale for happiness GDS Katz ADL scale Index of Social	NR

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
												Engagement MDS Behavior Rating Scale Non-Pharmacological Therapy Experience Scale	
Li, 2017[200] (27345629) China Small sample	Folk recreation intervention involving art, music, and games	Usual care	Long-term care facility Single site 48 PLWD	N=48 Physician diagnosis of dementia, CDR > 0.5	N =48 Age Percent female Education Race NR	NR	NR	NR	NR	NR	16 weeks	Barthel Index NPI	NR1
Pongan, 2017[71] (31288544) France Pilot	Directed singing led by a choir conductor	Painting sessions	Memory clinics Multisite 59 PLWD	N=59 Mild AD, DSM-V criteria	N=59 Age Percent female Education Race	NR	NR	NR	NR	NR	16 weeks	STAI GDS EQ-5D RSES	NR
Schall, 2017[201] (28914089) Germany Small sample	Directed visits to art museums plus art-making sessions	Unstructured visits to art museums	Community 44 PLWD	N=44 Diagnosis of mild to moderate dementia, criteria NR	N=44 Age Percent female Education NR Race NR	NR	N=44 NR	NR	NR	NR	12 weeks	GDS QoL-AD NPI FAHW Smiley Scale	NR
Lin, 2015[192] (607203463) China High RoB	Strategy board game sessions, 1-2 hours daily	Not stated	Hospital Single site 147 PLWD	N=147 NINCDS-ADRDA diagnosis of dementia	N=147 NR	NR	NR	NR	NR	NR	24 weeks	MADRS HADS RAND-36	NR
Van Haitsma, 2015[193] (24304555) US High RoB	Activity sessions tailored to individual preferences	Standard activity sessions, involving magazine reading and conversation	Nursing home Single site 180 PLWD	N=180	N=180 Age Percent female Education Race NR	NR	NR	NR	NR	NR	3 weeks	Direct observation of resident behavior MOSES MDS ADL scale	NR
Hattori, 2011[202] (21518170) Japan Small sample	Art therapy in groups	Basic mathematical exercises	Outpatient clinic Single site 39 PLWD	N=39 NINCDS-ADRDA diagnosis of dementia MMSE ≥ 20	N=39 Age Percent female Race NR Education NR	NR	NR	NR	NR	NR	12 weeks	GDS Apathy Scale SF-8 DBD	NR
Buettner, 2002[196] (11954670) US High RoB	15-minute wheelchair tandem bicycle ride with a staff member	Not stated	Nursing home and assisted living facility Multisite 70 PLWD	N=70 MMSE ≤ 24	N=70 NR	NR	NR	NR	NR	NR	2 weeks 12 weeks	GDS CMAI	NR

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	pedaling the bicycle												
Hopman-Rock, 1999[197] Netherlands (29403282) High RoB	Biweekly sporting activity and game sessions, preferably in a separate room, targeting communication, reactivation, resocialization, and function	Usual activities, including light household activities, bible reading, singing	Nursing homes Multisite 12 clusters 134 PLWD	N=134 NR	N=134 Age Percent female Race NR Education NR	NR	NR	NR	NR	NR	24 weeks	BIP SIPO	NR

Abbreviations: char=characteristics; EM=Evidence Map; FC=formal caregiver; IC=informal caregiver; N=number; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RS=Reporting Status; SES=socioeconomic status; MoCA=Montreal Cognitive Assessment; CDR=Clinical Dementia Rating; GDS=Geriatric Depression Scale; CMAI=Cohen-Mansfield Agitation Inventory; BIP=Behavioral Observation Scale for Intramural Psychogeriatry; SIPO=Social Interaction Scale for Psychogeriatric Older People; SF-8=Short-Form 8; DBD=Dementia Behavior Disturbance Scale; MADRS=Montgomery-Asberg Depression Rating Scale; HADS=Hospital Anxiety and Depression Scale; MOSES=Multidimensional Observation Scale for Elderly Subjects; MDS ADL=Minimum Data Set Activities of Daily Living Scale; STAI=State-Trait Anxiety Inventory; EQ-5D=EuroQoL 5 dimension scale; RSES=Rosenberg Self-Esteem Scale; QoL-AD: Quality of Life in Alzheimer's Disease scale; NPI=Neuropsychiatric Inventory; FAHW=Der Fragebogen zum allgemeinen habituellen Wohlbefinden (FAHW) [Questionnaire of General Habitual Well-being] scale; HCSS=Holden Communication Scale; MDS=Minimum Data Set…; ADL=Activities of Daily Living; RoB=Risk of Bias; NPI=Neuropsychiatric Inventory; QoL-AD: Quality of Life in Alzheimer's Disease scale; QCPR=Quality of Caregiver and Patient Relationship; DEMQOL=Dementia Quality of Life scale; CSDD=Cornell Scale for Depression in Dementia

Psychosocial Interventions

Appendix Table D.40. Risk of bias assessment: psychosocial interventions

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Onder 2005[203] (16260821)	25 weeks	Medium 12%	Low	High	Medium	Low	High	Italian government	High

Abbreviations: PMID=PubMed Identification Number

Evidence Map: Psychosocial Interventions

Appendix Table D.41. Characteristics of evidence map studies: psychosocial interventions

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Quinn 2016[204] (26674087) UK Pilot Quinn 2014[205] (24606601) UK Pilot	Self-management group intervention for 8 weeks: Weekly 90-minute sessions covering information sharing on various aspects such as enjoying hobbies, activities staying well, practical ways to manage memory difficulties, maintaining relationships and social networks, planning for the future, coping skills and accessing local resources.	TAU (n=11)	A memory clinic in a semi-rural area of North Wales RCT 24 PLWD	ICD-10 diagnosis of AD, vascular dementia, or mixed AD and vascular dementia with MMSE score ≥ 20	N=24 Mean age: 76 years Female: 25% % majority race: no Education: 63% college/university	NR	N=24 Mean age: 67 years Female: 79% % majority race: no Education: :42% college/university Relationship with PLWD: 79% spouse/partner	Living with PLWD: 92%	NA	NA	3 months 6 months	ACE-III GSES HADS CORE-OM EQ-5D-3L ICECAP-O	NR
Young 2014[206] (25587218) Hong Kong Small sample	10 weekly sessions of support group (structured, time limited, and allowed participants to share on different topics) for 90 minutes	standardized educational written material on dementia that provided basic information on dementia (n=19)	Non-governmental geriatric centers RCT 39 PLWD	Diagnosis of dementia, MMSE score ≥ 18	N=39 Mean age: 80 years Female: 44% % majority race: no Education: 33% illiterate	NR	NA	NA	NA	NA	10 weeks	GDS-C RSES-C GSE-C IMMEL	NA
Tappen 2009[207] (20077983) US Small sample	30 minutes modified counseling sessions, 3 times per week for 16 weeks	Usual care (n=15)	Long-term care facility RCT 36 PLWD	Clinical diagnosis of probable AD using NINCDS-ADRDA; an MMSE score ≤ 25	N=30 Mean age=87 years Female: no % majority race: no Education: 39% illiterate	NR	NA	NA	NA	NA	6 months 12 months	DMAS ADRD MADRS	NA
Burns 2005[208] (16055825)	Six, 50 minutes sessions of psychodynamic	TAU (n=20)	Referrals to memory clinic in South	Diagnosis of AD according to NINCDS–ADRDA	N=40 Mean age: 76 years Female: 48%	NR	NA	NR	NA	NA	6 weeks 3 months	CSDD BADLS RMPBC	GHQ BDI WCC

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
UK Small sample	interpersonal therapy		Manchester, UK RCT 40 PLWD	criteria with a clinical dementia rating of 1 and a score of 15 or above on MMSE	% majority race: no Education: no							MMSE CIB-GIC	
Onder 2005[203] (16260821) Italy High RoB	PLWD treated with donepezil got a reality orientation program. CG then trained to offer the group were trained to offer the program at home 3 days a week, 30 minutes/day, for 25 consecutive weeks, and were invited to stimulate and involve PLWD in reality-based communication.	No treatment	Community-dwelling PLWD RCT 156 PLWD	Diagnosis of AD according to NINCDS-ADRA with MMSE between 14 and 27, did not present with major aphasia or blindness and got donepezil treatment for at least 3 months	N=156 Mean age: 75.8 years Female: 72% % majority race: no Education: yes	NR	N=156 Mean age: 57 years Female: 63% % majority race: no Education: no	NA	NA	NA	25 weeks	MMSE ADAS-cog IADL NPI medication use	HRSD HRSA SF-36 Burden of care
Cohen 1999[209] (10495580) US Quasi-experimental	The Buddy Program: Nondemented residents were trained via 8 hours educational sessions and acted as "buddies" to their demented partner and encouraged to spend at least 30 minutes of social interaction (game/music/book /communication)	No training or partners (n=31)	Nursing homes Quasiexperimental 73 PLWD (assigned; not randomized)	MMSE score ≤ 24 were considered as potential dementia participants but did not show memory or verbal impairment	N=73 Mean age: 80 years Female: 70% % majority race: 50% African American Education: yes	NR	NA	NR	NA	NA	3 months 6 months	MMSE GDS CSDD CMAI BEHAVE-AD FAST PGCMS NPD ADL ESS NSS	NA
Wallis 1983[210](6354248) UK Small Sample	Reality Orientation therapy for 30 minutes, 5 days/week for 3 months	A variety of group and individual activities was offered to them each day (attention control)	High Royds Hospital Quasiexperimental Unclear	No diagnosis criteria mentioned	N=38 Mean age: 70 years Female: 34% % majority race: no Education: no	NR	NA	NR	NA	NA	2 weeks 3 months 4 months	Crichton scale for behavioral functioning Cognitive abilities	NA

Abbreviations: ACE-III=Addenbrooke's Cognitive Examination-III; AD=Alzheimer's disease; ADAS-cog=Alzheimer's Disease Assessment Scale-Cognitive Subscale; ADL=Activities of daily living; ADRD=Alzheimer's Disease and Related Disorders; BADLS=Bristol Activities of Daily Living Scale; BDI=Beck Depression Inventory; BEHAVE-AD=Behavioral Pathology in Alzheimer's Disease scale; char=characteristics; CIB-GIC=Clinician's Interview-Based Global Impression of Change; CG-Caregiver; CMAI= Cohen-Mansfield Agitation Inventory; CORE-OM=Clinical outcomes in routine evaluation–outcome measure; CSDD= Cornell Scale for Depression in Dementia; DMAS= Dementia Mood Assessment Scale; EQ-5D-3=3-level version of EuroQol; ESS=Environmental Satisfaction Scale; FAST= Functional Assessment Staging Tool; GDS=Geriatric Depression Scale; GDS-C=Chinese Geriatric Depression Scale; GHQ= General Health Questionnaire; GSE-C=General Self-Efficacy Chinese; GSES=General self-efficacy scale; HADS=Hospital anxiety and depression scale; HRSA=Hamilton Rating Scale for Anxiety; HRSD=Hamilton Rating Scale for Depression; IADL=Instrumental Activities of Daily Living; ICECAP-O=Icepop Capability measure for Older people; IMMEL=Index for Managing Memory Loss; MADRS=Montgomery-Asberg Depression Rating Scale; MMSE=Mini-Mental Status Exam; N=Number; NA=Not Applicable; NINCDS-ADRDA= National Institute of Neurological and Communicative Diseases and Stroke/Alzheimer's Disease and Related Disorders Association; NPD=Number of Physical Disorders; NPI=Neuropsychiatric Inventory; NR=Nor reported; NSS=Nursing Stress Scale; PGCMS=Philadelphia Geriatric Center Morale Scale; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RCT=Randomized controlled trial; RMBPC=Revised Memory and Behavior Problems Checklist; RoB=Risk of Bias; RS=Reporting status; RSES-C=Rosenberg Self-Esteem Scale-Chinese; SF-36=36 Item Short Form Survey; TAU=Treatment as usual; WCC=Ways of Coping Checklist

Creative Expression Therapy

Appendix Table D.42. Risk of bias assessment: creative-expression therapy

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Fritsch 2009[211] (19363009)		High	X	X	X	X	X	Nonprofit	High

X indicates domain not rated due to high ROB.
Abbreviations: PMID=PubMed Identification Number

Evidence Map: Creative-Expression Therapy

Appendix Table D.43. Characteristics of evidence map studies: creative-expression therapy

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Lin 2019[212] (31440055) China Pilot	Creative Expression Therapy (TimeSlip) twice a week for 6 weeks	Standard Cognitive Training	Long-Term Care Facilities, Prospective non-blinded RCT, 100 PLWD	Not specified	N=91 (43 treatment vs 48 control) Age: yes Sex: yes Race: yes Education: yes	NR	NA	NA	NA	NA	6 weeks	Cognitive Function, Quality of Life, Depression, Communication ability, Emotion status	NA
Houser 2014[213] (23602304) US Small sample	Two 1-hour TimeSlip sessions per week for 6 weeks	Facilities standard of care	Nursing homes Cluster RCT; 1 site 20 PLWD	Not specified	N=20 (10 treatment vs 10 control) Age: yes Sex: yes % majority race: no Education: no	NR	NA	NA	NA	NA	4 months	Mood score Behavior score	NA
Van Dijk 2012[214] (15802911) Netherlands Pilot	Group 1: Veder method living room theater group with trained care professionals	Standard Reminiscence group activity	Psychiatric Nursing Home, Quasi-experimental non-equivalent three group,	Alzheimer, Vascular dementia, Dementia NOS	N=155 (69 treatment 1, 31 treatment 2 vs 55 control) Age: yes Sex: yes	NR	NR	NR	NR	NR	1 week	Behavior Mood Quality of Life Alertness Memory recall	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	Group 2: Veder method living room group with professional actors		Multisite, 155 PLWD, 20 Trained professional caregivers, 10 professional actors, 11 therapists and nurses		% majority race: no Education: yes							Social isolation behaviors	
Phillips 2010[215] (21048483) US Pilot	TimeSlip sessions twice a week for 6 weeks	Facilities standard of care	Nursing homes and Assisted Living Facilities, Quasi-experimental repeated measures, Multisite 56 PLWD	Not specified	N=56 (28 treatment vs 28 control) Age Sex Race Education	Household characteristics	NA	NA	NA	NA	6 weeks	Cornell Scale for Depression in Dementia, Neuropsychiatric Inventory-Nursing Home Version, Functional Assessment of Communication Skills, Quality of Life-AD, Observed Emotion Rating Scale	NA
Fritsch 2009[211] (19363009) US High RoB	Staff members trained in TimeSlip; TimeSlips group once a week for 1 hour for 10 weeks	Facilities' standard of care	Nursing homes, randomized matched pair, 20 sites, Undefined N PLWD, Undefined N Daytime staff	Not specified	NR	NR	NA	NA	N=not given Age: yes Sex: yes Race: yes Education: no	Health status: no Training: yes Education: no Position: yes Service: yes	Two weeks	Resident Engagement, Resident Affect	FC: Staff-Initiated interactions with Residents, Attitudes towards PLWD, Job Satisfaction, Burnout

Abbreviations: AES=Apathy Evaluation Scale; APADEM-NH=Apathy Scale for Institutionalized Patients with Dementia Nursing Home; AWS==Revised Algase Wandering Scale–Nursing Home version; BARS=Brief Agitation Rating Scale; CMAI-SF=Cohen-Mansfield Agitation Inventory-Short Form; CSDD=Cornell Scale for Depression in Dementia; DSM=Diagnostic and Statistical Manual; EM=Evidence Map; GDS=Global Deterioration Scale; MMSE=Mini-mental State Examination; N=number; NA=Not Applicable; NIA=National Institute on Aging; NPI=Neuropsychiatric Inventory; NR=Not Reported; OERS=Observed Emotion Rating Scale; PMID=PubMed Identification Number; QoL-AD=Quality of Life in Alzheimer's Disease; QUALID=Quality of Life in Late-stage Dementia; RAID=Rating for Anxiety in Dementia; PLWD=Patient with Dementia; NOS=not otherwise specified; FC=Formal Caregiver

Multicomponent for PLWD Well-Being

Appendix Table D.44. Risk of bias assessment: multicomponent for PLWD well-being

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Overall Rating
Okamura 2018[216] (30036871)	3 months	Low 3 months: 1%	Medium	High	High	Low	Low	High
Rokstad 2018[217] (30445937)	24 months	NA	High	X	X	X	X	High
Masayuki Satoh 2017[218] (28222531)	6 months	High 6 months:27%	Medium	X	X	X	X	High
Middelstadt 2016[219] (27497474)	14 weeks	Medium 14 weeks:20%	Low	Low	Medium	Low	High	High
Fernandez-Calvo 2015[220] (25121567)	16 weeks	Low 16 weeks: 10%	Medium	Low	High	Low	High	High
Luttenberger 2012[221] (22468985)	6 months	Medium 6 months: 16%	Low	High	Medium	Low	Medium	Medium
Yamagami 2012[222] (23300492)	12 weeks	Low 12 weeks: 1%	Medium	High	High	Low	Medium	High
Brooker 2011[223] (21702705)	18 months	High 18 months: 32%	Low	X	X	X	X	High
Ferrero-Arias 2011[224] (21346517)	4 weeks 8 weeks	High Unclear	Medium	X	X	X	X	High
McCurry 2011[225] (21797835)	2 months	Low 2 months: 13%	Low	Medium	High	Low	Low	Medium
McCurry 2011[225] (21797835	6 months	Low 6 months: 16%	Low	Medium	High	Low	Low	Medium
Femia 2007[226] (18192631)	2 months	X	High	X	X	X	X	High
Chapman 2004[227] (15603468)	4 months	High 4 months: 24%	Low	X	X	X	X	High
Tadaka 2004[228] (No PMID)	3 months	Low 3 months: 8%	Low	Medium	Medium	Low	High	Medium
Tadaka 2004[228] (No PMID)	6 months	Medium 6 months: 17%	Low	Medium	Medium	Low	High	Medium
Wimo 1993[229] (8356361)	12 months	X	High	X	X	X	X	High

X indicates a domain not assessed due to high ROB.
Abbreviations: PMID=PubMed Identification Number; PLWD=persons with dementia

Appendix Table D.45. Characteristics of included studies: multicomponent for PLWD well-being

Study (PMID) **Country** **RoB*** **Type**	**Intervention** **Intervention Focus** **Theoretical Model** **Delivery Person** **Intervention Target Recipient** **Mode** **Components** **Frequency** **Duration**	**Comparison** **Target** **Mode** **Components** **Frequency** **Duration**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics** **Dementia Types** **Dementia Severity** **Diagnostic Criteria** **Age of Diagnosis**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Luttenberger 2012[221] (22468985) Germany Medium Explanatory	MAKS intervention consisting of motor stimulation, ADL activities and cognitive stimulation	Standard care	Nursing homes RCT	PLWD diagnosed with primary degenerative dementia MMSE <24 Exclusion criteria	N=30 Intervention group 22 Control group Age: Y Sex: Y Education: Y Race % majority: N	Marital Status	NA	NA	Education: Y	Training: Y	12 months Additional follow-up after 10 additional months	ADL	NA
McCurry 2011[225] (21797835) US Medium Explanatory	Increased walking and/or bright light exposure to improve sleep	Contact only	Community-based RCT	PLWD diagnosed with probable or possible AD Two or more sleep problems multiple times a week Average wake time of 1 hour per night or greater	N=27 Walking group 29 Light group 33Insomnia Treatment and Education group Age: Y Sex: Y Education: Y Race % majority: Y	NR	Age: Y Sex: Y Education: Y Race % majority: Y Spouse or other: Y	NR	Education: Y Experience: Y	Training: Y	6 months	Sleep Disorders Inventory Secondary sleep outcomes measurements	Satisfaction survey
Tadaka 2004[228] (PMID NR) Japan Medium Explanatory	Group care program of reminiscence and reality orientation care	Routine care	Community-based RCT	PLWD diagnosed with AD or vascular dementia CDR score of 1 or2 Exclusion criteria	N=2 Intervention group26 Control group Age: Y Sex: Y Education: N Race % majority: N	NR	Relation to PLWD: Y	NR	Education: Y Experience: Y	Training: Y	10 weeks with follow-up at 6 months	MMSE MOSES Self-care Disorientation Depression Irritability Withdrawal	NR

* High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: AD=Alzheimer's disease; ADL=Activities of Daily Living; -char=characteristics; FC=formal caregiver; IC=informal caregiver; N=number; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status; CST=Cognitive Stimulation Therapy; NR=Not Reported; DSM-Iv=Diagnostic and Statistical Manual for Mental Disorders, Fourth Edition; PLWD=Person With Dementia; RCT=Randomized controlled trial

Appendix Table D.46. PLWD outcomes summary low and medium risk of bias studies: multicomponent for PLWD well-being

Study (PMID) **Comparison** **RoB** **Category***	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Luttenberger 2012 [230] (22468985) MAKS therapy vs. Usual care Medium Explanatory	E-ADL test (Range 0 to 30, higher better) Cohen's d 12 months	No difference between groups for ITT analysis (Cohen's d 0.23) Significant difference in PP analysis (d=0.50)	NR	NR	NR
McCurry 2011[225] (21797835) NITE-AD (Sleep education) vs. contact control Medium Explanatory	Sleep Disorders Inventory Daily mean (SE) 6 months	No difference between groups	0.8 (0.2)	0.5 (0.1)	0.12

Study (PMID) **Comparison** **RoB** **Category***	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Tadaka 2004[228] (PMID NR) Group care program consisting of reminiscence and reality orientation care methods in addition to a routine day-care service vs. Routine day-care service Medium Explanatory	Self-care category of MOSES LS Mean (SE) adjusted for baseline and clinical dementia rating 6 months	No difference between groups	16.1 (1.0)	18.5 (1.0)	0.05
Tadaka 2004[228] (PMID NR) Group care program consisting of reminiscence and reality orientation care methods in addition to a routine day-care service vs. Routine day-care service Medium Explanatory	Disorientation category of MOSES LS Mean (SE) adjusted for baseline and clinical dementia rating 6 months	Favors intervention (lower score better)	16.0 (1.3)	18.3 (1.3)	0.01
Tadaka 2004[228] (PMID NR) Group care program consisting of reminiscence and reality orientation care methods in addition to a routine day-care service vs. Routine day-care service Medium Explanatory	Depression category of MOSES LS Mean (SE) adjusted for baseline and clinical dementia rating 6 months	No difference between groups	17.1 (1.2)	15.9 (1.2)	0.97
Tadaka 2004[228] (PMID NR) Group care program consisting of reminiscence and reality orientation care methods in addition to a routine day-care service vs. Routine day-care service Medium Explanatory	Irritability category of MOSES LS Mean (SE) adjusted for baseline and clinical dementia rating 6 months	No difference between groups	14.9 (1.0)	15.0 (1.0)	0.34
Tadaka 2004[228] (PMID NR) Group care program consisting of reminiscence and reality orientation care methods in addition to a routine day-care service vs. Routine day-care service Medium Explanatory	Withdrawal category of MOSES LS Mean (SE) adjusted for baseline and clinical dementia rating 6 months	Favors intervention (lower score better)	16.6 (1.1)	19.5 (1.1)	0.02

Abbreviations: NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number

Appendix Table D.47 Summary of strength of evidence for PLWD outcomes: multicomponent for PLWD well-being

Comparison **Outcome**	**Timing**	**# Studies/ Design (n analyzed)**	**Finding or Summary Statistic**	**Study Limitations**	**Consistency**	**Directness**	**Precision**	**Overall Grade/ Conclusion**
Instrumental Activities of Daily Living Multicomponent: motor stimulation, activities of daily living, and cognitive stimulation components contact control	6 months	1 RCT (n=98)	No difference in instrumental activities of daily living	Medium	Unknown	Direct	Imprecise	Insufficient
Sleep Walking, light,	6 months	1 RCT (n=66)	No difference in sleep disorders inventory	Medium	Unknown	Direct	Imprecise	Insufficient

combination treatment versus contact control								
Cognitive and Social Function Reminiscence and reality orientation care methods, routine day-care service versus usual care	6 months	1 RCT (n=60)	No difference in self-care, depression, or irritability Favors intervention for withdrawal and disorientation	Medium	Unknown	Direct	Imprecise	Insufficient

Evidence Map: Multicomponent for PLWD Well-Being

Appendix Table D.48. Characteristics of evidence map studies: multicomponent for PLWD well-being

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Sado 2020[231] (32116248) Japan Pilot	Combination of cognitive training and stimulation	Unspecified control group volunteers from within nursing home	Nursing homes Controlled Trial (CT) Cluster N=23 N=57 (non-randomized)	Aged 6 years or older Diagnosis of dementia Long-term-care insurance MMSE between 10 and 26 Living in nursing homes; No previous experience of the intervention	N=30 Age: Yes Sex: Yes Race: No Education: No	NR	NA	NA	NR	NR	12 months	ADL	NR
Young 2019[232] (29781725) Hong Kong Pilot	Structured cognitive stimulation therapy and tai chi	Treatment as usual; waitlist	Community-based RCT with waitlist for control group 101 PLWD	PLWD diagnosed with mild stage dementia MMSE >=18 Aged 60 or older	N=101 Age: Yes Sex: Yes Race % majority: No Education: Yes	Household characteristics: Yes	NR	NR	NA	NA	7 weeks	DSR dementia rating tests MMSE	NA
Chen 2018[233] (29881275) Taiwan Small sample	Music-based dual task training	Non-music-based walking	Community-based RCT 28 PLWD	PLWD diagnosed with mild to moderate dementia CDR score 0.5, 1 or 2; aged 55 or older, ambulatory Exclusion criteria applied	N=28 Age: Yes Sex: Yes % majority race: No Education: No	NR	NR	NR	NR	NR	2 months; up to 3 make-up sessions allowed	Evaluation of walking and stride Ability to stand Fall efficacy measurement Agitation Memory inventory	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Okamura 2018[216] (30036871) Japan High RoB	Combined exercise and cognitive training	Pedaling with arm ergometer	Combined day care and residential care RCT 100 PLWD	PLWD with diagnosis of dementia No restriction on type or severity Aged 65 or older and requiring assistance Exclusion criteria applied	N=100 Age: Yes Sex: Yes Race % majority: No Education: No	NR	NA	NA	NR	NR	6 weeks; 1 month 3 months	MMSE Trail making test ADL	NA
Reisberg 2017[234] (28122366) US Small sample	Comprehensive, Individualized, Person-Centered Management with following components: CG training, management assessment, therapeutic home visits and CG support groups	Usual community care	Community dwelling PLWD and CG RCT 20 PLWD	Diagnosis based on DSM-IV-TR criteria fulfilled NINCDS-ADRDA criteria for probable AD; moderate-to-severe AD with GDS 5 or 6; FAST≥6a; MMSE between 3 and 14	N=20 Age: yes Sex: yes Race % majority: no Education: yes	NR	NR	NA	NA	NA	4 weeks 12 weeks 28 weeks	NYU-CIBIC-Plus ADCS-ADLsev-abv MMSE FAST-DS BEHAVE-AD-FW RMBPC	NA
Rokstad 2018[217] (30445937) Norway High RoB	Attending daycare-based dementia programs at least 2 days per week	Care as usual	Community dwelling PLWD using daycare services and their CG Quasi-experimental 257 PLWD recruited	Dementia diagnosis according to ICD-10; MMSE≥15 and consent of CG	N=257 Age: yes Sex: yes Race % majority: no Education: yes	NR	N=257 Age: yes Sex: yes Race % majority: no Education: no Relation to PLWD=yes	NR	NA	NA	24 months	PSMS IADL MADRS NPI-Q REED	RSS MADRS
Kampragkou 2017[235] (ID# not available) Greece Small sample	Aerobic exercise, memory games and music therapy	No intervention	Institutional setting RCT 36 PLWD	PLWD diagnosed with moderate AD, ambulatory, aged 65 or older Exclusion criteria applied	N=30 Age: No Sex: Yes Race % majority: No Education: No	NR	NA	NA	NA	NA	12 weeks	MMSE ADAS ADL Ability to stand Balance	NA
Masayuki Satoh 2017[236] (28222531) Japan High RoB	Physical exercise with music (muscle training for the upper and lower extremities, hand clapping	Cognitive stimulation using a portable game console (Nintendo DS LL), and drills consisting of	PLWD using geriatric nursing services RCT 85 PLWD	Neurological specialist diagnosed dementia according to ICD-10; MMSE score between 16 and 26;	N=85 Age: yes Sex: no Race % majority: no Education: yes	NR	NA	NR	NA	NA	6 months	RCPM RBMT WF TMT-A FIM BEHAVE-AD VSRAD	NA

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
	to music, breath and voice training, and singing) for 40 minutes 1x week for 6 months	easy calculations, mazes, and mistake-searching in pictures for 40 minutes 1x week for 6 months											
Kim 2016[237] (ID# not available) South Korea Small sample	Cognitive stimulation, including art, music, recollection ad horticultural therapy	Pharmacological treatment only	Institutional setting RCT 64 PLWD	PLWD diagnosed with probable AD Exclusion criteria applied	N=53 Age: Yes Sex: Yes Race % majority: No Education: Yes	NR	NR	NR	NR	NR	6 months	MMSE Verbal fluency and word recall Depression Judgement and problem solving QoL	QoL
Middelstadt 2016[219] (27497474) Germany High RoB	Cognitive stimulation program twice weekly for eight weeks	Usual care	PLWD recruited from long term care facilities RCT 71 PLWD	Mild to moderate PLWD diagnosed according to ICD-10 and MMSE score 10-25	N=71 Age: Yes Sex: Yes Race % majority: No Education: No	NR	NA	NA	NA	NA	8 weeks 14 weeks	ADAS-cog QoL-AD NPI-NH ADCS-ADL	NA
Fernandez-Calvo 2015 [220] (25121567) Spain High RoB	Multicomponent intervention including new recreational and cognitive tasks, a module of functional activities based on real-life situations, cognitive training exercises to carry out at home with the caregiver; and psychoeducational activities; 48 sessions (90 minutes duration, and 3 sessions per	Waitlist group	Community dwelling PLWD RCT 61 PLWD	Diagnosis of probable AD using NINCDS/ADRDA; mild dementia; MMSE≥18 and having a CG for at least 6 months	N=61 Age: yes Sex: yes Race % majority: no Education: yes	NR	NA	NR	NA	NA	16 weeks	ADAS-Cog NPI-Q CSDD RDRS-2	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	week) for 16 weeks												
Wesson 2013[238] (24004682) Australia Pilot	Home hazard reduction program to reduce falls and Increase balance and strength	Usual care	Community-based RCT 22 PLWD and CG	PLWD diagnosed with dementia or ACE-R score <=82 Age 65 or older with non-paid caregiver MMSE.82 Exclusion criteria applied	N=22 Age: Yes Sex: Yes Race % majority: No Education: Yes	Household characteristics: Yes Prior disability: Yes	Sex: Yes Relation to PLWD: Yes	Living with PLWD	NA	NA	12 weeks	Fall risk tests Step and balance tests ADL Depression Agitation	Caregiver burden Task strategy management index
Yamagami 2012[222] (23300492) Japan High RoB	24 sessions for 1-hour 2x week, for 12-weeks of intervention based on brain-activating rehabilitation combined reality orientation and various activities (e.g. cooking, singing, and sewing) along with reminiscence therapy.	No treatment	Recruited from residential care homes (group living homes) RCT 54 PLWD	Dementia diagnosis without severe visual or auditory impairments	N=54 Age: Yes Sex: Yes Race % majority: No Education: No	NR	NA	NA	NA	NA	12 weeks	CDR MOSES HDS-R TMT-A Staff interview	NA
Brooker 2011[223] (21702705) UK High RoB	Occupational activities to foster well-being and goal achievement	Trained staff employed to try to increase PLWD activities	Assisted living Cluster RCT 293 PLWD	PLWD exhibiting confused behavior, communication, difficulties, challenging behavior or low mood Exclusion criteria applied	N=293 Age: Yes Sex: Yes Race % majority: No Education: No	Household characteristics: Yes	NA	NA	NR	Training: Yes Position: Yes	18 months	QoL Level of social support Quality of relationships Dementia Care Mapping index	NA
Burgener 2011[239] (20509596) US Small sample	Taiji exercises, cognitive-behavioral therapies and cognitive training exercises, as well as support	Education program for caregivers	Community-based RCT Self-referred, caregiver referred, or provider	PLWD diagnosed with dementia at early to middle disease stage	N=32 Age: No Sex: No Race% majority: No Education: No	NR	N=32 Age: Yes Sex: Yes Race % majority: No Education: Yes	NR	NA	NA	20 weeks	MMSE ECFR RSS	Stress Quality of family relationship

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	group participation		referred Unclear										
Ferrero-Arias 2011[224] (21346517) Spain High RoB	Occupational therapy sessions (music and art therapy and psychomotor activity)	Control participants remained in the day rooms performing activities of their own choosing	Recruited from centers of the Association of Alzheimer PLWD' Families of Burgos Crossover RCT 146 PLWD	Dementia criteria of CDR 1 or 2, undergoing occupational therapy	N=146 Age: yes Sex: yes Race% majority: No Education: yes	NR	NA	NA	NA	NA	4 weeks 8 weeks	NPI-Q DAIR	NA
Burgener 2008[240] (18453642) US Small sample	Taiji exercises, cognitive behavioral therapies and support group	Attention control education program	Community-based RCT Self-referred, caregiver referred, or provider referred 43 PLWD	PLWD diagnosed with dementia at early to middle disease stage	N=43 Age: Yes Sex: Yes Race % majority: No Education: Yes	NR	NR	NR	NA	NA	20 weeks; 40 weeks	MMSE Physical functioning Depression Self esteem	NR
Femia 2007[226] (18192631) US High RoB	Adult day service 3 days per week for 6 hours for 2 months: 5 to 6 different activities per day in addition to daily routines (i.e., lunch), which included 30 minutes of physical activities on average, 1 to 2 hours of social activities, and about 1 hour of cognitively stimulating activities	Not using adult day services	Community dwelling PLWD and their CG participating in the Dementia Day Care Program of the NJ Statewide Respite Care Program Quasi-experimental 234 PLWD recruited	Dementia diagnosis	N=201 Age: no Sex: yes Race % majority: no Education: yes	Income=yes	N=201 Age: yes Sex: yes Race % majority: yes Education: yes Relation to PLWD:yes	Employment=yes	NA	NA	2 months	BPSD Domains IADL PADL MMSE DRB	NA
Chapman 2004[227] (15603468)	Cognitive-communication program plus an	Donepezil treatment	Community-dwelling participants	Dementia diagnosis according to	N=54 Age: yes Sex: no	NR	NA	NA	NA	NA	4 months 8 months 12 months	ADAS-cog TFLS NPI	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
US High RoB	acetylcholinesterase inhibitor (donepezil): 1.5-hour sessions 1x week for 8 weeks		RCT 54 PLWD	NINCDS/ADRDA and MMSE ≥12	Race % majority: no Education: yes							CIBIC QoL	
Tappen 2000 (11186596) US	Skill training program	Traditional stimulation or regular care	Nursing home RCT 3 groups	PLWD diagnosed with dementia Able to stand with assistance Exclusion criteria applied	N=21 skill group 21 stimulation group 21 regular care group Age: NR by group Sex: NR by group Race % majority: N Education: N	NR	NA	NA	Education: Y	NR	20 weeks	Self-maintenance ADL Goal attainment	NA
Wimo 1993[229] (8356361) Sweden High RoB	6 hours of daycare activities including everyday routines such as meals, coffee, short walks, and excursions with stimulating elements, e.g. newspaper reading and videos	Not attending daycare	Non-institutionalized PLWD attending daycare in Sundsvall Quasi-experimental 99 PLWD	Dementia diagnosis according to DSM-IIIR criteria	N=99 Age: yes Sex: yes Race % majority: no Education: no	Home support=yes	NA	NA	NA	NA	12 months	MMSE MDDAS institutionalization	NA

Abbreviations: AD=Alzheimer’s disease; ADAS-cog=Alzheimer’s Disease Assessment Scale, cognitive subsection; ADCS-ADL=Alzheimer’s Disease Cooperative Study-Activities of Daily Living Inventory; ADCS-ADLsev-abv=Alzheimer’s Disease Cooperative Study Activities of Daily Living Inventory modified for more severe dementia, abbreviated first 12 questions version; ADL=Activities of Daily Living; BEHAVE-AD=Behavioral pathology in Alzheimer’s disease; BEHAVE-AD=FW=Behavioral Pathology in Alzheimer’s Disease Frequency-Weighted Severity Scale; BPSD=Behavioral and psychological symptoms of dementia; CDR=Clinical Dementia Rating; CG=Caregiver; char=characteristics; CIBIC=Clinician Interview-Based Impression of change; CSDD=Cornell Scale for Depression in Dementia; DAIR=Dementia Apathy Interview and Rating; DRB=Daily Record of Behavior; DSM-IV-TR=Diagnostic and Statistical Manual for Mental Disorders, Fourth Edition, Text Revision; DSR=Dementia Rating Scale; ECFR=Elder-Caregiver-Family Relationship scale; EM=Evidence Map; FAST-DS=Functional Assessment Staging-Disability Score; FC=formal caregiver; FIM=Functional independence measure; HADS=Hasegawa dementia scale revised; IADL=Instrumental Activities of Daily Living; ICD-10=International Classification of Diseases, Tenth Revision; IC=informal caregiver; MADRS=Montgomery-Asberg Depression Rating Scale; MDDAS=Multi-Dimensional Dementia Assessment Scale; MMSE=Mini-Mental Status Examination; MOSES=Multidimensional Observation Scale for Elderly Subjects; N=number; NA=Not Applicable; NINCDS-ADRDA=National Institute of Neurological and Communicative Diseases and Stroke/Alzheimer's Disease and Related Disorders Association; NJ=New Jersey; NPI=Neuropsychiatric Inventory; NPI-NH=Neuropsychiatric Inventory Home Version; NPI-Q=Neuropsychiatric Inventory Questionnaire; NR=Not Reported; NYC-CIBIC Plus=New York University Clinician’s Interview-Based Impression of Change-Plus Caregiver Input; PADL=Physical Activities of Daily Living Scale; PMID=PubMed Identification Number; PSMS=Physical Self-Maintenance Scale; PLWD=Persons with Dementia; QoL=Quality of Life; QoL-AD: Quality of Life in Alzheimer’s Disease scale; RBMT=Rivermead Behavioral Memory Test; RCPM=Raven’s Colored Progressive Matrices-Japanese; RDRS-2=Rapid Disability Rating Scale – Version 2; REED=The Anosognosia Rating Scale; RMBPC=Revised Memory and Behavior Problems Checklist; RoB=Risk of Bias; RS=Reporting Status; RSS=Relatives’ Stress Scale; SES=socioeconomic status; TFLS=Texas Functional Living Scale; TMT-A=Trail-Making Test A; WF=Word Fluency; VSRAD=Voxel-based specific regional analysis system for Alzheimer’s disease

Assistive Technology

Evidence Map: Assistive technology

Appendix Table D.49. Characteristics of evidence map studies: assistive technology

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Lauriks, 2018 [241] Amsterdam Pilot	Application of Assistive Home Technology (AHT); life circles, pathway lighting, automated lighting, automated alerts, automated sun blinds	Lived in same type of group home, but w/out AHT	Group homes in residential care facility (N=9) RCT PLWD (N=54) Caregivers (N=25)	Diagnosis of dementia confirmed by a physician	N=54 (30 treatment vs 24 control) Age: yes Sex: yes Race: NR	NR	NA	NA	N=25 (14 treatment vs 11 control) Sex	Training	On average four months after baseline measurement completed and AHT switched on.	Quality of life (Qaulidem instrument)	FC: Job satisfaction and general health
Tchalla, 2013 [242] France Pilot	Home-based technologies coupled with teleassistance service (HBTec-TS); nightlight path and electronic bracelet coupled with a teleassistance service	No HBTec-TS system was implemented	Community Experimental prospective study	Suffering from Alzheimer's disease, living at home and registered on the frail elderly people register Considered high risk of falling and were receiving a county allocation	N=96 (49 treatment vs 47 control) Age: yes Sex: yes Race: NR	Comorbidity	NA	NA	NA	NA	12 months	Incidence of falls	NA
Rowe, 2010 [243] United States Pilot	Home monitoring system designed to reliably awaken a caregiver when the PLWD left the bed at night	Paid $15 at each data collection point and provided with some education material unrelated to any study goals	Community Pretest-posttest control group design Caregivers (N=49)	Medical diagnosis of Alzheimer's disease or other dementia	NR	NR	N=49 Age Sex Race Education Relation to PLWD	Living with PLWD Health status Employment status	NA	NA	Post-test months; 2, 3, 4, 5, 6, 8, 10 and 12 (7 consecutive nights at each data collection month)	NA	IC: Subjective sleep, objective sleep and distress
Gaugler 2019 (29982413)[244] United States Pilot	Wearable / on-body monitoring system alerts caregiver to activities, provides reports behavioral patterns associated potential health problems	Usual care	Community RCT PLWD (N=132) Caregivers (N=132)	English speaking Diagnosis of NINCDS/ADRDA Not receiving similar services Age ≥ 55 years	N=132 Age yes Sex yes Race yes Education yes	SES Household Characteristics Health Insurance Race Information	N=132 Age yes Sex yes Race yes Education yes Relation to PLWD: yes	Living with PLWD Employment Status	NA	NA	6 months	NA	Sense of competence (SSCQ), Caregiver Distress (ZBI), Depression (CES-D)

Abbreviations: CES-D=Center for Epidemiologic Studies Depression Scale; NA=Not Applicable; NINCDS/ADRDA= National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's disease and Related Disorders Association; NR=Not Reported; PMID=PubMed Identification Number; PLWD=Patients living with Dementia; SSCQ=Short Sense of Competence Questionnaire; ZBI=Zarit Burden Index

Electrostimulation

Evidence Map: Electrostimulation

Appendix Table D.50. Characteristics of evidence map studies: assistive technology

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Elder 2019 (30658705) UK Small sample	2 consecutive 20-min sessions of active (0.048mA/cm^2) tDCS separated by a 30-min break, over 5 consecutive days. The anodal electrode was applied to the right parietal cortex (P4) and the cathodal electrode was applied to the occipital cortex.	Sham tDCS	Community dwelling PLWDs RCT 40 PLWD	Clinical diagnosis of Lewy body dementia; experiencing visual hallucinations of a moderate to severe nature and MMSE score e≥ 12	N=40 Mean age: 76 years % Female: no % majority race: no Education: no	None	NA	None	NA	NA	Day 5 1 month 3 months	MMSE CAMCOG GDS-15 TMT A/B ODFAS computerized attentional and visuoperceptual tasks	NPI CAF ODFAS CGI
Khedr 2019[245] (30940012) Egypt Small sample	tDCS, 20 minutes on each side. 2 weeks, 10 sessions	21 PLWD got tDCS	1 clinical center RCT N=44	Diagnosis of probable AD	N=23 Age: yes Sex: yes Education: yes Race: no	NR	NA	NA	NA	NA	2 weeks	MMSE MoCA Clock drawing test Cornell Depression Scale	NA
Sabbagh 2019 (31879235) US and Israel Safety study	Combines short bursts of rTMS with computerized cognitive training. Daily sessions applied across three targeted regions, with a total of 1300 rTMS pulses at 10 Hz in short bursts of 20 pulses.	Sham rTMS.	Community dwelling PLWDs RCT 129 PLWD	Diagnosis of mild to moderate AD using DSM-IV and MMSE score of between 18 to 26; ADAS-Cog >17;	N=129 Mean age: 77 years % Female: 46 % majority race: no Education: yes	None	NA	None	NA	NA	Week 7 week 12	ADAS-Cog ADCS-CGI-C	NA
Zhang 2019 (xxx) China Small sample	Repetitive transcranial magnetic stimulation combined with cognitive training: rTMS operation lasted approximately 10 minutes at one targeted encephalic region. Every day, the magnetic coil was first placed over the left DLPFC and then over the left temporal lobe. The treatment protocol was applied for 4 weeks (5 times/week) and with no	Sham rTMS	PLWDs were recruited from Department of Neurology in Tongji Hospital at Huazhong University of Science and Technology (Wuhan, China) RCT 30 PLWD	Diagnosis of AD (mild to moderate) using NINCDS-ADRDA	N=28 Mean age: 69 years % Female: 79 % majority race: no Education: no	None	NA	None	NA	NA	Week 4 week 8	ADAS-Cog MMSE ACE-III ADL NPI	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Elder 2019 (30658705) UK Small sample	2 consecutive 20-min sessions of active (0.048mA/cm^2) tDCS separated by a 30-min break, over 5 consecutive days. The anodal electrode was applied to the right parietal cortex (P4) and the cathodal electrode was applied to the occipital cortex.	Sham tDCS	Community dwelling PLWDs RCT 40 PLWD	Clinical diagnosis of Lewy body dementia; experiencing visual hallucinations of a moderate to severe nature and MMSE score e≥ 12	N=40 Mean age: 76 years % Female: no % majority race: no Education: no	None	NA	None	NA	NA	Day 5 1 month 3 months	MMSE CAMCOG GDS-15 TMT A/B ODFAS computerized attentional and visuoperceptual tasks	NPI CAF ODFAS CGI
	maintenance sessions												
Lozano 2016[246] (27567810) Canada, US Small sample Leoutsakos 2018[247] (29914028) Canada, US	12 months continuous Fornix deep brain stimulation post-surgery	21 control PLWD got sham procedure	7 centers in Canada and the US RCT- Phase II N=42	Mild dementia with CDR-SB of 0.5 or 1 or ADAD-Cog 13 of 12 to 24	N=21 Age: yes Sex: yes Race: no Education: no	NR	NA	NA	NA	NA	12 months	Adverse events Cerebral glucose metabolism Effects of age on metabolism	NA
Wu 2015[248] (26977125) China Pilot	Risperidone 1 mg per day plus rTMS treatments for a total of 20 sessions, 5 days a week for 4 consecutive weeks	Risperidone 1 mg per day plus sham rTMS treatments for a total of 20 sessions, 5 days a week for 4 consecutive weeks	1 clinical center (The Wuxi Mental Health Center) RCT N=54	Diagnosis of probable AD according to NINCDS/ ADRDA criteria with MMSE score less than 24 and BEHAVE-AD score greater than 8	N=27 Age: yes Sex: yes Education: yes Race: no	NR	NA	NA	NA	NA	4 weeks	BEHAVE-AD ADAS-Cog Vital signs TESS Routine blood tests, urine tests, electrocardiogram, blood biochemistry adverse events	NA
Cotelli 2014[249] (24678298) Italy Small sample	AtDCS (25 minutes) plus IC Memory training (5 days per week) for 2 weeks	12 PLWD got PtDCS (25 minutes) plus IC Memory training (5 days per week) 12 PLWD got AtDCS (25 minutes) plus motor training (5 days per week)	1 clinical center 3 arm RCT N=36	Diagnosis of mild to moderate AD, according to the NINCDS-ADRDA criteria,	N=12 Age: yes Sex: yes Race: no Education: yes	NR	NA	NA	NA	NA	3 months 6 months	MMSE ADL IADL Balance and gait NPI Language Complex figure copy Attention and executive function	NA
Olazaran 2014[250] (24898637) Spain Pilot study	2 hours of REAC NPO per day for 2 weeks	60 PLWD were treated with sham procedure	Residential care facility Crossover RCT Single site N=60	Diagnosis of AD or probable AD Nursing home PLWD capable of standing alone; day care PLWD GDS level 6 or 7	N=60 Age: yes Sex: yes Race: no Education: no	NR	NA	NA	NA	NA	2 weeks each arm	GDS Study to assess safety of stimulation in AD PLWD	NA
Olazaran 2013[251] (23603397) Spain Pilot,	1 treatment of REAC NPO for 2 hours with follow-up at 2 to 3 weeks	14 control PLWD got sham treatment	Nursing home PLWD RCT N=31	Diagnosis of probable AD, not bedridden, some gait dysfunction	N=17 Age: yes Sex: yes Race: no Education: no N of medications: yes	NR	NA	NA	NA	NA	2 to 3 weeks	Axial movement test RSGE-CD Walking test SMMSE Barthel Index NPI	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Elder 2019 (30658705) UK Small sample	2 consecutive 20-min sessions of active ($0.048 mA/cm^2$) tDCS separated by a 30-min break, over 5 consecutive days. The anodal electrode was applied to the right parietal cortex (P4) and the cathodal electrode was applied to the occipital cortex.	Sham tDCS	Community dwelling PLWDs RCT 40 PLWD	Clinical diagnosis of Lewy body dementia; experiencing visual hallucinations of a moderate to severe nature and MMSE score e≥ 12	N=40 Mean age: 76 years % Female: no % majority race: no Education: no	None	NA	None	NA	NA	Day 5 1 month 3 months	MMSE CAMCOG GDS-15 TMT A/B ODFAS computerized attentional and visuoperceptual tasks	NPI CAF ODFAS CGI
Suemoto 2013[252] (24262299) Brazil Small sample	Anodal tDCS for 20 minutes; 2 weeks; 6 sessions	20 PLWD got sham tDCS	1 clinical center RCT-Phase II N=40	Diagnosis of possible or probable AD and score of 14 or more on Starkstein Apathy Scale	N=20 Age: yes Sex: yes Education: yes Race: yes	NR	NA	NA	NA	NA	1 week 2 weeks 3 week	Starkstein Apathy Scale Cornell Depression Scale NPI Caregiver Distress ADAS-Cog Digit Cancellation Task Word list learning task Word recognition task	NA
Ahmed 2012[253] (21671144) Egypt Small sample	1 daily treatment of rTMS on DLPFC (20 Hz) with follow-up at 1 month and 3 months	15 PLWD got rTMS on DLPFC (1 Hz) 15 PLWD sham procedure	1 clinical center 3 arm RCT N=45	Diagnosis of probable AD; Dementia assessed using MMSE, IADL, GDS	N=15 Age: yes Sex: yes Education: yes Residence: yes Duration of illness: yes	NR	NA	NA	NA	NA	3 months	MMSE IADL GDS	NA
Scherder 2006[254] (16788393) The Netherlands Small sample	High frequency CES 30 min per day, 5 days per week for 6 weeks	10 control PLWD treated same way without any current	Institutionalized PLWD; treatment and control groups blindly selected N=21	Diagnosis based on NINCDS-ADRDA for probable AD and stage 5 of GDS	N=11 Age: no Sex: yes Race: no Education: yes	NR	NA	NA	NA	NA	6 weeks	BOP BDI	NA
Van Dijk 2005[255] (15802911) The Netherlands Pilot	Electrical stimulation was given 30 minutes a day for 7 days a week for 6 weeks	Placebo stimulation	1 clinical center and 1 home care center RCT N=68	Diagnosis of AD according to NINCDS/ ADRDA criteria with MMSE of 26 or lower along with sufficient hearing and vision	N=34 Age: yes Sex: yes Education: yes Race: no	NR	NA	NA	NA	NA	6 weeks of treatment for 30 min per day Additional follow-up for 6 weeks	Cognitive measures Behavioral measures	NA
Hozumi 1996[256] (9003961) Japan Small sample	Transcranial electro-stimulation was given for 20 minutes for 2 weeks	13 PLWD got placebo transcranial electro-stimulation	1 clinical center RCT N=27	Elderly PLWD with sleep-wake disorder and dementia	N=14 Age: yes Sex" yes Education: no Race: no Severity: yes	NR	NA	NA	NA	NA	2 weeks	Motivation Behavior disorder Sleep disorder Intelligence Emotion Language Neurological signs Subjective complaint Activity level	NA

Abbreviations: AD=Alzheimer's Disease; ADAS-Cog=Alzheimer's Disease Assessment Scale-Cognitive Subscale; ADAS-Cog13=Alzheimer's Disease Assessment Scale-13; ADCS-CGI-C= Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change; ACE-III= Addenbrooke's cognitive examination III; ADL=Activities of daily living; AtDCS=Anodal Transcranial Direct Current Stimulation; BEHAVE-AD=Behavioral Pathology in Alzheimer's Disease Rating Scale; BDI=Beck Depression Inventory; BOP=Beoordelingsschaal voor Oudere Patienten; CAF=Clinical Assessment of Fluctuation; CAMCOG=Cambridge Cognitive Examination; CES=Cranial Electrostimulation; CDR-SB=Clinical Dementia Rating Sun of Boxes; CGI=Clinical Global Impression; DLPFC=Dorsolateral Prefrontal Cortex; DSM-IV=Diagnostic and Statistical Manual of Mental Disorders 4th edn; GDS=Global Deterioration Scale; GDS-15=Geriatric Depression Scale 15; Hz=Hertz; IADL=Instrumental Daily Living Activity Scale; IC=Individualized Computerized; MMSE=Mini-mental State Examination; MoCA=Montreal Cognitive Scale; N=number; NA=Not Applicable; NINCDS/ADRDA=National Institute of Neurological and Communicative Disorders and Stroke/ Alzheimer's Disease and Related Disorders Association; NPI=Neuropsychiatric Inventory; NR=Not Reported; ODFAS=One Day Fluctuation Scale; PMID=PubMed Identification Number; PtDCS=Placebo Transcranial Direct Current Stimulation; REAC-NPO=Radio Electric Asymmetric Conveyer- Neuropostural optimization; RSGE-CD=Rating Scale for Gait Evaluation in Cognitive Deterioration; rTMS=repetitive transcranial magnetic stimulation; SMMSE=Severe Mini-Mental State Examination; tDCS=Transcranial Direct Current Stimulation; TESS=Treatment Emergent Symptom Scale; TMT A/B= Trail Making Test A and B

Other Interventions for PLWD Well-being

Evidence Map: Other Interventions for PLWD Well-being

Appendix Table D.51. Characteristics of evidence map studies: other Interventions for PLWD well-being

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Liu 2018[257] (30464426) China Small sample	Passive finger movement exercise program based on active finger exercise along with routine care	Routine care	Residents from Hangzhou Love Heart Older's home in China RCT 54 PLWD	Diagnosis of dementia by medical doctors with PLWD's fingers free from disease restricting hand movement along with visual and oral communication function and no history of taking anti-dementia drugs	N=18 Mean age=80 years Female: 67% majority race: no Education: 39% illiterate	NR	NA	NA	NA	NA	12 weeks	Grip strength (electrical hand muscle dynamometer) Barthel index	NA
Rostad 2018[258] (29763832) Norway Pilot	Pain assessment twice a week for 12 weeks using Doloplus-2 pain scale	Usual care	Nursing home Cluster RCT 121 PLWD	Dementia diagnosis in medical record with being non-verbal or inability to self-report pain	N=58 Mean age: 84 years Female: 78% % majority race: no Education: no	NR	NA	NR	NA	NA	Twice a week for 12 weeks	Doloplus-2 pain scale ATC N02A ATC N02B ATC M01A OMEQ	NA
Batchelor-Murphy 2017[259] (28165618) US Pilot	I1: Direct Hand (DH): CG holds the utensil or cup for the resident without PLWD active involvement I2: Over Hand (OH): CG puts his/her hand over the resident's hand to assist the PLWD. I3: Under Hand (UH): CG holds the utensil or cup and places his/her hand under the resident's hand. This technique theoretically allows the resident to feel as though he/she initiated the movement, and is in control	NR	Nursing Homes 3 arm RCT 53 PLWD	Diagnosis of AD or related dementia, BIMS score between 0-12	N=23 Mean age: 84 years Female: 59% % majority race: yes Education: no	NR	NA	NA	NA	NA	2 years	EdFED	NA
Kim 2017[260] (27594544) Korea Quasi-experimental	Participated in a suicide prevention program twice a week for 5 weeks with one pretest and 2 posttests.	NR	Recruited from geriatric daycare centers Randomized Pretest Posttest design 66 PLWD	Early-stage and questionable dementia selected based on MMSE—KC (score between 16 to 19); score > 5 on both SIS and GDSSF-K scale	N=32 Mean age: 82 years Female: 77% % majority race: no Education: 55% illiterate	NR	NA	NR	NA	NA	5 weeks 7 weeks	SIS Perceived health status Barthel index SS-A scale GDSSF-K	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Hobbelen 2012[261] (22185768) Netherlands Pilot Hobbelen 2007[261] (18093298) Netherlands Study Protocol	PLWD, 20 minutes session of PMT by trained physical therapists, 3 times a week for 4 weeks	No PMT (attention control)	Nursing home residents RCT 102 PLWD	Dementia diagnosis based on DSM-IV-TR and have paratonia with a MAS score of at least 2 in at least 1 limb;	N=35 41% Female 82 years Race NR Education NR Use of psychotropic meds: 51%	NR	NA	NA	NA	NA	2 weeks 4 weeks	MAS CGI PCS PACSLAC-D	NA
Coyne 1997[262] (9281930 2) US Pilot	Using directed verbal prompts (6 sets) and positive reinforcements to complete eating tasks	Unclear	Dementia unit of SNF 3 arm RCT 24 PLWD	Diagnosis of dementia; eat more than half of the meal without assistance in the communal dining hall of the facility;	N=12 Mean age: 82 years Female: 100% % majority race: no Education: no	NR	NA	NA	NA	NA	Day 6 Day 7 Day 12 Day 13	LEI	NA

Abbreviations: AD=Alzheimer's Disease; ATC=Anatomical Therapeutic Chemical; ATC-M01A=Anti-inflammatory and anti-rheumatic products; ATC-N02A=opioids; ATC-N02B=Other analgesics and antipyretics; BIMS=Brief Interview for Mental Status; Char=Characteristics; CG=Caregiver; CGI=Clinical Global Impression; Doloplus-2=Behavioral pain assessment scale for the elderly presenting with verbal communication disorders; EdFED=Edinburgh Feeding Evaluation in Dementia; GDSSF-K=Korean Geriatric Depression Scale Short Form; LEI=Level of eating independence; MAS=Modified Ashworth scale; MMSE-KC=Korean Mini-Mental Status Exam; N=Number; NA=Not Applicable; OMEQ=Oral morphine equivalents; PACSLAC-D=Pain Assessment Checklist for Elderly with Limited Ability to Communicate, Dutch version; PMID=PubMed Identification Number; PMT=Passive Movement Therapy; PSC=Patient specific complaints-modified; PLWD=Persons with Dementia; RCT=Randomized controlled trial; RoB=Risk of Bias; SIS=Suicidal Ideation Scale; SNF=Skilled Nursing Facility; SS-A=Social support appraisal

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Appendix E. Psychosocial Interventions for Caregiver Well-Being

Psychosocial Interventions for Caregiver Well-Being

Appendix Table E.1. Risk of bias assessment: Psychosocial Interventions for Caregiver Well-being

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Au 2020[1] (no PMID)	8 weeks	Low 8%	Low	Low	Low	Low	Low	University	Low
Au 2019[2] (31279613)	5 months	Low 15%	Low	Medium	Medium	Low	Low	Government	Low
Kunik 2020[3] (32115311)	3 months 6 months 12 months	Low 18%	Low	Medium	High	Low	Low	National Institute of Nursing	Low
Bjorge 2019[4] (31651321)	3 months	Low 15%	Low	Medium	Medium	Low	Medium	None	Medium
Ghaffari 2019[5] (no PMID)	8 weeks	Low 7%	Low	Medium	Medium	Medium	Medium	University	Medium
Meng 2019[6] (30884961)	3 months	Low 0%	Medium	Medium	Medium	Low	Medium	Government	Medium
Moskowitz 2019[7] (31045422)	6 weeks	Low 9%	Low	Medium	Medium	Low	Medium	Government	Medium
Nordheim 2019[8] (30775982)	6 months	Medium 19%	Low	Medium	Medium	Low	Medium	Government	Medium
Terracciano[9] 2019 (31866419)	6 weeks	High 27%	X	X	X	X	X	Government Nonprofit	High
Uyar 2019[10] (no PMID)	16 weeks	Medium 12%	Medium	Medium	Medium	Low	Medium	NR	High Very unclear methods and intervention description
Wawrziczny 2019[11] (29665714)	10 weeks	X	High	X	X	X	X	Government	High
Boots 2018[12] (30006327)	8 weeks	Medium 16%	Low	Low	Medium	Low	Low	Alzheimer Nederland and the Alzheimer Research Fund Limburg.	High
Gitlin 2018[13] (29192967)	4 months	Medium 31%	Low	Low	Medium	Low	Low	Government	Medium
Spalding-Wilson 2018[14] (30258974)	1, 3, 6 months	Low 9%	Medium	Medium	High	Low	Low	National Science Foundation, private foundations	High
Wilz 2018[15] (29190357)	6 months Follow up at 12 month	Medium 17%	Low	High	Medium	Low	Low	The German Federal Ministry of Health	High
Callahan 2017[16] (27893087)	2 years	Medium 35%	Low	Low	High	Low	Medium	NIA	High
Whitlatch 2017[17] (29171296)	6 months	Medium 15%	Medium	Medium	High	Low	High	Government	High
Charlesworth 2016[18] (27521377)	5 months 1 year	Low 5 months: 7% 12 months: 13%	Low	Low	Medium	Low	Medium	Government	Low
Cheng 2016[19] (27401052)	2 months	NR	Medium	Medium	Medium	Low	Medium	Government	Medium
Gonyea 2016[20] (24855313)	3 months 6 months	Low 15%	Medium	Medium	Medium	Low	Medium	Nonprofit	Medium
Laakkonen 2016[21] (27060101)	3 months 9 months	Low 4%	Low	Medium	Medium	Low	Medium	Government Nonprofit University	Medium
Taati 2016[22] (no PMID)	8 weeks	High 23%	Low	X	X	X	X	No funding	High

Study (PMID)	**Outcome Timing**	**Attrition Bias** **Attrition %**	**Selection Bias**	**Detection Bias**	**Performance Bias**	**Reporting Bias**	**Fidelity Bias**	**Funder**	**Overall Rating**
Blom 2015[23] (no PMID)	5-6 months	Medium 28%	Low	Medium	Low	Low	High	the Alzheimer's Society in the Netherlands, the health care provider Geriant and the VU University	High
Chiu 2015[24] (25615434)	4 weeks	Medium 16%	High	High	Low	Low	Low	The UHN AMO Innovation Fund	High
Gallagher-Thompson 2015[25] (25590939)	10 months	High 25%	Medium	X	X	X	X	The National Office of the Alzheimer's Association & the Alzheimer's Disease Center at University of California, Davis	High
Losada 2015[26] (26075381)	2 % 6 months	High 30%	X	X	X	X	X	NR	High
Otero 2015[27] (25331992)	1, 3, 6, 12 months	Low 4.62%	Low	Low	Medium	Low	Low	Spanish government	Low
Tremont 2015[28] (25074341)	6 months	Medium 15%	Low	Medium	Medium	Low	Medium	Government	Medium
Arango-Lasprilla 2014[29] (24550547)	3 months	High Unclear	X	X	X	X	X	No funding	High
Livingston 2014[30] (25300037)	4 months 8 months	Low 4 months: 9% 8 months: 13%	Low	Medium	Medium	Low	Low	Government	Low
Martin-Carrasco 2014[31] (24113563)	4 months	Medium 4 months: 26% 8 months: 39%	Low	Low	Medium	Low	Medium	Government	Medium
Passoni 2014[32] (24614271)	6 months	X	High	X	X	X	X	Not reported	High
Bruvik 2013[33] (24348500)	12 months	Medium 13%	Low	Low	Medium	Low	High	Government, foundations	High
Huang 2013[34] (23933422)	2 weeks, 3 & 6 months	Medium 10%	Medium	Medium	Low	Low	High	Government	High
Judge 2013[35] (22899427)	15 weeks	Medium 13%	Medium	Medium	High	Low	Low	NR	High
Kajiyama 2013[36] (23461355)	3 months	High 31%	Medium	X	X	X	X	The National Institute on Aging, part of the National Institutes of Health.	High
Kuo 2013[37] (22778053)	2 weeks, 3 & 6 months	Low 16%	Medium	Medium	Low	Low	High	Government	High
Moore 2013[38] (23916631)	6 weeks	Low 14%	Low	Medium	Medium	Low	Low	National Institute on Aging	Low
Joling 2012[39] (22303473)	12 months	Low 13%	Low	Medium	Medium	Low	Low	Government	Low
Waldorff 2012[40] (22807076)	1 year	Medium 16%	Low	Low	Medium	Low	Medium	Government	Medium
Chu 2011[41] (20847363)	1 month	High 29%	X	X	X	X	X	University	High
de Rotrou 2011[42] (20922772)	3 months 6 months	Medium 31%	Low	Medium	Medium	Low	Medium	Government	Medium
Guerra 2011[43] (20602013)	6 months	Low 3%	Low	Low	High	Low	High	Nonprofit	Medium
Losada 2011[44] (21061414)	3 months	High 29%	X	X	X	X	X	NR	High
Spijker 2011[45] (21358385)	12 months	Medium 36%	Low	Medium	Low	Low	High	The Dutch Organization of Health Research and Development (ZonMw).	High
Voight-Radloff 2011[46] (22021760)	6 weeks 16 weeks 26 weeks 52 weeks	Low 6-16 weeks Medium 26-52 weeks 6 weeks: 9% 16 weeks: 19%	Low	Medium	Medium	Low	Medium	Government	Low 6-16 weeks Medium 26-52 weeks

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
		26 weeks: 25% 52 weeks: 26%							
Wang 2011[47] (21752121)	6 months	Low 2%	Medium	Medium	Medium	Low	Medium	University	Medium
Wilz 2011[48] (no PMID)	3 months	Medium 25%	Medium	Medium	Medium	Low	Low	Government	Medium
Gitlin 2010[49] (20662955)	4 months 9 months	High 12%	Low	Medium	Medium	Low	Low	The National Institute on Aging and National Institute	High
Gitlin 2010[50] (20810376)	4 months 9 months	Medium 12% 27% at 9 month	Low	Medium	High	Low	High	In part by funds from the National Institute on Aging & the National Institute on Nursing Research & the Pennsylvania Department of Health, Tobacco Settlement	High
Kurz 2010[51] (19946869)	15 months	High Unclear	X	X	X	X	X	German Federal Ministry of Education and Research	High
Williams 2010[52] (20978227)	3, 6 months	X	High	X	X	X	X	National Institutes on Aging	High
Gavrilova 2009[53] (18814197)		Medium 12%	Low	Low	Medium	Low	High	The World Health Organization (WHO)	High
Martin-Carrasco 2009[54] (18949763)	4 months 10 months	Medium 10%	Low	Medium	Medium	Low	Medium	Industry	Medium
Andrén 2008[55] (18269429)	6 & 12 months	X	High	X	X	X	X	Swedish Council for Social Research, foundations, university, and municipality	High
Gallagher- Thompson 2008[56] (25067886)	6 months	Medium 15%	Medium	Medium	Medium	Medium	Medium	Government	Medium
Marquez-Gonzalez 2007[57] (18074249)	2 months	High 47%	X	X	X	X	X	Not reported	High
Ulstein 2007[58] (17986818)	1 year	Medium 14%	Low	Medium	Medium	Low	High	Government, foundation	High
Gonyea 2006[59] (17169938)	6 weeks	Medium 12%	Low	Medium	High	Low	High	Foundations	High
Graff 2006[60] (17114212)	6 weeks 3 months	Medium 6 weeks High 12 weeks 6 weeks: 16% 12 weeks: 23%	Low	Medium	Medium	Low	Medium	Nonprofit University	Medium 6 weeks High 12 weeks
Beauchamp 2005[61] (no PMID)	1 month	Low 3%	Medium	High	High	Low	Low	Not reported	High
Farran 2004[62] (41552352)	18 months	Medium 17%	Low	Medium	Medium	Low	Medium	Government	Medium
Burgio 2003[63] (12937335)	6 months	Medium 16%	Medium	High	Medium	Low	Low	National Institute for Nursing Research	High
Burns 2003[64] (12937333)	2 years	High 55%	X	X	X	X	X	National Institute on Aging, National Institute of Nursing Research, Department of Veterans Affairs	High
Coon 2003[65] (14570964)	4, 7 months	High 23%	X	X	X	X	X	National Institute of Mental Health	High
Gallagher Thompson 2003[66] (12937336)	3 months	Low 0%	Medium	Medium	Medium	Medium	Medium	Government	Medium
Gitlin 2003[67] (12937332)	3 months	Medium 15%	Medium	High	Medium	Low	Low	Government	Medium
Hebert 2003[68] (12496309)	4 months	Medium 18%	Low	Medium	High	Low	Low	The Quebec Health Research Fund, the Alzheimer Society of Canada, the FRSQ Network	High

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
								for Geronto-Geriatric Research, and the Quebec Council for Social Research	
Fung 2002[69] (12037799)	3 months	Medium 13%	Medium	High	High	Low	Low	Not reported	High
Stolley 2002[70] (11954669)	3, 6 &12 months	High 27%	Medium	X	X	X	X	NR	High
Wright 2001[71] (11885210)	2 & 6 weeks, 3, 6 & 12 months	High Unclear	X	X	X	X	X	Foundation	High
Buckwalter 1999[72] (10222636)	6 & 12 months	High 29%	X	X	X	X	X	National Institutes of Health	High
Chang 1999[73] (10337848)	4, 8 & 12 weeks	Medium 25%	Medium	Medium	Medium	Low	High	NR	High
Ostwald 1999[74] (10396888)	5 months	Low 19.7%	Low	Medium	High	Low	Low	National Institute of Nursing Research	Medium

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Appendix Table E.2. Characteristics of included studies: Psychosocial Interventions for Caregiver Well-being

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Au 2020[1] (no PMID) Hong Kong Low Explanatory	Connecting through caregiving Intergenerational perspective-taking reappraisals Aim to promote balance between self-care and caring of others: (1) enhance self-awareness (2) connect with PLWD through empathetic understanding (3) connect with help Initial home visit, then 7 weekly telephone sessions 8 weeks total	Basic skill building intervention Initial home visit, then 7 weekly telephone sessions 8 weeks total	Home-based RCT N=72 dyads	Alzheimer's disease NPI 20 Physician-diagnosed	N=72 79 years 72% Female Race NR Education NR	NR	N=72 52 years 81% Female Race NR Education 11 Years formal education (mean) 100% Child	3 years caregiving (mean) 57% Living with PLWD 53% Employed	8 weeks	NR	CESD ZBI Satisfaction with Life Survey (all Chinese versions)
Au 2019[2] (31279613) Hong Kong	Telephone-administered psycho-education with	Telephone based psycho-education with general monitoring. 8	Home-based RCT N=111	Alzheimer's disease NINCDS-ADRDA	NR	NR	N=111 57 years 81% Female Race NR	4+ years caregiving (mean) 11 hours daily caregiving	5 months	NR	CESD ZBI RAS Caregiver: self-

Study (PMID) **Country** **RoB*** **Type**	**Intervention** **Intervention Focus** **Theoretical Model** **Delivery Person** **Intervention Target Recipient** **Mode** **Components** **Frequency** **Duration**	**Comparison** **Target** **Mode** **Components** **Frequency** **Duration**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics** **Dementia Types** **Dementia Severity** **Diagnostic Criteria** **Age of Diagnosis**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Low Explanatory	behavioral activation intervention. 8 biweekly sessions.	biweekly monitoring sessions.					Education 32% Primary 50% Secondary 18% Tertiary 29% Spouse or partner 65% Child				efficacy for controlling upsetting thoughts 5 item
Kunik 2020[3] (32115311) United States Low Pragmatic	Psychosocial approach to understanding behavioral problems / Unmet Needs Model including education, 6 to 8 weekly skills sessions, and telephone wrap-up session for PLWD and caregivers for 3 months	booklet on memory problems, community resources and caregivers, eight brief, weekly calls, and encouraged to bring concerns to primary care physician for 3 months	Community N=228	Documented diagnosed dementia	N=228 77 years 42% Female 67% Non-Hispanic white 69% 14 years	48% $20k-49,999/yr 21% Black 9% Hispanic 2% Other	N=228 68 years 77% Female 66% Non-Hispanic white 78% 14 years 69% Spouse	88% Living with PLWD	3 months 6 months 12 months	Aggression (CMAI) Pain (PGPIS)	Depression (GDS) Pain (PGPIS) Burden (ZBS)
Bjorge 2019[4] (31651321) Norway Medium Explanatory	Psychosocial intervention (education about dementia, counselling and group sessions) over 12 months	Usual care	Community-based RCT N=208 dyads	Non-specified dementia ICD 10	N=208 79 years 53% Female Race NR 9 Years of education	NR	N=208 64 years 76% Female Race NR Education NR 57% Spouse or partner 44% Child	58% Live with PLWD	3 months	MMSE NPI-Q Lawton & Brody's IADL CSDD PLWD nursing home placement	RSS GDS FEERS
Ghaffari 2019[5] (no PMID) Iran Medium Explanatory	Resilience education 8 weekly 45-minute group sessions Training and education program aimed to promote resilience PowerPoint presentations and educational pamphlets	No treatment Received resilience development education after the study finished	Community-based RCT N=54 caregivers	Alzheimer's disease Physician-diagnosed	NR	NR	N=54 43 years 74% Female Race NR Education 22% Primary education 35% High school diploma 35% University education 77% Spouse or partner 23% Child	Months caregiving 4% <6 months 54% 6-24 months 42% >24 months Employment 18% Retired 50% Working 32% Homemaker	8 weeks	NR	GHQ
Meng 2019[6] (30884961) USA Medium	Telephone based cognitive behavioral therapy	In-person cognitive behavioral therapy	Home and Community-based RCT N=109 dyads	Alzheimer's disease or progressive dementia Physician-diagnosed	N=109 81 years 66% Female 100% African-	NR	N=109 59 years 50% Female 100% African-American	4 years caregiving (mean) 66% Live with PLWD	3 months	NR	Caregiver health (physician office visits, mental health visits,

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Explanatory					American 12 Years education		15 Years education 23% Spouse or partner 66% Child				prescription medication, ER visits, hospital days, out of pocket expenditures in dollars, total monthly expenditures in dollars)
Moskowitz 2019[7] (31045422) USA Medium Explanatory	Life Enhancing Activities for Family Caregivers (LEAF). Taught eight emotion-regulating skills over 6 sessions.	Waitlist control, emotion-reporting	Home-based RCT N=170	Alzheimer's disease Frontotemporal Lewy body Parkinson's dementia Nonspecified dementia	NR	NR	N=170 63 years 84% Female 88% White Education 6% High school education or less 40% College degree or some college 40% Postgraduate education 67% Spouse or partner 27% Child	4+ years caregiving (mean)	6 weeks	Dementia Severity Rating Scale	PROMIS (depressive symptoms, mental health, physical health) NeuroQOL ZBI Caregiver Strain Index (CSI) Differential Emotions Scale (DES) the Positive Aspects of Caregiving Scale The Perceived Stress Scale
Nordheim 2019[8] (30775982) Germany Medium Explanatory	Couple-based interdisciplinary psychosocial intervention 9 sessions over 10-12 weeks	Usual care	Community-based RCT N=108 dyads	Non-specified dementia NIA criteria	N=108 81 years 39% Female Race NR Education NR	NR	N=108 78 years 61% Female Race NR Education NR	NR	6 months	QOL in Alzheimer's Disease (QOLAD) ADL IADL Older Adults Overprotection Scale (OPSA) Geriatric depression scale (GDS) PLWD social support: (F-SOZU) MMSE	WHOQOL-BREF short form Global QOL subscale Sense of Competence Questionnaire (SCQ) (personal life, performance as a caregiver, satisfaction with PLWD) Caregiver social support: (F-SOZU) Perceived stress GDS
Gitlin 2018[13] (29192967) Gitlin 2013[75]	Home-based Tailored Activity Program. 8	Attention control using 8 telephone visits.	Home-based RCT N=160 dyads	Veterans with dementia and their carers. MMSE ≤23	N=160 80 years 3% Female	NR	N=160 72 years 98% Female	100% Living with PLWD	4 months	Neuropsychiatric Inventory – Clinician (NPI-C) -	CES-D ZBI Short Form (12 item)

Study (PMID) **Country** **RoB*** **Type**	**Intervention** **Intervention Focus** **Theoretical Model** **Delivery Person** **Intervention Target Recipient** **Mode** **Components** **Frequency** **Duration**	**Comparison** **Target** **Mode** **Components** **Frequency** **Duration**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics** **Dementia Types** **Dementia Severity** **Diagnostic Criteria** **Age of Diagnosis**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
(29192967) USA Medium Explanatory	sessions with occupational therapists to customize activities to the interests and abilities of the veterans and educate their caregivers about dementia and use of customized activity. Delivery by occupational therapist. 4 months.			and documented dementia diagnosis.	79% White <41% High school diploma or less		82% White <38% High school diploma or less 87% Spouse or partner			number of behavioral symptoms Caregiver Assessment of Function and Upset Scale (CAFU) (number of ADL/IADL dependencies, level of dependence) PLWD QOL (caregiver perception of affect)	Neuropsychiatric Inventory – Clinician (NPI-C) distress Time spent caregiving (time on ADLs and IADLs, hours on duty, hours on doing things)
Charlesworth 2016[18] (27521377) Melunsky 2015[76] (24381218) Charlesworth 2011[77] (21917187) UK Low Explanatory	1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP) 2) Group reminiscence therapy Remembering Yesterday, Caring Today (RYCT) Once a week for the first we weeks followed by monthly meetings for the next 7 months (12 months total)	3) Usual care	Community-based RCT N=291 dyads	Alzheimer's disease Vascular dementia Non-specified dementia DSM-IV	N=291 80 years 53% Female 88% White 75% High school education or less	NR	N=291 67 years 67% Female 89% White 62% High school education or less 64% Spouse or partner	4+ years caregiving (mean)	5 months 1 year	QOL-AD (self and proxy reported) Alzheimer's Disease Cooperative Study-ADL NPI	SF-12 (mental, physical component) Hospital Anxiety and Depression Scale (HADS) (anxiety, Depression) EQ-5D global health visual analog scale Carers of Older People in Europe Index (COPE index) positive aspects Caregiver Quality of Caregiver–PLWD Relationship (QCPR)
Cheng 2016[19] (27401052) Cheng 2019a[78] (31076215) Cheng 2019b[79] (31556447) Cheng 2016[19]	1) Benefit finding intervention (BF) 2) Simplified psychoeducation (SIM-PE)	3. Standard psychoeducation (STD-PE)	Community-based Cluster-randomized RCT N=129 dyads	Alzheimer's disease NINCDS-ADRDA	N=129 NR	NR	N=129 55 years 85% Female Race NR Education 28% Primary or less 57% Secondary	2 years caregiving (mean) 13 hours per day 31% Employed	2 months	NR	Hamilton Depression Rating Scale ZBI Caregiver role overload Ryff's

Study (PMID) **Country** **RoB*** **Type**	**Intervention** **Intervention Focus** **Theoretical Model** **Delivery Person** **Intervention Target** **Recipient** **Mode** **Components** **Frequency** **Duration**	**Comparison** **Target** **Mode** **Components** **Frequency** **Duration**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics** **Dementia Types** **Dementia Severity** **Diagnostic Criteria** **Age of Diagnosis**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
(28287803) Cheng 2014[80] (24688081) Hong Kong Medium Explanatory							15% Tertiary 27% Spouse or partner 73% Child				Psychological Well-being Scale
Gonyea 2016[20] (24855313) USA Medium Explanatory	Circulo de Cuidado, a culturally-sensitive, cognitive behavioral (CBT) group intervention. (1) 5 weekly 90-minute group sessions (2) Telephone coaching at week 3, 6, 9 and 12	Psychoeducational (PED) control condition	Community-based RCT N=67 dyads	Possible or probable Alzheimer's Disease Criteria NR	N=291 75 years 63% Female Race NR Education NR	NR	N=291 54 years 51% Female 100% Latino 28% Less than high school education 48% High school certificate or GED 24% Spouse or partner 55% Child	Employment 37% Fulltime 24% Part time 63% Living together 12 hours daily caregiving	3 months 6 months	Neuropsychiatric Inventory-Severity scale (NPI-S) (Spanish)	NPI distress Revised Scale for Caregiving Self-Efficacy (RSCSE) CES-D State Anxiety Inventory-State (STAI-S) (all Spanish)
Laakkonen 2016[21] (27060101) Laakkonen 2013[81] (52813196) Laakkonen 2012[82] (22871107) Finland Medium Explanatory	Self-management groups. 4-hour group sessions in a day center once a week for an 8-week period.	Usual care	Clinic-based RCT N=136 dyads	Non-specified dementia	N=136 77 years 27% Female Race NR 45% <8 years education	NR	N=136 74 years 63% Female Race NR 40% <8 years education 100% Spouse or partner	NR	3 months 9 months	PLWD quality of life: 15D Verbal Fluency (VF) Clock Drawing Test (CDT) PLWD Health & social services cost	SF-36 Caregiver quality of life (physical, mental) Spousal Sense of Competence Questionnaire (SCQ) Caregiver mastery Pearlin Mastery Scale (PMS) Caregiver Health & Social services cost
Otero 2015[83] (25331992) Spain High ROB	Group-based cognitive behavioral intervention for problem solving 5 90-minute weekly sessions	Usual care	Community-based RCT N=173 informal caregivers	Dementia diagnosis (47%)	NR	NR	N=173 54 years Sex NR Race NR 75% primary/higher education 51% Daughter or son	Mean of 10 years caring for PLWD 84% unemployed	1, 3, 6, 12 months	NA	CES-D SCID-CV
Tremont 2015[28] (25074341) Tremont 2017[84] (28008609) Tremont 2013[85] (23916916)	Telephone Tracking–Caregiver (FITT-C) received 16 15-60min telephone	Telephone Support Control: Received non-directive support through empathic and	Academic medical center RCT N=250	NR	NR	NR	N=250 63 years 78% Female 96% White 15. years 51% Spouse or	80% Living together 3.8 years caregiving	6 months	NR	CESD ZBI RMBPC-RT Reaction Score Family Assessment

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
USA Medium Explanatory	contacts over 6 months. Provided education, emotional support, directing to resources, encouraging caregivers to attend to their physical, emotional, and social needs, and teaching caregivers strategies to cope with ongoing problems	reflective listening and open-ended questioning without directive strategies, such as education, problem-solving, advice-giving, or task directives.					partner 42% Child				Device (FAD) Self-Efficacy Questionnaire (symptom management, support services) Positive Aspects of Caregiving (PAC) EuroQoL Visual Analog scale
Martin-Carrasco 2014[31] (24113563) Spain Medium Explanatory	Psychoeducational Intervention Program to teach strategies for confronting problems of PLWD care. 7 biweekly 90-120 min sessions over 4 months.	Usual care	Clinic-based RCT N=238 dyads	Alzheimer's disease Vascular dementia Non-specified dementia DSM-IV-TR	N=238 78 years 62% Female Race NR Education 61% Primary school 10% Secondary school 7% College	NR	N=238 62 years 77% Female Race NR Education 48% Primary school 30% Secondary school 13% College 59% Spouse or partner 45% Child	5 years providing care 12 hours per day 25% Working 39% Homemaker 27% Retired	4 months	NR	ZBI General Health Questionnaire 28 item (GHQ-28) SF-12 (all Spanish)
Waldorff 2012[40] (22807076) Phung 2013 (370414872) Denmark Medium Explanatory	DAISY plus support (multifaceted and semi-tailored counselling, education, and support). Up to 7 sessions over 12 months.	Support control group	Home and clinic-based RCT N=330 dyads	Alzheimer's disease Vascular dementia Non-specified dementia Mixed-type DSM-IV NINCDS-ADRDA	N=330 76 years 54% Female Race NR Education 36% NR 26% <3 years 38% ≥3 years	NR	N=330 66 years 67% Female Race NR Education 24% NR 33% <3 years 43% ≥3 years 65% Spouse or partner 27% Child	65% Live with PLWD	1 year	MMSE CSDD EQ-VAS (PLWD and proxy rated) QoL-AD (PLWD and proxy rated) NPI ADSC-ADL	Geriatric depression scale
de Rotrou 2011[42] (20922772) France Medium Explanatory	Psycho Education Program. 12 weekly 2-hour sessions. Content included education, problem-solving techniques and	Usual care	Memory clinic RCT N=167 dyads	Alzheimer's disease DSM-IV	N=167 79 years 60% Female Race NR 9 Years education	NR	N=167 65 years 68% Female Race NR 11 Years education 57% Spouse or partner 29% Daughter	NR	3 months 6 months	NR	MADRS ZBI Caregiver perception of disease understanding Caregiver coping

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	emotion-centered coping strategies, management of PLWD behavior, communication skills, crisis management, resource information and practical advice. Both groups also received antidementia drugs.										
Guerra 2011[43] (20602013) Peru Medium Explanatory	10/66 Caregiver Intervention. Provide education and training on managing problem behaviors. Delivered in 3 modules over 5 30-min weekly sessions.	Waitlist	Home-based RCT N=58	Nonspecified dementia DSM-IV NPI-Q 4.6	N=58 Age 82 72% Female Race NR Education NR	NR	N=58 51 years 88% Female Race NR Education NR 12% Spouse 43% Child	NR	6 months	NPI-Q DEMQOL	ZBI Self-Reporting Questionnaire 20 NPI-Q WHOQOL-BREF
Voight-Radloff 2011[46] (22021760) Voight-Radloff 2011[86] (no PMID) Voight-Radloff 2009[87] (355485226) Germany Low 6-16 weeks Medium 26-52 weeks Explanatory	Community Occupational Therapy in Dementia Program. 10 home visits over 5 weeks by an occupational therapist.	Usual care (one session home consultation)	Home-based RCT N=141 dyads	Alzheimer's disease or mixed-type dementia ICD-10	N=141 78 years 58% Female Race NR 22% High school diploma 77% Less than high school education	NR	N=141 65 years 70% Female Race NR Education NR 57% Spouse or partner 37% Child	NR	6 weeks 16 weeks 26 weeks 52 weeks	Interview for Deterioration in Daily Living Activities in Dementia (IDDD) (performance, initiative) Cornell Scale for Depression in Dementia Perceive, Recall, Plan and Perform System of Task Analysis (PRPP) (independence) Dementia Quality of Life Instrument - overall SF-12 (physical, mental) Number of adverse events Resource	Sense of Competence Questionnaire Center for Epidemiologic Depression Scale Dementia QOL Instrument SF-12 (physical, mental) Resource utilization in Dementia - Basic ADL Care by primary carer (hours per day)

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
										Utilization in Dementia (nights in nursing home, night in hospital)	
Wang 2011[47] (21752121) USA Medium Explanatory	Family Mutual Support Program in Dementia Care (FMSP-DC). 8 2-hour biweekly sessions over 6 months.	Usual care	Home-based N=80 dyads	Alzheimer's disease DSM-IV	N=80 68 years 81% Female Race NR Education NR	NR	N=80 41 years 65% Female Race NR 73% Secondary education 40% Spouse or partner 38% Child	NR	6 months	MMSE (Chinese) PLWD institutionalizations (number, duration)	Family Caregiving Burden Inventory (FCBI) WHOQOL-BREF Six-item Social Support Questionnaire (SSQ6)
Gitlin 2010[49] (20662955) USA Medium Explanatory	Advancing Caregiving Training (ACT) Health professionals helped target behavioral symptoms of dementia, created plan to help caregivers manage 11 home and phone contacts over 4 months	No treatment or contact	Home-based RCT N=272 dyads	MMSE<24	N=272 82 years 53% Female 70% White 30% Nonwhite Education NR	NR	N=272 66 years 82% Female 70% White 30% Nonwhite Education 7% <High school 26% High school degree 67% Higher education 51% Spouse	4 years caregiving	4, 6 months	Frequency of problem behavior being targeted	ZBI CES-D Perceived Change Index Skill enhancement
Martin-Carrasco 2009[54] (18949763) Spain Medium Explanatory	Psychoeducational Intervention Program to teach strategies for confronting problems of PLWD care. 8 sessions over 4 months.	Usual care	Hospital and outpatient clinics N=115 dyads RCT	Alzheimer's disease DSM-IV	N=115 77 years 63% Female Race NR Education NR	NR	N=115 77 years 63% Female Race NR Education NR 55% Spouse or partner 37% Child	12 Hours per day caregiving 3 years caregiving 39% Retired 28% Homemaker 25% Working	4 months 10 months	PLWD Caregiver healthcare and social resources use (number of visits, time spent on medical care)	ZBI Spanish SF-36 GHQ-28 Caregiver healthcare and social resources use (number of visits, time spent on medical care)
Gallagher-Thompson 2008[56] (25067886) USA Medium Explanatory	Coping with Caregiving (CWC). Instruction and practice in small groups to learn specific cognitive and behavioral skills. Weekly 2-	Minimal telephone-based control condition (TSC). Empathetic support via 15-20 min telephone calls every 2 weeks.	Home-based RCT N=184	NR	NR	NR	N=184 58 years 100% Female 52% White 48% Latina 13 Years education 33% Spouse or partner	10 Hours per day caregiving 65% Live with PLWD	6 months	NR	CES-D Perceived Stress Scale (PSS-10) RMBPC-CB (both)

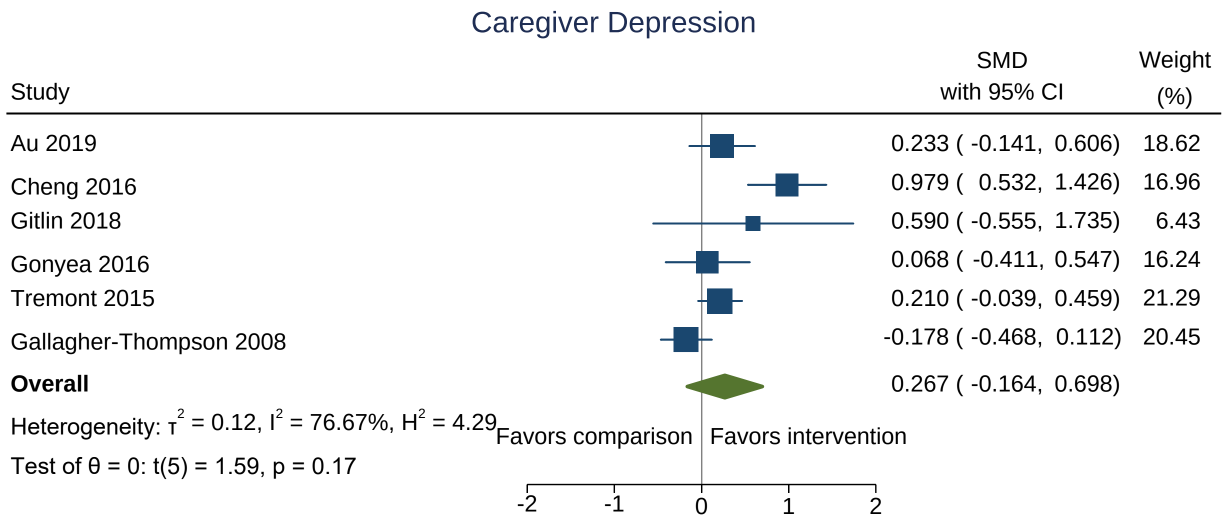
Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	hour sessions over 4 months.										
Graff 2006[60] (17114212) Graff 2008[88] (18171718) Graff 2007[89] (17895439) Netherlands Medium Explanatory	Community based occupational therapy program. 10 sessions over 5 weeks.	Waitlist for occupational therapy	Home-based RCT N=135 dyads	Mild to moderate dementia Diagnosed with DSM-IV	N=135 78 years 56% Female Race NR Education NR	NR	N=135 63 years 70% Female Race NR Education NR 59% Spouse or partner 32% Child	NR	6 weeks 3 months	Assessment of Motor and Process Skills (AMPS) (process) Interview of Deterioration in Daily Activities in Dementia (IDDD) (performance)	Sense of Competence Questionnaire (SCQ)
Farran 2004[62] (41552352) Farran 2007[90] (175) Farran 2004[91] USA Medium Explanatory	Caregiver skill building (CSB) 12 weekly sessions (Five group sessions & 7 individual telephone contacts), 2 group booster sessions & as-needed phone contacts	Information and support group (ISO) Information & support oriented (ISO) group: Routine care-related issues were addressed, but did not include individualized skill enhancement	Home-based RCT N=295	NR	NR	NR	N=295 65 years 83% Female 88% White 62% High school education or less 58% Spouse or partner	NR	18 months	RMPBC Time to institutionalization	CES-D Behavior Management Skill-Revised (BMS-R)
Gallagher-Thompson 2003[66] (12937336) Rabinowitz 2006[92] (16861368) USA Medium Explanatory	Coping With Caregiving psychoeducational program (instruction and practice in small groups to learn specific cognitive and behavioral skills) a) Once a week for the first 10 weeks b) once a month during the ''booster phase'' for the next 8 months.	Enhanced Support Group condition (guided discussion and empathic listening to develop reciprocal support within the group)	Community-based RCT N=213	NR	NR	NR	N=213 57 years 100% Female 57% White 43% Latino 12 years 38% Spouse or partner 62% Child	5 years (mean)	3 months	NR	CES-D Revised Ways of Coping Checklist (RWCCL) (positive, negative) Inventory of Socially Supportive Behaviors (ISSP) (satisfaction, negative interaction) RMBPC

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Gitlin 2001[93] (11220813) USA Medium Explanatory	Home Environmental Intervention Five 90-min home visits by occupational therapists who provided education and physical and social environmental modifications.	Usual care	Home-based RCT N=202 dyads	NR	N=202 78 years 66% Female Race NR Education NR	NR	N=202 61 years 73% Female 74% White 14 years 25% Spouse or partner	100% Living with PLWD	3 months	Functional Independence Measure (modified) (ADL, IADL) MBPC	Caregiver self-efficacy and upset (managing ADL, IADL, behaviors, dependency)

*High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: ADL= Activities of Daily Living; ADSC-ADL= the Alzheimer’s Disease Cooperative Study activities of daily living scale; AMPS= Assessment of Motor and Process Skills; char=characteristics; CAFU= Caregiver Assessment of Function and Upset Scale; CES-D= Center for Epidemiological Studies of Depression scale; CSDD= Cornell Scale for Depression in Dementia; DEMQOL= Dementia Quality of Life measure; DSM-IV= Diagnostic and Statistical Manual of Mental Disorders Fourth edition; EQ-5D= the European Quality of Life-5 Dimensions; EQ-VAS= European quality of life visual analogue scale; FC=formal caregiver; FEERS= Felt Expressed Emotion Rating Scale; GDS== Geriatric Depression Scale; GHQ-28= General Health Questionnaire-28 item version; HADS-T= Hospital Anxiety and Depression Scale Total Score; IADL= Instrumental Activities of Daily Living; IC=informal caregiver; IDDD= Interview of Deterioration in Daily Activities in Dementia; MBPC= Memory and Behavior Problems Checklist; MMSE= Mini-Mental State Examination; N=number; NINCDS-ADRDA= National Institute of Neurological and Communicative Diseases and Stroke/Alzheimer's Disease and Related Disorders Association; NPI-C= Neuropsychiatric Inventory – Clinician; NPI-Q= The brief form of the Neuropsychiatric Inventory; NPI-S= Neuropsychiatric Inventory-Severity scale (Spanish); PMID=PubMed Identification Number; PLWD=Persons with Dementia; QOL-AD= the Quality of Life in Alzheimer’s Disease; RAS= Relationship Assessment Scale; RMBPC= Revised Memory and Behavior Problems Checklist; RSCSE= Revised Scale for Caregiving Self-Efficacy; RoB=Risk of Bias; RS=Reporting Status; Relatives’ Stress Scale (RSS); SCQ= Sense of Competence Questionnaire; SCID-CV=Structured Clinical Interview for Axis 1 Disorders of the DSM-IV; SES=socioeconomic status; SF-12= Short-Form Health Survey 12; SSQ6= Six-item Social Support Questionnaire; STAI-S= State Anxiety Inventory-State (all Spanish); WHOQOL-BREF= World Health Organization Quality of Life Instruments; ZBI= Zarit Burden Interview; ZBI Spanish SF-36= Spanish validated version of the Zarit Caregiver Burden Interview

Appendix Figure E.2 SMD calculated from difference between baseline and FU in intervention minus difference between baseline and FU in comparison group



Appendix Table E.3 Intervention components of psychosocial interventions for informal caregivers

Study (PMID) Intervention & Comparison Country	Duration of Intervention	Interventionist	Dose/Format	Components
Au 2020[1] (no PMID) Intergenerational perspective-taking in-home intervention vs. basic skill building in-home intervention Hong Kong	8 weeks	Therapists	1 40-minute in-home session followed by 7 weekly 35-minute telephone sessions Total hours: 5	Connecting through Caregiving an Intergenerational Perspective-Taking Intervention: discussed the following topics through the lens of intergenerational perspective-taking: self-monitoring mood, scheduling pleasant events, monitoring behavioral problems of PLWD, communicating with PLWD, identifying help, creating implementation plans Basic Skill Building Intervention: discussed the same topics more generally
Au 2019[2] (31279613) Telephone-administered psycho-education with behavioral activation intervention vs. telephone-based psycho-education with general monitoring Hong Kong	20 weeks	Social workers, paraprofessionals	4 weekly individual telephone sessions with social worker followed by 8 biweekly sessions with a paraprofessional, each session lasted approximately 20 minutes Total hours: 4	Behavioral Activation Intervention: Updating recent caregiving situation; Reporting health and needs of CG and CR; Reporting daily routines; Reporting family communication; Activity planning; Review to improve on scheduling; Develop new help-seeking skills; Reviewing to improve communication General Monitoring Intervention: Update caregiving situation: Discuss caregiver's health; Update care giving situation; Discuss care-recipient's needs; Update caregiving situation; Discuss daily/weekly routines; Review support from family/ friends/ agencies;
Bjorge 2019[4] (31651321) Psychosocial intervention vs. usual care Norway	1 year	Nurses, occupational therapists	5 1-hour individual counseling sessions followed by 6 2-hour group meetings Total hours: 17	Psychosocial support intervention: Education about dementia; counselling on problem solving and setting limits; and group sessions Usual care intervention: information on available support
Ghaffari 2019[5] (no PMID) Resilience education group classes vs. usual care Iran	8 weeks	Study researchers	8 weekly 45 minute sessions Total hours: 6	Resilience Education Program: education on Alzheimer's disease, internal supportive factors (self-esteem, optimism, etc), external supportive factors and responsibility, resilience promotion solutions (commitment, control, challenging, coping), problem solving Usual care: received resilience development education after the study finished
Meng 2019[6] (30884961) Telephone based cognitive behavioral therapy vs. in-person cognitive behavioral therapy United States	12 weeks	NR	Telephone based cognitive therapy Dose not reported	Cognitive Behavioral Therapy
Moskowitz 2019[7] (31045422) Life Enhancing Activities for Family Caregivers (LEAF) vs. waitlist control United States	6 weeks	Facilitator discipline not specified	6 weekly live online sessions using a computer tablet	Life Enhancing Activities for Family Caregivers (LEAF): positive emotion regulation skills: noticing positive events; capitalizing on positive events; gratitude; mindfulness, positive reappraisal; personal strengths; setting attainable goals; acts of kindness Waitlist control: completed daily emotion survey for 6 weeks then crossed over to LEAF program.

Study (PMID) **Intervention & Comparison** **Country**	**Duration of Intervention**	**Interventionist**	**Dose/Format**	**Components**
Nordheim 2019[8] (30775982) Couple-based Interdisciplinary Psychosocial Intervention vs. 1-2 hours of memory care consultation Germany	10-12 weeks	Psychotherapist, social worker	7 home-based couples' sessions with two additional telephone sessions	Sessions included information about dementia, couple communication training, coping and problem-solving strategies, network and activity analysis, counseling for living space adaptions, and relaxation techniques Manualized program
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits United States Veterans	NR	Occupational therapists	8 in-home sessions	Customize activities to the interests and abilities of the veterans and educate their caregivers about dementia and use of customized activity.
Voigt-Radloff 2017[94] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Germany	5 weeks	Occupational therapists	10 1-hour in-home sessions Total hours: 10	Evidence-based manual Educating PLWD in the performance of simplified daily activities and in the use of aids to compensate for cognitive decline; and educating carers in coping with behavior of the PLWD and in giving supervision to the PLWD. Content included: (1) The PLWD preferences and history of daily activities; (2) their ability to perform activities and to use compensatory strategies within the familiar environment; (3) the possibilities of modifying the PLWD home; (4) the carer's activity preferences, problems in care giving, coping strategies and abilities to supervise; and (5) the interaction between carer and PLWD. Carer received practical and emotional support and was coached in effective supervision, problem-solving and coping strategies by means of cognitive-behavioral interventions.
Charlesworth 2016[18] (27521377) Carer Supporter Programme (CSP) program vs. Remembering Yesterday Caring Today (RYCT) program England	8 months 10 months	CSP: Volunteer carer supporters RYCT: Unspecified	CSP: 12 one-to-one peer support 1-hour sessions occurring weekly, followed by twice monthly meetings for the next 5 months - Total hours: 22 RYCT: 12 weekly 2-hour sessions followed by 7 months of monthly sessions – 19 sessions over 10 months Total hours: 38	CSP: One-to-One Peer support. Volunteer carer supporters asked to listen, encourage and give moral support. Though they could also signpost to resources and services, we instructed them not to offer tangible support, respite or direct advice. RYCT: Group Reminiscence
Cheng 2016[19] (27401052) Benefit finding intervention vs. simplified lecture only psychoeducation vs. standard psychoeducation Hong Kong	8 weeks	Research Assistants with undergraduate degree in psychology or related field.	8 weekly 2-hour group sessions of 7-11 caregivers Total hours: 16	Benefit finding intervention: Benefit finding, positive reappraisal cognitive techniques; Information on dementia, communication skills, and stress management; causes and coping strategies for BPSD; homebased activities; Skills for helping with ADLs, creating an appropriate home environment for the care recipient, and community resources; goal setting Simplified lecture only psychoeducation Intervention: Lectures and discussions, no practical elements Standard psychoeducation intervention: same benefit finding intervention components excluding dysfunctional thoughts, maintenance cycle, and positive reappraisal
Gonyea 2016[20] (24855313) Circulo de Cuidado, a culturally-sensitive, cognitive behavioral therapy group intervention vs. psychoeducational control condition United States	17 weeks	MSW Social workers bilingual in Spanish	5 weekly 90-minute small group sessions, followed by 10-15-minute individual telephone coaching sessions at 3, 6, 9- and 12-weeks post-group Total hours: 5.5	Culturally-sensitive Cognitive Behavioral Group Intervention; antecedents-behaviors-consequences (A-B-C) problem solving approach to behavior change; relaxation techniques or exercises; increasing engagement in pleasant activities for caregiver and PLWD; improving communication with PLWD; stress management; relaxation techniques; weekly at-home assignments Psychoeducational group control intervention: dementia education; finding community resources; working with physicians; home safety; communication in context of dementia
Laakkonen 2016[21] (27060101) Self-management group rehabilitation Finland	8 weeks	Nurses, Occupational therapists, Physiotherapists	8 weekly 4-hour group sessions Total hours: 32	Group sessions aim to enhance self-efficacy and problem-solving skills and to provide peer support. Self-management capabilities such as problem-solving skills, self-efficacy, and mastery are built gradually during the intervention Usual preferred topics were dementia, medication, nutrition, active lifestyle, marital relationship, caregiving, available social and health services, and advance care planning.

Study (PMID) Intervention & Comparison Country	Duration of Intervention	Interventionist	Dose/Format	Components
Otero 2015[83] (25331992) Cognitive behavioral problem solving vs. usual care Spain	5 weeks	Psychologists	5 1.5-hour group sessions occurring weekly Total hours: 7.5	Cognitive behavioral problem solving group-based program including: problem solving moduel, goal setting, decision making and planning, and relapse prevention.
Tremont 2015[28] (25074341) Family Intervention Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) attention control. United States	6 months	Master's degree prepared therapists with training in dementia and caregiving	16 telephone contacts averaging 36 minutes each Total hours: 9.6	Providing dementia education, emotional support, directing caregivers to appropriate resources, encouraging caregivers to attend to their physical, emotional, and social needs, and teaching caregivers' strategies to cope with ongoing problems.
Livingston 2014[30] (25300037) START (STrAtegies for RelaTives vs. usual care United Kingdom	unspecified	Supervised psychology graduates	8 home-based individual sessions	REACH Palo Alto Coping with Caregiving program modified with fewer sessions and home-based sessions. Coping with Caregiving Manual Individual sessions Topics: Psychoeducation about dementia, carer stress and understanding behaviors, discussion of behaviors or situations the carer finds difficult, incorporating behavioral management, identifying and changing unhelpful thoughts, assertive communication, increasing communication, acceptance, accessing emotional support and positive reframing. future planning, pleasant activities, maintaining skills over time, & stress reduction techniques
Martin-Carrasco 2014[31] (24113563) Group psychoeducational intervention (PIP) vs. usual care Spain	14 weeks	Therapist (unspecified training)	7 90-120-minute group sessions administered biweekly Total hours: 10.5-14 hours	REACH Palo Alto Coping with Caregiving program modified for Latinos living in Spain and group sessions. Modified Martin-Carrasco 2014 intervention from individual to group sessions. Caregivers received standardized information about the clinical course of dementia and were trained on cognitive and behavioral skills and relaxation techniques to increase their care abilities, communicative skills, and emotional control. 7 modules related with strain and well-being, changing maladaptive behaviors, negative thoughts, ways to communicate, planning the future, and planning enjoyable activities.
Waldorff 2012[40] (22807076) Danish Alzheimer's Study (DAISY) vs. control support Denmark	4 months	Nurse trained in counselling approach	Up to 7 counselling sessions including: 2 sessions with the PLWD and care giver; 2 sessions with the PLWD alone; 2 sessions with the care giver alone; and an optional network session with the PLWD, caregiver, and family network. 5 2-hour courses for caregiver 5 2-hour courses for PLWD 5-8 telephone contacts with study coordinator to discuss counselling session and course information.	The counselling was based on a philosophical approach in which each PLWD or care giver was given the possibility of expressing his or her life story and what is of personal importance and of great value. The counsellor offered the participants guidance with common decision making, advice, and activities that help the participants construct a meaningful life. Caregiver courses: formalized education program on Alzheimer's disease, also supported by printed handouts with information on specific topics. PLWD courses: information on key issues of the disease and its consequences supported by printed handouts with information on specific topics.
de Rotrou 2011[42] (20922772) Psych-Educational Program vs. waitlist control group France	12 weeks	Psychologists were group leaders Disease education provided by health professional (geriatrician, psychiatrist, psychologist, social worker, speech therapist, occupational therapist)	12 weekly 2-hour group sessions of 6-10 caregivers Total hours: 24	Education on dementia, problem-solving techniques and emotion-centered coping strategies, management of PLWD behavior, communication skills, crisis management, resource information and practical advice, ecological stimulation - stimulate their relative in daily activities and social situations Waitlist control: PLWD in both groups received cholinesterase-inhibitor pharmacotherapy
Guerra 2011[43] 10/66 Helping Carers to Care vs waitlist control Peru	5 weeks	Junior Psychologists, social workers	5 weekly 30-minute sessions over 5 weeks Total hours: 2.5	Helping carers to care: dementia education, training on managing problem behaviors
Wang 2011[47] (21752121) Family Mutual Support Programme in Dementia Care (FMSP-DC) vs. usual care China	6 months	Psychiatric nurse	8 biweekly 2-hour group sessions Family led Total hours: 16	Community based program addressing (1) information about client's illness, prognosis and current treatment and care; (2) development of social relationships with close relatives and friends and thus a satisfactory extended social support network; (3) sharing and adaptation of emotional impacts of caregiving; (4) learning about self-care and motivation; (5) improvement of interpersonal relationships with family members and the client; (6)establishing support from the community groups and health-care resources; and (7) improvement of problem solving skills in family care.

Study (PMID) **Intervention & Comparison** **Country**	**Duration of Intervention**	**Interventionist**	**Dose/Format**	**Components**
Gitlin 2010[49] (20662955) Advancing Caregiving Training (ACT) vs. no treatment United States	16-week active phase followed by 8-week maintenance phase	Occupational therapists Advanced Practice Nurses	During active phase, up to 9 OT sessions & 2 nursing sessions (one home visit, one telephone visit) During maintenance phase: 3 telephone calls from occupational therapist Total hours: 16	Advanced Caregiver Training (ACT): identification of PLWD unmet needs, discomfort, & medical problems, caregiver skill building, problem solving, and communication building, caregiver stress reduction & self-care techniques, environmental modifications & provision of low-cost assistive devices No treatment control group
Martin-Carrasco 2009[54] (18949763) Psychoeducational Intervention Program (PIP) vs. usual care Spain	4 months	Clinical psychologist, nurse or social worker	8 individual 90-minute sessions at 1-2-week intervals over 4 months Total hours: 12	REACH Palo Alto Coping with Caregiving program modified for Latinos living in Spain. Structured psycho-educational-type psychosocial intervention program Skills training: (a) to help the caregiver control tension and stress deriving from caregiving; (b) to teach the caregiver different strategies for handling their relative's behavioral problems; and (c) to increase their satisfaction with life.
Gallagher-Thompson 2008[56] (25067886) Coping with Caregiving vs. Minimal telephone-based control condition United States	13-16 weeks	Post-doctoral fellows or advanced graduate students in psychology or related fields who had relevant bilingual/bicultural backgrounds. 2 Interventionists led each session	Weekly 2-hour group sessions of 4-8 female caregivers. Total hours: 26-32	REACH Palo Alto Coping with Caregiving Program updated (Gallagher-Thompson 2003 (12937336)) Coping with Caregiving: cognitive behavioral therapy to develop cognitive and behavioral skills to reduce stress and depression; education about dementia, helpful techniques for managing care recipient's problem behaviors; skills to take better care of the caregiver, including changing unhelpful thoughts, increasing assertive communication, and identifying everyday pleasant activities (both for self and shared with care recipient); planning for the care-recipient's future needs; develop action plan for future Minimal telephone-based control intervention: Individual sessions of empathic support (7 biweekly calls lasting 15-20 minutes)
Graff 2006[60] (17114212) Community based occupational therapy program vs. Waitlist for occupational therapy The Netherlands	5 weeks	Occupational therapists	10 1-hour sessions with caregiver and PLWD Total hours: 10	Cognitive and behavioral interventions, to train PLWD in the use of aids to compensate for cognitive decline and care givers in coping behaviors and supervision Diagnostics and goal defining, PLWD and primary care givers learnt to choose and prioritize meaningful activities they wanted to improve optimize these compensatory and environmental strategies to improve their performance of daily activities
Farran 2004[62] (41552352) Caregiver Skill (CSB) intervention vs. Information and Support Oriented (ISO) Intervention United States	1 year	Nurses, social workers	12 weekly sessions consisting of 5 group sessions and 7 individual telephone contact sessions; Followed with 2 booster sessions at 6 and 12 months and as needed telephone sessions.	CSB: Improve caregiver skill in managing behavioral symptoms. 5 major topics: introduction to CSB conceptual model, potential causes and contributing factors to behavioral symptoms, prevention of behavior during cares, management of restless behaviors, management of hallucinations and delusions. ISO: Standardized implementation of psychoeducational methods, generalized information and support, no individualized behavioral symptom management. 5 topics: understanding dementia, dealing with difficult behaviors, providing personal care, caring for the caregivers, and finding/using help.
Gallagher-Thompson 2003[66] (12937336) Coping with Caregiving vs. Enhanced support group condition United States	120 weeks (10 months)	Psychologists, social workers or other helping professionals, and predoctoral or postdoctoral psychology and social work graduate students	First 10 weeks used 2-hour group sessions of 7-9 female caregivers followed by 8 monthly booster sessions. Total hours: 28	Both programs were tailored to be sensitive to the cultural concerns of Anglo and Latino caregivers, and they were delivered in either English or Spanish by trained interventionists. REACH Palo Alto Coping with Caregiving Group: dementia education, cognitive–behavioral mood management skills Enhanced Support Group: dementia education, guided discussion, empathic listening
Gitlin 2001[93] (11220813) Home Environmental Intervention vs. usual care United States	3 months	Occupational therapists	5 90-minute home visits occurring every other month Total hours: 7.5	Education and physical and social environmental modifications. Dementia education; Education on daily care needs specified by caregiver; role-play, direct observation, and interviewing to problem solve; Problem solving; Environmental simplification and task breakdown strategies

Abbreviations: PLWD=person with dementia

Appendix Table E.4. PLWD outcomes summary low and medium risk of bias studies: Psychosocial Interventions for Caregiver Well-being

Study (PMID) **Comparison** **RoB** **Category*** **Country**	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Bjorge 2019[4] (31651321) Psychosocial intervention vs. usual care Medium Explanatory Norway	Between-group differences as estimated regression coefficient (95% CI) PLWD Cognition: MMSE 12 weeks	−0.78 (−1.78 to 0.22)	NR	NR	0.12
Bjorge 2019[4] (31651321) Psychosocial intervention vs. usual care Medium Explanatory Norway	Between-group differences as estimated regression coefficient (95% CI) PLWD neuropsychiatric symptoms: Neuropsychiatric Inventory (NPI-Q) 12 weeks	−0.29 (−0.83 to 0.26)	NR	NR	0.31
Bjorge 2019[4] (31651321) Psychosocial intervention vs. usual care Medium Explanatory Norway	Between-group differences as estimated regression coefficient (95% CI) PLWD function IADL: Lawton & Brody's IADL 12 weeks	0.48 (−0.73 to 1.69)	NR	NR	0.44
Bjorge 2019[4] (31651321) Psychosocial intervention vs. usual care Medium Explanatory Norway	Between-group differences as estimated regression coefficient (95% CI) PLWD depression: Cornell scale for depression in dementia. 12 weeks	0.34 (−0.81 to 1.49)	NR	NR	0.57
Bjorge 2019[4] (31651321) Psychosocial intervention vs. usual care Medium Explanatory Norway	N (percent) PLWD nursing home placement 12 months	NR	24 (22.9%)	23 (22.3%)	NR
Moskowitz 2019[7] (31045422) Life Enhancing Activities for Family Caregivers (LEAF) vs. waitlist control Medium Explanatory USA	Cohen's d (95% CI) Mean (SE) PLWD cognition: Dementia Severity Rating Scale 6 weeks	-0.03 (-0.33, 0.27)	23.12 (1.07) baseline 23.42 (1.09) 6 weeks	22.49 (1.09) baseline 23.06 (1.10) 6 weeks	Interaction 0.71
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care Medium Explanatory Germany	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months PLWD quality of life: Quality of Life in Alzheimer's Disease (QOLAD) 6 months	Cohens d = –0.4	36.7 (0.8) baseline 34.7 (0.8) 6 months	37.2 (0.8) baseline 36.4 (0.9) 6 months	Interaction NS
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care Medium Explanatory Germany	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months PLWD ADL: 6 months	Cohens d = 0.1	90.5 (2.1) baseline 86.3 (2.3) 6 months	87.1 (2.2) baseline 83.7 (2.4) 6 months	Interaction $p > 0.05$
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care Medium Explanatory Germany	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months PLWD IADL: 6 months	Cohens d = 0.1	5.3 (0.3) baseline 4.2 (0.3) 6 months	4.9 (0.3) baseline 3.9 (0.3) 6 months	Interaction $p > 0.05$
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care Medium Explanatory Germany	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months PLWD function: Older Adults Overprotection Scale (OPSA) 6 months	Cohens d = 0.1	39.5 (0.8) baseline 39.1 (0.8) 6 months	38.8 (0.8) baseline 38.8 (0.9) 6 months	Interaction NS
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care Medium Explanatory Germany	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months PLWD depressive symptoms: Geriatric depression scale (GDS) 6 months	Cohens d = 0.0	5.6 (0.3) baseline 5.9 (0.3) 6 months	5.4 (0.3) baseline 5.0 (0.3) 6 months	Interaction NS

Study (PMID) **Comparison** **RoB** **Category*** **Country**	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care Medium Explanatory Germany	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months PLWD cognition: MMSE 6 months	Cohens d = 0.4	23.0 (0.6) baseline 21.6 (0.7) 6 months	22.7 (0.7) baseline 19.6 (0.8) 6 months	Interaction p < 0.05
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care Medium Explanatory Germany	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months PLWD social support: (F-SOZU) 6 months	Cohens d = -0.1	54.8 (1.4) baseline 54.0 (1.3) 6 months	54.1 (1.4) baseline 55.1 (1.4) 6 months	Interaction NS
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) PLWD neuropsychiatric symptoms: Neuropsychiatric Inventory – Clinician (NPI-C) -number of behavioral symptoms 4 months	-0.68 (-1.23; -0.13)	NR	NR	0.02
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) PLWD neuropsychiatric symptoms: Neuropsychiatric Inventory – Clinician (NPI-C) 4 months	-24.3 (-45.6; -3.1)	NR	NR	0.02
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) PLWD function ADL/IADL: Caregiver Assessment of Function and Upset Scale (CAFU) - number of ADL/IADL dependencies subscale 4 months	-0.80 (-1.41; -0.20)	NR	NR	0.009
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) PLWD function ADL/IADL: Caregiver Assessment of Function and Upset Scale (CAFU) - level of ADL/IADL dependence (total) 4 months	4.09 (1.06; 7.13)	NR	NR	**0.009**
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) PLWD QOL: affect (caregiver perception) 4 months	0.47 (-1.37; 0.43)	NR	NR	0.30
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) PLWD function ADL: Caregiver Assessment of Function and Upset Scale (CAFU) - number of ADL dependencies subscale 4 months	-0.61 (-1.08; -0.14)	NR	NR	0.01
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) PLWD function IADL: Caregiver Assessment of Function and Upset Scale (CAFU) - number of IADL dependencies subscale 4 months	-0.25 (-0.54; 0.04)	NR	NR	0.09
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) PLWD function ADL: Caregiver Assessment of Function and Upset Scale (CAFU) - level of ADL dependence subscale 4 months	2.37 (0.32; 4.42)	NR	NR	0.02
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI)PLWD function IADL: Caregiver Assessment of Function and Upset Scale (CAFU) - level of IADL dependence subscale 4 months	1.57 (0.05; 3.08)	NR	NR	0.04

Study (PMID) Comparison RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Tremont 2017[84] (28008609) companion to Tremont 2015 (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) PLWD health care use: Number of monthly emergency department visits during intervention 6 months	NR	0.08 (0.16)	0.08 (0.17)	0.83
Tremont 2017[84] (28008609) companion to Tremont 2015 (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) PLWD health care use: Number of monthly doctor visits during intervention 6 months	NR	1.32 (1.35)	1.30 (1.05)	0.88
Tremont 2017[84] (28008609) companion to Tremont 2015 (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) PLWD community support use: Number of community support services used in final month of intervention 6 months	NR	6.79 (13.72)	5.11 (10.68)	0.34
Tremont 2017[84] (28008609) companion to Tremont 2015 (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Frequency (%) PLWD nursing home admission: number of PLWD admitted to nursing home during the intervention	12 (6%)	NR	NR	0.70 (no group difference)
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for CSP vs other 2 groups PLWD Health related quality of life: QOL-AD self-reported 12 months	−0.162 (−1.87 to 1.54)	Means reported	Means reported	0.85
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for RYCT vs other 2 groups PLWD Health related quality of life: QOL-AD self-reported 12 months	0.702 (−1.05 to 2.45)			0.43
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for CSP vs other 2 groups PLWD Health related quality of life: QOL-AD proxy reported 12 months	0.050 (−1.21 to 1.31)			0.94
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for RYCT vs other 2 groups PLWD Health related quality of life: QOL-AD proxy reported 12 months	0.0660 (−1.17 to 1.30)			0.92
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for CSP vs other 2 groups PLWD function: Alzheimer's Disease Cooperative Study—Activities of Daily Living 12 months	−2.18 (−6.07 to 1.71)			0.27

Study (PMID) **Comparison** **RoB** **Category*** **Country**	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for RYCT vs other 2 groups PLWD function: Alzheimer's Disease Cooperative Study—Activities of Daily Living 12 months	−2.45 (−5.95 to 1.06)			0.17
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for CSP vs other 2 groups PLWD neuropsychiatric symptoms: neuropsychiatric inventory (NPI) 12 months	−1.20 (−6.64 to 4.23)			0.66
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for RYCT vs other 2 groups PLWD neuropsychiatric symptoms: neuropsychiatric inventory (NPI) 12 months	0.236 (−4.83 to 5.30)			0.93
Gonyea 2016[20] (24855313) Circulo de Cuidado, a culturally-sensitive, cognitive behavioral (CBT) group intervention vs. psychoeducational (PED) control condition Medium Explanatory USA	Mean (SD) PLWD neuropsychiatric symptoms: Spanish version of the Neuropsychiatric Inventory-Severity scale (NPI-S) 12 week 24 week	NR	21.70 (6.90) baseline 20.67 (6.94) 12 weeks 20.52 (6.98) 24 weeks	21.76 (7.98) baseline 22.03 (9.10) 12 weeks 22.09 (8.46) 24 weeks	Repeated measures ANCOVA <0.001
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium Explanatory Finland	Adjusted Mean change (95% CI) PLWD quality of life: 15D 9 months	d=NR	-0.03 (-0.0 to -0.01)	-0.04 (-0.05 to -0.02)	0.55
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium Explanatory Finland	Adjusted Mean change (95% CI) PLWD cognition: Verbal Fluency (VF) 3 months	d=NR	0.26 (-0.38 to 0.91)	-0.60 (-1.26 to 0.07)	0.07
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium Explanatory Finland	Adjusted Mean change (95% CI) PLWD cognition: Verbal Fluency (VF) 9 months	d=NR	-0.38 (-1.03 to 0.27)	-1.60 (-2.26 to -0.94)	0.01
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium Explanatory Finland	Adjusted Mean change (95% CI) PLWD cognition: Clock Drawing Test (CDT) 3 months	d=NR	0.22 (-0.13 to 0.58)	-0.18 (-0.55 to 0.18)	0.12
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium Explanatory Finland	Adjusted Mean change (95% CI) PLWD cognition: Clock Drawing Test (CDT) 9 months	d = 0.28	-0.11 (-0.46 to 0.25)	-0.65 (-1.02 to -0.30)	0.03
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium	Adjusted Mean cost in € per year (95% CI) PLWD Health & social services cost: 24 months	-436 (-4,986; 4,115)	8,947 (6,455–12,415)	9,383 (6,398–13,374)	.035

Study (PMID) Comparison RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Explanatory Finland					
Livingston 2014[30] (25300037) START (STrAtegies for RelaTives) manual-based coping strategy programme in promoting the mental health of carers of people with dementia vs. usual care Low Explanatory UK	Adjusted mean difference (95% CI) PLWD QOL: (QOL-AD) 2 years	0.17 (–1.37 to 1.70)	NR	NR	NR
Waldorff 2012[40] (22807076) DAISY plus support (multifaceted and semi-tailored counselling, education, and support) vs. support control group Medium Explanatory Denmark	Mean change score (95% CI) PLWD QOL: European quality of life visual analogue scale (EQ-VAS) score 12 months	NR	−0.31 (−3.41 to 2.79)	0.20 (−2.31 to 2.71)	0.7799
Waldorff 2012[40] (22807076) DAISY plus support (multifaceted and semi-tailored counselling, education, and support) vs. support control group Medium Explanatory Denmark	Mean change score (95% CI) PLWD cognition: MMSE 12 months	NR	−1.55 (−2.19 to −0.91)	−1.80 (−2.56 to −1.04)	0.6502
Waldorff 2012[40] (22807076) DAISY plus support (multifaceted and semi-tailored counselling, education, and support) vs. support control group Medium Explanatory Denmark	Mean change score (95% CI) PLWD depression: Cornell depression scale 12 months	NR	−0.20 (−1.04 to 0.64)	1.38 (0.49 to 2.27)	0.0103
Waldorff 2012[40] (22807076) DAISY plus support (multifaceted and semi-tailored counselling, education, and support) vs. support control group Medium Explanatory Denmark	Mean change score (95% CI) PLWD QOL: proxy rated European quality of life visual analogue scale (EQ-VAS) (proxy rated) score 12 months	NR	−3.88 (−7.38 to −0.37)	−6.83 (−10.10 to −3.56)	0.2308
Waldorff 2012[40] (22807076) DAISY plus support (multifaceted and semi-tailored counselling, education, and support) vs. support control group Medium Explanatory Denmark	Mean change score (95% CI) PLWD QOL: European quality of life visual analogue scale EQ VAS (PLWD rated) 12 months	NR	0.73 (−2.41 to 3.88)	−4.20 (−8.29 to −0.11)	0.0667
Waldorff 2012[40] (22807076) DAISY plus support (multifaceted and semi-tailored counselling, education, and support) vs. support control group Medium Explanatory Denmark	Mean change score (95% CI) PLWD WOL: Quality of life scale for Alzheimer's disease QoL-AD (PLWD rated) 12 months	NR	−0.82 (−1.77 to 0.12)	−1.04 (−2.04 to −0.04)	0.7213
Waldorff 2012[40] (22807076) DAISY plus support (multifaceted and semi-tailored counselling, education, and support) vs. support control group Medium Explanatory Denmark	Mean change score (95% CI) PLWD QOL: quality of life scale for Alzheimer's disease QoL-AD (proxy rated) 12 months	NR	−0.82 (−1.77 to 0.12)	−2.61 (−3.58 to −1.64)	0.0013
Waldorff 2012[40] (22807076) DAISY plus support (multifaceted and semi-tailored counselling, education, and support) vs. support control group Medium Explanatory Denmark	Mean change score (95% CI) PLWD neuropsychiatric symptoms: neuropsychiatric inventory questionnaire NPI-Q 12 months	NR	0.85 (0.16 to 1.53)	0.43 (−0.26 to 1.13)	0.4045

Study (PMID) Comparison RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Waldorff 2012[40] (22807076) DAISY plus support (multifaceted and semi-tailored counselling, education, and support) vs. support control group Medium Explanatory Denmark	Mean change score (95% CI) PLWD function: Alzheimer's Disease Cooperative Study activities of daily living scale. ADSC-ADL 12 months	NR	−6.39 (−8.51 to -4.27)	−4.63 (−6.92 to −2.53)	0.2689
Guerra 2011[43] 10/66 Helping Carers to Care vs waitlist control Medium Explanatory Peru	Standardized Mean Difference (95% CI) PLWD neuropsychiatric symptoms: Neuropsychiatric Inventory brief form (NPI-Q) 6 months	-0.05 (-0.59 to .52)	NR	NR	NR
Guerra 2011[43] 10/66 Helping Carers to Care vs waitlist control Medium Explanatory Peru	Mean change (SD) PLWD neuropsychiatric symptoms: Neuropsychiatric Inventory brief form (NPI-Q) 6 months	NR	-1.7 (3.3)	-1.6 (206)	0.87
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	Mean difference (95% CI) PLWD function: Interview for Deterioration in Daily Living Activities in Dementia (IDDD) – performance subscale 52 weeks	-2.4 (-7.1; 2.3)	NR	NR	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	Mean difference (95% CI) PLWD function: Interview for Deterioration in Daily Living Activities in Dementia (IDDD) – initiative subscale 52 weeks	-1.0 (-5.0; 3.0)	NR	NR	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	Mean difference (95% CI) PLWD depression: Cornell Scale for Depression in Dementia 52 weeks	-2.0 (-5.1; 1.0)	NR	NR	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	Mean difference (95% CI) PLWD function: Perceive, Recall, Plan and Perform System of Task Analysis (PRPP)– independence subscale 26 weeks	3.3 (-8.3; 14.9)	NR	NR	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	Mean difference (95% CI) PLWD QOL: Dementia Quality of Life Instrument - overall 26 weeks	0.2 (-0.1; 0.5)	NR	NR	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	Mean difference (95% CI) PLWD QOL: Short-Form 12 Health Survey Questionnaire -Physical component 26 weeks	3.0 (-1.6; 7.6)	NR	NR	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation)	Mean difference (95% CI) PLWD QOL: Short-Form 12 Health Survey	-0.8 (-4.9; 3.3)	NR	NR	NS

Study (PMID) Comparison RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Medium 26-52 weeks Explanatory Germany	Questionnaire – mental component 26 weeks				
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	N PLWD harms: number of adverse events 52 weeks	NR	0	0	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	N PLWD nursing home: Resource Utilisation in Dementia, nights in nursing home (except respite care) 52 weeks	NR	2	1	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	N PLWD hospitalization: Resource Utilisation in Dementia, nights in hospital 52 weeks	NR	14 PLWD were admitted to hospital for an average of 15 nights	10 PLWD were admitted to hospital for an average of 18 nights.	0.1
Wang 2011[47] (21752121) Family Mutual Support Program in Dementia Care (FMSP-DC) vs. usual care Medium Explanatory USA	Mean (SD) baseline Mean (SD) 6 months PLWD cognition: MMSE (Chinese) 6 months	NR	17.5 (4.7) baseline 18.1 (4.0) 6 months	17.3 (3.9) baseline 17.2 (4.1) 6 months	NS
Wang 2011[47] (21752121) Family Mutual Support Program in Dementia Care (FMSP-DC) vs. usual care Medium Explanatory USA	Mean (SD) baseline Mean (SD) 6 months PLWD institutionalization: Number 6 months	NR	5.1 (0.9) baseline 3.8 (1.0) 6 months	5.5 (1.2) baseline 5.2 (1.3) 6 months	<0.01
Wang 2011[47] (21752121) Family Mutual Support Program in Dementia Care (FMSP-DC) vs. usual care Medium Explanatory USA	Mean (SD) baseline Mean (SD) 6 months PLWD institutionalization: duration 6 months	NR	13.8 (4.0) baseline 10.1 (5.1) 6 months	14.2 (3.8) baseline 17.9 (7.1) 6 months	<0.001
Gitlin 2010[49] (20662955) Advancing Caregiver Training (ACT) vs. no treatment control Medium Explanatory USA	Percentage reporting improvement in problem behavior PLWD neuropsychiatric symptoms: number of problem behaviors 4 months	NR	67.5	45.8	0.002
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Frequency (percent) PLWD Caregiver healthcare and social resources use: number of visits 4 months	NR	0 visits: 29/44 (66%) 1-2 visits: 13/44 (36%)	0 visits: 25/38 (66%) 1-2 visits: 13/38 (36%)	NR (NS)
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean (SD) PLWD Caregiver healthcare and social resources use: time spent on medical care 4 months	NR	28.5 (25.5)	21.8 (11.0)	NR
Graff 2006[60] (17114212) Community based occupational therapy program vs. Waitlist for occupational therapy	Adjusted Mean difference (95% CI) Effect size Number needed to treat	1.5 (1.3; 1.7) 2.5	NR	NR	<0.0001

Study (PMID) Comparison RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Medium Explanatory	PLWD function: Assessment of Motor and Process Skills (AMPS) – process subscale 6 weeks	1.3 (1.2 to 1.4) NNT			
Graff 2006[60] (17114212) Community based occupational therapy program vs. Waitlist for occupational therapy Medium Explanatory	Adjusted Mean difference (95% CI) PLWD function: Interview of Deterioration in Daily Activities in Dementia (IDDD) – performance subscale 6 weeks	- 11.7 (-13.6; -9.7) 2.3 1.5 (1.4 to 1.6) NNT	NR	NR	<0.0001
Graff 2006[60] (17114212) Graff 2007[89] (17895439) Community based occupational therapy program vs. Waitlist for occupational therapy Medium Explanatory	Adjusted treatment difference (95% CI) Effect size Mean (SD) PLWD quality of life: Dementia Quality of Life Instrument 6 weeks	0.8 (0.6 to 1.1) 1.3 (effect size)	4.0 (0.6)	3.1 (0.8)	< 0.0001
Graff 2006[60] (17114212) Community based occupational therapy program vs. Waitlist for occupational therapy Medium Explanatory	Adjusted treatment difference (95% CI) Effect size Mean (SD) PLWD depression: Cornell scale for depression 6 weeks	-2.8 (-4.3 to -1.3) 0.7 effect size	6.5 (5.3)	9.2 (6.4)	< 0.0001
Farran 2004[62] (41552352) Caregiver skill building (CSB) vs. Information and support group (ISO) Medium Explanatory USA	Regression coefficient (SE) PLWD neuropsychiatric symptoms: Revised Memory and Problem Behavior Checklist (RMPBC) 18 months	-0.046 (0.035)	NR	NR	0.193
Farran 2004[62] (41552352) Caregiver skill building (CSB) vs. Information and support group (ISO) Medium Explanatory USA	Log rank from lifetable PLWD Time to institutionalization 18 months	0.11, df=1	NR	NR	p>0.75
Gitlin 2001[93] (11220813) Home Environmental Intervention vs. usual care Medium Explanatory USA	Adjusted mean difference (95% CI) Mean (SD) baseline Mean (SD) 3 month PLWD function ADL: Functional Independence Measure (modified) ADL subscale 3 months	-0.06 (-0.30 to 0.18)	2.93 (1.49) baseline 3.24 (1.59) 3 months	3.23 (1.36) baseline 3.57 (1.38) 3 months	0.599
Gitlin 2001[93] (11220813) Home Environmental Intervention vs. usual care Medium Explanatory USA	Adjusted mean difference (95% CI) Mean (SD) baseline Mean (SD) 3 month PLWD function IADL: Functional Independence Measure (modified) IADL subscale 3 months	-0.13 (-0.24 to -0.01)	5.43 (.62) baseline 5.54 (.60) 3 months	5.56 (.50) baseline 5.75 (.36) 3 months	0.030
Gitlin 2001[93] (11220813) Home Environmental Intervention vs. usual care Medium Explanatory USA	Adjusted mean difference (95% CI) Mean (SD) baseline Mean (SD) 3 month PLWD neuropsychiatric symptoms: Memory and Behavior Problems Checklist (MBPC) 3 months	1.85 (-0.42 to 4.13)	20.25 (5.39) baseline 17.20 (7.73) 3 months	18.74 (6.31) baseline14.43 (9.82) 3 months	0.110

Abbreviations: ADL= Activities of Daily Living; CI= Confidence Interval; IADL= Instrumental Activities of Daily Living; MMSE= Mini-Mental State Examination; NR=Not Reported; PMID=PubMed Identification Number; QOL-AD= the Quality of Life in Alzheimer's; SD= Standard Deviation; SE= Standard Error

Appendix Table E.5. Caregiver outcomes summary low and medium risk of bias studies: Psychosocial interventions for Caregiver Well-being

Study (PMID) Comparison Caregiver Type RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Au 2020[1] (no PMID) Intergenerational perspective-taking in-home intervention vs. basic skill building in-home intervention Low Explanatory Hong Kong	Mean (SD) Caregiver life satisfaction: Satisfaction With Life Scale 8 weeks	NR	17.20 (3.79) baseline 23.46 (5.90) 8 weeks	18.09 (4.98) baseline 19.66 (5.62) 8 weeks	p<0.001
Au 2020[1] (no PMID) Intergenerational perspective-taking in-home intervention vs. basic skill building in-home intervention Low Explanatory Hong Kong	Mean (SD) Caregiver depression: Center for Epidemiological Studies-Depression (CESD) 8 weeks	NR	15.97 (4.02) baseline 10.76 (4.34) 8 weeks	15.02 (3.53) baseline 13.34 (3.76) 8 weeks	p<0.001
Au 2020[1] (no PMID) Intergenerational perspective-taking in-home intervention vs. basic skill building in-home intervention Low Explanatory Hong Kong	Mean (SD) Caregiver burden: Zarit Burden Interview 8 weeks	NR	23.32 (7.49) baseline 16.30 (7.14) 8 weeks	22.83 (6.66) baseline 21.14 (6.14) 8 weeks	p<0.001
Au 2019[2] (31279613) Telephone-administered psycho-education with behavioral activation intervention vs. telephone-based psycho-education with general monitoring Low Explanatory Hong Kong	Cohen's d (95% CI) Mean (SD) Caregiver depression: Center for Epidemiological Studies-Depression (CESD) 20 weeks	-0.66 (-1.04, -0.74)	13.29 (7.63) baseline 8.62 (8.53) 20 months	13.92 (9.05) baseline 15.55 (11.35) 20 months	p<0.001
Au 2019[2] (31279613) Telephone-administered psycho-education with behavioral activation intervention vs. telephone-based psycho-education with general monitoring Low Explanatory Hong Kong	Cohen's d (95% CI) Mean (SD) Caregiver burden: Zarit Burden Interview 20 weeks	-1.14 (-1.54. -0.75)	32.26 (17.43) baseline 21.82 (14.06) 20 months	29.47 (17.06) baseline 37.47 (17.28) 20 months	p<0.001
Au 2019[2] (31279613) Telephone-administered psycho-education with behavioral activation intervention vs. telephone-based psycho-education with general monitoring Low Explanatory Hong Kong	Cohen's d (95% CI) Mean (SD) Caregiver satisfaction with relationship with care recipient: Relationship Assessment Scale (RAS) 20 weeks	0.44 (0.82, 0.07)	27.78 (5.90) baseline 30.05 (4.79) 20 months	27.41 (5.86) baseline 27.60 (6.08) 20 months	p = 0.01
Au 2019[2] (31279613) Telephone-administered psycho-education with behavioral activation intervention vs. telephone-based psycho-education with general monitoring Low Explanatory Hong Kong	Cohen's d (95% CI) Mean (SD) Caregiver : self-efficacy for controlling upsetting thoughts 5 item 20 weeks	0.86 (1.24, 0.46)	36.08 (8.03) baseline 40.15 (9.02) 20 months	33.58 (10.03) baseline 34.05 (10.07) 20 months	p<0.01
Kunik 2020[3] (32115311) Unmet Needs Psychosocial vs education and information support Low Explanatory United States	Cohen's d (95% CI) Mean (SD) 3 months	-6.9 (2.32, 0.78)	NR	NR	p=0.27
Bjorge 2019[4] (31651321) Psychosocial intervention vs. usual care Medium	Between-group differences as estimated regression coefficient (95% CI)	1.12 (−1.23 to 3.48)	NR	NR	0.35

Study (PMID) Comparison Caregiver Type RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Explanatory Norway	Caregiver stress: Relatives' Stress Scale (RSS) 12 months				
Bjorge 2019[4] (31651321) Psychosocial intervention vs. usual care Medium Explanatory Norway	Between-group differences as estimated regression coefficient (95% CI) Caregiver depression: Geriatric Depression Scale (GDS) 12 months	1.70 (0.41 to 3.0)	NR	NR	0.01
Bjorge 2019[4] (31651321) Psychosocial intervention vs. usual care Medium Explanatory Norway	Between-group differences as estimated regression coefficient (95% CI) Caregiver emotions: Felt Expressed Emotion Rating Scale (FEERS) 12 months	0.36 (−0.62 to 1.34)	NR	NR	0.47
Ghaffari 2019[5] (no PMID) Resilience education group classes vs. usual care Medium Explanatory Iran	Mean difference (SD) Quality of life: General Health Questionnaire 28 item (GHQ-28) 8 weeks		39.9 (8.4) baseline 16.08 (3.7) 8 weeks	32.0 (7.0) baseline 32.9 (7.2) 8 weeks	p<0.001
Meng 2019[6] (30884961) Telephone based cognitive behavioral therapy vs. in-person cognitive behavioral therapy Medium Explanatory USA	Mean (SD) Caregiver health service use: physician office visits 3 months	NR	3.6 (2.9) baseline 2.9 (2.6) 3 months	2.4 (3.1) baseline 3.6 (4.3) 3 months	NS
Meng 2019[6] (30884961) Telephone based cognitive behavioral therapy vs. in-person cognitive behavioral therapy Medium Explanatory USA	Mean (SD) Caregiver health service use: mental health visits 3 months	NR	1.7 (0.6) baseline 2 (0) 3 months	0.1 (0.3) baseline 1.5 (.7) 3 months	NS
Meng 2019[6] (30884961) Telephone based cognitive behavioral therapy vs. in-person cognitive behavioral therapy Medium Explanatory USA	Mean (SD) Caregiver health service use: prescription medication 3 months	NR	3.5 (2.2) baseline 3.5 (2.5) 3 months	3.5 (3.1) baseline 4.1 (2.6) 3 months	NS
Meng 2019[6] (30884961) Telephone based cognitive behavioral therapy vs. in-person cognitive behavioral therapy Medium Explanatory USA	Mean (SD) Caregiver health service use: ER visits 3 months	NR	1.8 (1.2) baseline 1.6 (0.9) 3 months	0.1 (0.5) baseline 1.2 (0.4) 3 months	NS
Meng 2019[6] (30884961) Telephone based cognitive behavioral therapy vs. in-person cognitive behavioral therapy Medium Explanatory USA	Mean (SD) Caregiver health service use: hospital days 3 months	NR	1.4 (0.9) baseline 3 (1.4) 3 months	0.1 (0.8) baseline 3.3 (1.5) 3 months	NS
Meng 2019[6] (30884961) Telephone based cognitive behavioral therapy vs. in-person cognitive behavioral therapy Medium Explanatory USA	Mean (SD) Caregiver health service use: out of pocket expenditures in dollars 3 months	NR	104.9 (94.4) baseline 216.3 (504.3) 3 months	41 (72.7) baseline 191.7 (228.8) 3 months	NS
Meng 2019[6] (30884961) Telephone based cognitive behavioral therapy vs. in-person cognitive behavioral therapy Medium Explanatory USA	Mean (SD) Caregiver health service use: total monthly expenditures in dollars 3 months	NR	1019.9 (1412.1) baseline 883.2 (749.5) 3 months	844 (1851) baseline 768.9 (661.2) 3 months	NS
Moskowitz 2019[7] (31045422) Life Enhancing Activities for Family Caregivers (LEAF) vs. waitlist control Medium	Cohen's d (95% CI) Mean (SE)	-.25 (-.55, .06)	65.85 (2.02) baseline 55.18 (2.08) 6 weeks	65.62 (2.04) baseline 59.65 (2.15) 6 weeks	Interaction 0.02

Study (PMID) Comparison Caregiver Type RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Explanatory USA	Caregiver depression: PROMIS depressive symptoms scale 6 weeks				
Moskowitz 2019[7] (31045422) Life Enhancing Activities for Family Caregivers (LEAF) vs. waitlist control Medium Explanatory USA	Cohen's d (95% CI) Mean (SE) Caregiver mental health: PROMIS mental health scale 6 weeks	0.21 [-.09, .52]	37.4 (4.10) baseline 39.8 (4.10) 6 weeks	39.8 (4.10) baseline 39.8 (4.10) 6 weeks	Interaction 0.49
Moskowitz 2019[7] (31045422) Life Enhancing Activities for Family Caregivers (LEAF) vs. waitlist control Medium Explanatory USA	Cohen's d (95% CI) Mean (SE) Caregiver physical health: PROMIS physical health scale 6 weeks	0.24 [-.07, .54]	42.3 (4.20) baseline 44.9 (4.30) 6 weeks	44.9 (4.30) baseline 44.9 (4.30) 6 weeks	Interaction 0.03
Moskowitz 2019[7] (31045422) Life Enhancing Activities for Family Caregivers (LEAF) vs. waitlist control Medium Explanatory USA	Cohen's d (95% CI) Mean (SE) Caregiver anxiety: Quality of Life in Neurological Disorders (NeuroQOL) anxiety measure 6 weeks	-0.32 [-.63, -.02]	52.15 (1.63) baseline 44.64 (1.68) 6 weeks	51.38 (1.65) baseline 48.91 (1.76) 6 weeks	Interaction .009
Moskowitz 2019[7] (31045422) Life Enhancing Activities for Family Caregivers (LEAF) vs. waitlist control Medium Explanatory USA	Cohen's d (95% CI) Mean (SE) Caregiver burden: Zarit Burden Interview 6 weeks	-0.16 [-.46, .14]	42.19 (1.58) baseline 38.18 (1.60) 6 weeks	42.18 (1.59) baseline 41.13 (1.65) 6 weeks	Interaction .066
Moskowitz 2019[7] (31045422) Life Enhancing Activities for Family Caregivers (LEAF) vs. waitlist control Medium Explanatory USA	Cohen's d (95% CI) Mean (SE) Caregiver strain: Caregiver Strain Index (CSI) 6 weeks	.01 [-.30, .30]	8.40 (.33) baseline 8.46 (.33) 6 weeks	8.061 (.35) baseline 8.55 (.33) 6 weeks	Interaction 0.74
Moskowitz 2019[7] (31045422) Life Enhancing Activities for Family Caregivers (LEAF) vs. waitlist control Medium Explanatory USA	Cohen's d (95% CI) Mean (SE) Caregiver positive emotion: Differential Emotions Scale (DES) 6 weeks	0.58 [.27, .88]	4.64 (.16) baseline 4.86 (.16) 6 weeks	4.92 (.17) baseline 4.31 (.17) 6 weeks	Interaction <.001
Moskowitz 2019[7] (31045422) Life Enhancing Activities for Family Caregivers (LEAF) vs. waitlist control Medium Explanatory USA	Cohen's d (95% CI) Mean (SE) Caregiver negative emotion: Differential Emotions Scale (DES) 6 weeks	-0.22 [-.52, .08]	3.66 (.13) baseline 2.6 (.13) 6 weeks	3.70 (.13) baseline 2.91 (.14) 6 weeks	Interaction 0.13
Moskowitz 2019[7] (31045422) Life Enhancing Activities for Family Caregivers (LEAF) vs. waitlist control Medium Explanatory USA	Cohen's d (95% CI) Mean (SE) Caregiver positive aspects of caregiving: the Positive Aspects of Caregiving Scale 6 weeks	0.35 [.05, .66]	35.92 (1.09) baseline 39.04 (1.12) 6 weeks	26.88 (1.11) baseline 36.41 (1.16) 6 weeks	Interaction 0.001
Moskowitz 2019[7] (31045422) Life Enhancing Activities for Family Caregivers (LEAF) vs. waitlist control Medium Explanatory USA	Cohen's d (95% CI) Mean (SE) Caregiver perceived stress: The Perceived Stress Scale 6 weeks	-0.20 [-.50, .11]	30.64 (.71) baseline 27.48 (.72) 6 weeks	31.08 (.73) baseline 29.24 (.76) 6 weeks	Interaction 0.10
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care Medium Explanatory Germany	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months Caregiver quality of life: World Health Organization Quality of Life questionnaire (WHOQOL-BREF) short form Global QOL subscale 6 month	Cohens d = –0.2	60.9 (2.4) baseline 53.2 (2.4) 6 months	58.5 (2.4) baseline 54.5 (2.6) 6 months	NS (p-value NR)
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care.	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months	Cohens d = -0.5	16.9 (1.1) baseline 19.9 (1.0) 6 months	17.4 (1.1) baseline 16.5 (1.1) 6 months	NS (p-value NR)

Study (PMID) **Comparison** **Caregiver Type** **RoB** **Category*** **Country**	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Medium Explanatory Germany	Caregiver confidence: Sense of Competence Questionnaire (SCQ) personal life subscale 6 months				
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care Medium Explanatory Germany	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months Caregiver confidence: Sense of Competence Questionnaire (SCQ) performance as a caregiver subscale 6 months	Cohens d = -0.4	17.2 (1.0) baseline 20.9 (0.9) 6 months	18.0 (1.0) baseline 20.0 (1.0) 6 months	NS (p-value NR)
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care Medium Explanatory Germany	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months Caregiver confidence: Sense of Competence Questionnaire (SCQ) satisfaction with PLWD subscale 6 months	Cohens d = -0.5	8.9 (0.7) baseline 10.4 (0.7) 6 months	10.1 (0.7) baseline 9.7 (0.7) 6 months	NS (p-value NR)
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care Medium Explanatory Germany	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months Caregiver social support: (F-SOZU) 6 months	Cohens d =-0.1	53.3 (1.1) baseline 50.5 (1.3) 6 months	53.2 (1.4) baseline 53.5 (1.4) 6 months	NS (p-value NR)
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care Medium Explanatory Germany	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months Caregiver perceived stress 6 months	Cohens d=0.1	25.5 (1.0) baseline 27.3 (1.2) 6 months	27.2 (1.) baseline 26.9 (1.2) 6 months	NS (p-value NR)
Nordheim 2019[8] (30775982) couple-based interdisciplinary psychosocial intervention vs. usual care Medium Explanatory Germany	Estimated marginal mean (SE) baseline Estimated marginal mean (SE) 6 months Caregiver depressive symptoms: Geriatric depression scale (GDS) 6 months	Cohens d = 0.0	4.9 (0.3) baseline 4.8 (0.3) 6 months	4.5 (0.3) baseline 5.0 (0.3) 6 months	NS (p-value NR)
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) Caregiver depressive symptoms: Centers for Epidemiologic Study Depression Scale (CES-D) 4 months	-0.59 (-1.74 to 0.55)	NR	NR	0.31
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) Caregiver burden: Zarit Burden Short Form (12 item) 4 months	-0.39 (-2.06 to 1.29) .65	NR	NR	0.65
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) Caregiver distress: Neuropsychiatric Inventory – Clinician (NPI-C) distress subscale 4 months	-0.07 (-0.14 to -0.01)	NR	NR	0.03
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) Caregiver time spent caregiving: hours on ADLS 4 months	-0.53 (-1.20 to 0.14)	NR	NR	0.12
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) Caregiver time spent caregiving: hours on IADLs 4 months	-1.09 (-2.34 to 0.15)	NR	NR	0.08
Gitlin 2018[13] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium	Mean difference (95% CI) Caregiver time spent caregiving: hours on duty 4 months	-0.28 (-2.25 to 1.68)	NR	NR	0.78

Study (PMID) Comparison Caregiver Type RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Explanatory USA					
Gitlin 2018[13, 20] (29192967) Home-based Tailored Activity Program vs. attention control using telephone visits Medium Explanatory USA	Mean difference (95% CI) Caregiver time spent caregiving: hours on doing things 4 months	-0.99 (-2.28 to 0.30)	NR	NR	0.13
Tremont 2017[84] (28008609) companion to Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) Caregiver health service use: Number of monthly emergency department visits during intervention 6 months	NR	0.02 (0.06)	0.05 (0.13)	0.02
Tremont 2017[84] (28008609) companion to Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) Caregiver health service use: Number of monthly hospital visits during intervention 6 months	NR	0.01 (0.04)	0.04 (0.10)	0.006
Tremont 2017[84] (28008609) companion to Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) Caregiver health service use: number of monthly doctor visits during intervention 6 months	NR	0.85 (0.89)	0.71 (0.61)	0.88
Tremont 2017[84] (28008609) companion to Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Absolute risk reduction (95% CI) Caregiver hospital admissions 6 months	11.4% (0.023 to 0.25)	NR	NR	0.01
Tremont 2017[84] (28008609) companion to Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Absolute risk reduction (95% CI) Caregiver emergency department visits 6 months	9.5% (0.01 to 0.19)	NR	NR	0.048
Tremont 2017[84] (28008609) companion to Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) Caregiver community support use: Number of community support services used in final month of intervention 6 months	NR	8.47 (5.14)	5.14 (7.05)	0.02
Tremont 2017[84] (28008609) companion to Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) Caregiver out of pocket cost on formal care for PLWD for final month of intervention in dollars 6 months	$274.43 (901.68)	NR	NR	0.73 (no difference between groups)
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for CSP vs other 2 groups Caregiver Health related Quality of life: SF-12 mental component 12 months	0.52 (−1.28 to 2.32)	NR	NR	0.57
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low	Adjusted mean difference (95% CI) for RYCT vs other 2 groups Caregiver Health related Quality of life: SF-12 mental component 12 months	0.10 (-1.72 to 1.93)	NR	NR	0.91

Study (PMID) **Comparison** **Caregiver Type** **RoB** **Category*** **Country**	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Explanatory UK					
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for CSP vs other 2 groups Caregiver Health related Quality of life: SF-12 physical component 12 months	0.613 (−1.23 to 2.46)	NR	NR	0.52
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for RYCT vs other 2 groups Caregiver Health related Quality of life: SF-12 physical component 12 months	−0.428 (−2.29 to 1.43)	NR	NR	0.65
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for CSP vs other 2 groups Caregiver anxiety: Hospital Anxiety and Depression Scale (HADS) anxiety subscale 12 months	−0.33 (−1.31 to 0.60)	NR	NR	0.47
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for RYCT vs other 2 groups Caregiver depression: Hospital Anxiety and Depression Scale (HADS) anxiety subscale 12 months	0.298 (−0.65 to 1.25)	NR	NR	0.54
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for CSP vs other 2 groups Caregiver depression: Hospital Anxiety and Depression Scale (HADS) depression subscale 12 months	0.0144 (−0.85 to 0.88)	NR	NR	0.97
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for RYCT vs other 2 groups Caregiver depression: Hospital Anxiety and Depression Scale (HADS) depression subscale 12 months	−0.0700 (−0.95 to 0.81)	NR	NR	0.88
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for CSP vs other 2 groups Caregiver Health-related quality of life: EQ-5D global health visual analog scale 12 months	0.384 (−4.20 to 4.96)	NR	NR	0.87
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low	Adjusted mean difference (95% CI) for RYCT vs other 2 groups Caregiver Health-related quality of life: EQ-5D global health visual analog scale 12 months	0.915 (−3.65 to 5.48)	NR	NR	0.69

Study (PMID) Comparison Caregiver Type RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Explanatory UK					
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for CSP vs other 2 groups Caregiver Positive Aspects of Caring: Carers of Older People in Europe Index (COPE index) positive aspects subscale 12 months	0.0125 (−0.54 to 0.56)	NR	NR	0.96
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for RYCT vs other 2 groups Caregiver Positive Aspects of Caring: Carers of Older People in Europe Index (COPE index) positive aspects subscale 12 months	0.0784 (−0.45 to 0.61)	NR	NR	0.77
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for CSP over other 2 groups Caregiver Quality of Caregiver–PLWD Relationship (QCPR) 12 months	1.416 (−0.47 to 3.30)	NR	NR	0.14
Charlesworth 2016[18] (27521377) 3 groups: 1) One-to-one peer support to family carers from experienced carers (Carer Supporter Programme (CSP), 2) group reminiscence therapy Remembering Yesterday, Caring Today (RYCT), & 3) usual care Low Explanatory UK	Adjusted mean difference (95% CI) for RYCT over other 2 groups Caregiver Quality of Caregiver–PLWD Relationship (QCPR) 12 months	1.869 (−0.02 to 3.75)	NR	NR	0.05
Cheng 2016[19] (27401052) Benefit finding intervention (BF) vs. simplified psychoeducation (SIM-PE) vs. standard psychoeducation (STD-PE) Medium Explanatory Hong Kong	d effect size Adjusted mean (SD) Caregiver depressive symptoms: Hamilton Depression Rating Scale 8 weeks	d = -0.77	2.441 (3.499) BF	5.137 (3.476) SIM-PE	Regression p<0.001
Cheng 2016[19] (27401052) Benefit finding intervention (BF) vs. simplified psychoeducation (SIM-PE) vs. standard psychoeducation (STD-PE) Medium Explanatory Hong Kong	d effect size Adjusted mean (SD) Caregiver burden: Zarit Caregiver Burden Interview (ZBI) 8 weeks	d = -0.47	27.133 (11.704) BF	32.544 (11.431) SIM-PE	Regression p=0.028
Cheng 2016 [19](27401052) Benefit finding intervention (BF) vs. simplified psychoeducation (SIM-PE) vs. standard psychoeducation (STD-PE) Medium Explanatory Hong Kong	d effect size Adjusted mean (SD) Caregiver role overload: 8 weeks	d = -0.43	9.650 (2.424) BF	10.705 (2.478) SIM-PE	Regression p=0.046
Cheng 2016[19] (27401052) Benefit finding intervention (BF) vs. simplified psychoeducation (SIM-PE) vs. standard psychoeducation (STD-PE) Medium Explanatory Hong Kong	d effect size Adjusted mean (SD) Caregiver psychological wellbeing: Ryff's Psychological Well-being Scale 8 weeks	d = 0.42	66.652 (6.753) BF	63.867 (6.559) SIM-PE	Regression p=0.048

Study (PMID) Comparison Caregiver Type RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Cheng 2016[19] (27401052) Benefit finding intervention (BF) vs. simplified psychoeducation (SIM-PE) vs. standard psychoeducation (STD-PE) Medium Explanatory Hong Kong	d effect size Adjusted mean (SD) Caregiver depressive symptoms: Hamilton Depression Rating Scale 8 weeks	d = -0.96	2.441 (3.499) BF	5.833 (3.432) STD-PE	Regression p<0.001
Cheng 2016[19] (27401052) Benefit finding intervention (BF) vs. simplified psychoeducation (SIM-PE) vs. standard psychoeducation (STD-PE) Medium Explanatory Hong Kong	d effect size Adjusted mean (SD) Caregiver burden: Zarit Caregiver Burden Interview (ZBI) 8 weeks	d = -0.65	27.133 (11.704) BF	34.749 (11.886) STD-PE	Regression p=0.003
Cheng 2016[19] (27401052) Benefit finding intervention (BF) vs. simplified psychoeducation (SIM-PE) vs. standard psychoeducation (STD-PE) Medium Explanatory Hong Kong	d effect size Adjusted mean (SD) Caregiver role overload: 8 weeks	d = NR	9.650 (2.424) BF	10.243 (2.387) STD-PE	Regression p=0.234
Cheng 2016[19] (27401052) Benefit finding intervention (BF) vs. simplified psychoeducation (SIM-PE) vs. standard psychoeducation (STD-PE) Medium Explanatory Hong Kong	d effect size Adjusted mean (SD) Caregiver psychological wellbeing: Ryff's Psychological Well-being Scale 8 weeks	d = NR	66.652 (6.753) BF	65.027 (6.894) STD-PE	Regression p=0.264
Gonyea 2016[20] (24855313) Circulo de Cuidado, a culturally-sensitive, cognitive behavioral (CBT) group intervention vs. psychoeducational (PED) control condition Medium Explanatory USA	Mean (SD) Caregiver distress of PLWD neuropsychiatric symptoms: Spanish version of the Neuropsychiatric Inventory-Distress (NPI-D) 12 week 24 week	NR	17.94 (6.84) baseline 16.64 (7.02) 12 weeks 16.39 (7.02) 24 weeks	17.91 (7.30) baseline 17.85 (7.26) 12 weeks 18.26 (7.37) 24 weeks	Repeated measures ANCOVA < 0.001
Gonyea 2016[20] (24855313) Circulo de Cuidado, a culturally-sensitive, cognitive behavioral (CBT) group intervention vs. psychoeducational (PED) control condition Medium Explanatory USA	Mean (SD) Caregiver self-efficacy: Spanish version of the Revised Scale for Caregiving Self-Efficacy (RSCSE) 12 week 24 week	NR	69.11 (12.75) baseline 70.36 (12.44) 12 weeks 70.27 (12.43) 24 weeks	69.19 (9.01) baseline 69.29 (8.80) 12 weeks 69.15 (8.88) 24 weeks	Repeated measures ANCOVA < 0.001
Gonyea 2016[20] (24855313) Circulo de Cuidado, a culturally-sensitive, cognitive behavioral (CBT) group intervention vs. psychoeducational (PED) control condition Medium Explanatory USA	Mean (SD) Caregiver depressive symptoms: Spanish version of the Center for Epidemiological Studies-Depression Scale (CES-D) 12 week 24 week	NR	14.39 (6.14) baseline 13.79 (5.85) 12 weeks 13.82 (5.88) 24 weeks	14.41 (6.31) baseline 14.38 (6.10) 12 weeks 14.44 (6.07) 24 weeks	Repeated measures ANCOVA <0.01
Gonyea 2016[20] (24855313) Circulo de Cuidado, a culturally-sensitive, cognitive behavioral (CBT) group intervention vs. psychoeducational (PED) control condition Medium Explanatory USA	Mean (SD) Caregiver anxiety: Spanish version of the State Anxiety Inventory-State (STAI-S) 12 week 24 week	NR	37.09 (10.25) baseline 36.85 (9.88) 12 weeks 36.96 (10.00) 24 weeks	37.12 (9.69) baseline 37.09 (9.61) 12 weeks 37.12 (9.68) 24 weeks	Repeated measures ANCOVA p>0.05 NS
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium Explanatory Finland	Adjusted Mean change (95% CI) Caregiver quality of life: physical component SF-36 3 months	d = 0.38	1.0 (-0.5 to 2.5)	-2.0 (-3.5 to -0.5)	.006
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium	Adjusted Mean change (95% CI) Caregiver quality of life: physical component SF-36 9 months	d=NR	-0.0 (-1.5 to 1.4)	-1.7 (-3.2 to -0.2)	0.13

Study (PMID) **Comparison** **Caregiver Type** **RoB** **Category*** **Country**	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Explanatory Finland					
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium Explanatory Finland	Adjusted Mean change (95% CI) Caregiver quality of life: mental component SF-36 3 months	d=NR	NR	NR	0.99
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium Explanatory Finland	Adjusted Mean change (95% CI) Caregiver quality of life: mental component SF-36 9 months	d=NR	NR	NR	0.58
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium Explanatory Finland	Adjusted Mean change (95% CI) Caregiver competence: spousal Sense of Competence Questionnaire (SCQ) 3 months	d=NR	NR	NR	0.76
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium Explanatory Finland	Adjusted Mean change (95% CI) Caregiver competence: spousal Sense of Competence Questionnaire (SCQ) 9 months	d=NR	NR	NR	0.38
Laakkonen 2016 [21](27060101) Self-management groups vs. usual care Medium Explanatory Finland	Adjusted Mean change (95% CI) Caregiver mastery Pearlin Mastery Scale (PMS) 3 months	d=NR	NR	NR	0.06
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium Explanatory Finland	Adjusted Mean change (95% CI) Caregiver mastery Pearlin Mastery Scale (PMS) 9 months	d=NR	NR	NR	0.11
Laakkonen 2016[21] (27060101) Self-management groups vs. usual care Medium Explanatory Finland	Adjusted Mean cost in € per year (95% CI) Caregiver Health & Social services cost: 24 months	-896 (-3,657; 1,864)	2,658 (1,473–4,176)	3,555 (1,674–6,718)	0.51
Otero 2015[83] (25331992) Cognitive behavioral problem solving vs. usual care Low Explanatory Spain	Relative risk (RR) Number needed to treat (NNT) Caregiver depression: Structured Clinical Interview for Axis 1 Disorders of the DSM-IV (SCID-CV) 12 months	0.40 RR 6.7 NNT			0.010
Otero 2015[83] (25331992) Cognitive behavioral problem solving vs. usual care Low Explanatory Spain	Standardized mean difference Center for Epidemiologic Depression Scale (CESD) Spanish version 12 months	1.14			NR
Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) baseline Mean (SD) 6 months Caregiver depressive symptoms: Center for Epidemiology Studies Depression Scale (CESD) 6 months	NR	17.04 (10.22) baseline 14.15 (10.00) 6 months	15.19 (9.98) baseline 15.62 (10.18) 6 months	0.003
Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium	Mean (SD) baseline Mean (SD) 6 months Caregiver burden: Zarit Burden Interview (ZBI) 6 months	NR	38.61 (13.98) baseline 35.95 (14.34) 6 months	38.82 (14.63) baseline 37.17 (13.93) 6 months	0.485

Study (PMID) Comparison Caregiver Type RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Explanatory USA					
Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) baseline Mean (SD) 6 months Caregiver reactions to care: Revised Memory and Behavior Problem Checklist (RMBPC-RT) Reaction Score 6 months	NR	22.98 (12.89) baseline 20.04 (13.68) 6 months	22.59 (13.94) baseline 22.00 (12.82) 6 months	0.160
Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) baseline Mean (SD) 6 months Caregiver : Family Assessment Device (FAD) 6 months	NR	2.11 (0.61) baseline 2.09 (0.63) 6 months	2.05 (0.55) baseline 2.00 (0.50) 6 months	0.798
Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) baseline Mean (SD) 6 months Caregiver confidence: Self-Efficacy Questionnaire (SEQ-SM) Symptom Management subscale 6 months	NR	29.35 (10.78) baseline 34.17 (9.55) 6 months	29.74 (11.86) baseline 32.27 (10.04)6 months	0.108
Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) baseline Mean (SD) 6 months Caregiver confidence: Self-Efficacy Questionnaire (SEQ-SS) Support Services subscale 6 months	NR	23.39 (10.89) baseline 31.06 (7.77) 6 months	24.00 (9.93) baseline 30.64 (7.28) 6 months	0.467
Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) baseline Mean (SD) 6 months Caregiver : Positive Aspects of Caregiving (PAC) 6 months	NR	31.51 (7.58) baseline 34.13 (8.31) 6 months	30.35 (9.65) baseline 35.24 (7.55) 6 months	0.041
Tremont 2015[28] (25074341) Telephone Tracking–Caregiver (FITT-C) vs. Telephone Support (TS) Medium Explanatory USA	Mean (SD) baseline Mean (SD) 6 months Caregiver health related quality of life; EuroQoL Visual Analog scale 6 months	NR	80.08 (16.07) baseline 79.87 (15.00) 6 months	77.14 (17.61) baseline 77.59 (15.69) 6 months	0.748
Livingston 2014[30] (25300037) START (STrAtegies for RelaTives) manual-based coping strategy programme in promoting the mental health of carers of people with dementia vs. usual care Low Explanatory UK	Adjusted mean difference (95% CI) Caregiver Affective symptoms [Hospital Anxiety and Depression Scale-total (HADS-T)] 2 years	–2.58 (–4.26 to –0.90)	NR	NR	NR
Livingston 2014[30] (25300037) START (STrAtegies for RelaTives) manual-based coping strategy programme in promoting the mental health of carers of people with dementia vs. usual care Low Explanatory UK	Adjusted mean difference (95% CI) Caregiver Anxiety: Hospital Anxiety and Depression Scale-anxiety (HADS-A) 2 years	–1.16 (–2.15 to –0.18)	NR	NR	NR
Livingston 2014 [30](25300037) START (STrAtegies for RelaTives) manual-based coping strategy programme in promoting the mental health of carers of people with dementia vs. usual care Low Explanatory UK	OR (95% CI) Caregiver Anxiety: Hospital Anxiety and Depression Scale-anxiety (HADS-A) (score ≥ 9) 2 years	0.57 (0.26 to 1.24)	57 (43.2) N (%)	32 (50.0) N (%)	NR
Livingston 2014[30] (25300037) START (STrAtegies for RelaTives) manual-based coping strategy programme in promoting the mental health of carers of people with dementia vs. usual care Low	Adjusted mean difference (95% CI) Caregiver Depression: Hospital Anxiety and Depression Scale-depression (HADS-D) 2 years	–1.45 (–2.32 to –0.57)	NR	NR	NR

Study (PMID) Comparison Caregiver Type RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Explanatory UK					
Livingston 2014[30] (25300037) START (STrAtegies for RelaTives) manual-based coping strategy programme in promoting the mental health of carers of people with dementia vs. usual care Low Explanatory UK	OR (95% CI) Caregiver Depression: Hospital Anxiety and Depression Scale-depression (HADS-D) (score ≥ 9) 2 years	0.14 (0.04 to 0.53)	30 (22.7) N (%)	19 (29.7) N (%)	NR
Livingston 2014[30] (25300037) START (STrAtegies for RelaTives) manual-based coping strategy programme in promoting the mental health of carers of people with dementia vs. usual care Low Explanatory UK	Adjusted mean difference (95% CI) Caregiver QOL: Health Status Questionnaire (HSQ) – mental health 2 years	7.47 (2.87 to 12.08)	NR	NR	NR
Livingston 2014[30] (25300037) START (STrAtegies for RelaTives) manual-based coping strategy programme in promoting the mental health of carers of people with dementia vs. usual care Low Explanatory UK	OR (95% CI) Caregiver Abusive behaviors: Modified Conflict Tactic Score (MCTS) (at least one item with score of ≥ 2) 2 years	0.83 (0.36 to 1.93)	28 (29.5) N (%)	11 (23.4) N (%)	NR
Livingston 2014[30] (25300037) START (STrAtegies for RelaTives) manual-based coping strategy programme in promoting the mental health of carers of people with dementia vs. usual care Low Explanatory UK	Mean difference (95% CI) Caregiver health care cost: Quality-Adjusted Life-Years (QALYs) from the EQ-5D 2 years	£336 (95% CI –£223 to £895)	NR	NR	NR
Livingston 2014[30] (25300037) START (STrAtegies for RelaTives) manual-based coping strategy programme in promoting the mental health of carers of people with dementia vs. usual care Low Explanatory UK	Mean difference (95% CI) Caregiver health care cost: Quality-Adjusted Life-Years (QALYs) from the Hospital Anxiety and Depression Scale-total (HADS-T) 2 years	£303 (95% CI –£206 to £812)	NR	NR	NR
Martin-Carrasco 2014[31] (24113563) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean difference (95% CI) SMD (95% CI) Caregiver burden: Spanish Zarit caregiver burden interview 4 months	-0.55 (-3.64; 2.55) – Mean difference -0.04 (-0.30; 0.21) - SDM	-1.17 (12.3)	-0.63 (12.0)	0.73
Martin-Carrasco 2014[31] (24113563) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean difference (95% CI) SMD (95% CI) Caregiver psychological distress: Spanish General Health Questionnaire 28 item (GHQ-28) 4 months	-2.34 (-5.27; 0.59) mean diff -0.20 (-0.46; 0.05) SDM	-4.76 (12.6)	-2.42 (10.3)	>.05
Martin-Carrasco 2014[31] (24113563) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean difference (95% CI) SMD (95% CI) Caregiver quality of life: Spanish SF-12 physical function 4 months	-1.02 (-11.10 to 9.06) -0.03 (-0.30 to 0.25)	-1.02 (30.0)	0.0 (41.3)	>.05
Martin-Carrasco 2014[31] (24113563) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium	Mean difference (95% CI) SMD (95% CI) Caregiver quality of life: Spanish SF-12 role physical 4 months	1.80 (-5.63 to 9.22) 0.07 (-0.21 to 0.34)	3.09 (26.9)	1.30 (26.7)	>.05

Study (PMID) **Comparison** **Caregiver Type** **RoB** **Category*** **Country**	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Explanatory Spain					
Martin-Carrasco 2014[31] (24113563) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean difference (95% CI) SMD (95% CI) Caregiver quality of life: Spanish SF-12 bodily pain 4 months	6.85 (-1.58 to 15.28) 0.22 (-0.05 to 0.50)	6.38 (25.7)	-0.47 (34.3)	0.11
Martin-Carrasco 2014[31] (24113563) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean difference (95% CI) SMD (95% CI) Caregiver quality of life: Spanish SF-12 general health 4 months	-5.01 (-10.48 to 0.45) -0.25 (-0.53 to 0.02)	-3.12 (19.3)	1.89 (20.0)	0.07
Martin-Carrasco 2014[31] (24113563) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean difference (95% CI) SMD (95% CI) Caregiver quality of life: Spanish SF-12 vitality 4 months	3.71 (-4.34 to 11.76) 0.13 (-0.15 to 0.40)	2.04 (28.6)	-1.67 (29.5)	>.05
Martin-Carrasco 2014[31] (24113563) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean difference (95% CI) SMD (95% CI) Caregiver quality of life: Spanish SF-12 social functioning 4 months	-0.78 (-9.33 to 7.77) -0.02 (-0.30 to 0.25)	-4.08 (31.6)	-3.30 (30.3)	>.05
Martin-Carrasco 2014[31] (24113563) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean difference (95% CI) SMD (95% CI) Caregiver quality of life: Spanish SF-12 role emotional 4 months	-4.25 (-11.48 to 2.98) -0.16 (-0.44 to 0.11)	-3.06 (27.7)	1.19 (24.5)	>.05
Martin-Carrasco 2014[31] (24113563) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean difference (95% CI) SMD (95% CI) Caregiver quality of life: Spanish SF-12 mental health 4 months	-1.23 (-7.22 to 4.75) -0.06 (-0.33 to 0.22)	1.53 (23.8)	2.76 (19.2)	>.05
Waldorff 2012[40] (22807076) DAISY plus support (multifaceted and semi-tailored counselling, education, and support) vs. support control group Medium Explanatory Denmark	Mean change score (95% CI) Caregiver depressive symptom: Geriatric depression scale 12 months	NR	0.96 (0.05 to 1.86)	0.26 (−0.51 to 1.03)	0.2500
de Rotrou 2011[42] (20922772) Psycho Education Program vs. usual care Medium Explanatory France	Imputed mean (SD) Caregiver depressive symptoms: Montgomery and Asberg Depression Rating Scale (MADRS) Baseline 3 months	NR	9.03 (0.79) baseline 8.61 (0.94) 3 months	10.16 (1.22) baseline 10.11 (1.18) 3 months	NS Value not reported
de Rotrou 2011[42] (20922772) Psycho Education Program vs. usual care Medium Explanatory France	Imputed mean (SD) Caregiver burden: Zarit Caregiver Burden Interview (ZBI) Baseline 3 months	NR	22.97 (2.79) baseline 22.23 (1.59) 3 months	24.30 (4.15) baseline 23.53 (2.05) 3 months	NS Value not reported

Study (PMID) Comparison Caregiver Type RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
de Rotrou 2011[42] (20922772) Psycho Education Program vs. usual care Medium Explanatory France	Imputed mean (SD) Caregiver perception of disease understanding: Visual Analogue Scales (VAS) Baseline 3 months	NR	12.52 (0.27) baseline 14.44 (0.47) 3 months	12.05 (0.27) baseline 12.54 (0.53) 3 months	NR
de Rotrou 2011[42] (20922772) Psycho Education Program vs. usual care Medium Explanatory France	Imputed mean (SD) Caregiver coping: Visual Analogue Scales (VAS) Baseline 3 months	NR	12.53 (0.24) baseline 13.47 (0.44) 3 months	12.72 (0.29) baseline 12.63 (0.52) 3 months	NR
de Rotrou 2011[42] (20922772) Psycho Education Program vs. usual care Medium Explanatory France	Imputed mean (SD) Caregiver depressive symptoms: Montgomery and Asberg Depression Rating Scale (MADRS) Baseline 6 months	NR	9.03 (0.79) baseline 9.28 (0.99) 3 months	10.16 (1.22) baseline 11.43 (1.24) 3 months	Interaction 0.373
de Rotrou 2011[42] (20922772) Psycho Education Program vs. usual care Medium Explanatory France	Imputed mean (SD) Caregiver burden: Zarit Caregiver Burden Interview (ZBI) Baseline 6 months	NR	22.97 (2.79) baseline 23.90 (1.86) 3 months	24.30 (4.15) baseline 25.95 (2.09) 3 months	Interaction 0.657
de Rotrou 2011[42] (20922772) Psycho Education Program vs. usual care Medium Explanatory France	Imputed mean (SD) Caregiver perception of disease understanding: Visual Analogue Scales (VAS) Baseline 6 months	NR	12.52 (0.27) baseline 15.03 (0.38) 3 months	12.05 (0.27) baseline 12.52 (0.50) 3 months	Interaction 0.003
de Rotrou 2011[42] (20922772) Psycho Education Program vs. usual care Medium Explanatory France	Imputed mean (SD) Caregiver coping: Visual Analogue Scales (VAS) Baseline 6 months	NR	12.53 (0.24) baseline 13.63 (0.44) 3 months	12.72 (0.29) baseline 12.24 (0.57) 3 months	Interaction 0.025
Guerra 2011[43] 10/66 Helping Carers to Care vs waitlist control Medium Explanatory Peru	Standardized mean difference (95%CI) summary finding Mean change score (SD) Caregiver burden: Zarit Caregiver Burden Interview (ZBI) 6 months	-1.05 (-1.60 to -0.48)	-3.6 (4.6)	0.3 (2.9)	<0.001
Guerra 2011[43] 10/66 Helping Carers to Care vs waitlist control Medium Explanatory Peru	Standardized mean difference (95%CI) summary finding Mean change score (SD) Caregiver mental health: Self reporting questionnaire 20 (SRQ-20) psychological morbidity 6 months	-0.01 (-0.55 to 0.55)	-3.1 (4.0)	-3.0 (3.1)	0.97
Guerra 2011[43] 10/66 Helping Carers to Care vs waitlist control Medium Explanatory Peru	Standardized mean difference (95%CI) summary finding Mean change score (SD) Caregiver distress: Neuropsychiatric Inventory (NPI-Q) carer distress score 6 months	0.01 (-0.55 to 0.57)	-2.3 (4.7)	-2.4 (4.6)	0.96
Guerra 2011[43] 10/66 Helping Carers to Care vs waitlist control Medium Explanatory Peru	Standardized mean difference (95%CI) summary finding Mean change score (SD) Caregiver QOL: WHOQOL-BREF physical subscale 6 months	0.36 (-0.19 to 0.92)	-9.7 (18.7)	-15.5 (13.9)	0.19
Guerra 2011[43] 10/66 Helping Carers to Care vs waitlist control Medium Explanatory Peru	Standardized mean difference (95%CI) summary finding Mean change score (SD) Caregiver QOL: WHOQOL-BREF psychological subscale 6 months	0.10 (-0.44 to 0.65)	10.0 (11.5)	8.9 (11.1)	0.71

Study (PMID) Comparison Caregiver Type RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Guerra 2011[43] 10/66 Helping Carers to Care vs waitlist control Medium Explanatory Peru	Standardized mean difference (95%CI) summary finding Mean change score (SD) Caregiver QOL: WHOQOL-BREF social subscale 6 months	0.39 (-0.15 to 0.94)	7.1 (12.6)	1.7 (15.2)	0.16
Guerra 2011[43] 10/66 Helping Carers to Care vs waitlist control Medium Explanatory Peru	Standardized mean difference (95%CI) summary finding Mean change score (SD) Caregiver QOL: WHOQOL-BREF environmental subscale 6 months	-0.15 (-0.70 to 0.39)	7.6 (11.4)	9.5 (13.0)	0.58
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	Mean difference (95% CI) Caregiver interaction with PLWD: Sense of Competence Questionnaire 52 weeks	3.8 (-3.5 to 11.2)	NR	NR	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	Mean difference (95% CI) Caregiver depression: Center for Epidemiologic Depression Scale 52 weeks	-1.4 (-5.1 to 2.3)	NR	NR	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	Mean difference (95% CI) Caregiver QOL: Dementia Quality of Life Instrument overall 52 weeks	0.2 (-0.1 to 0.5)	NR	NR	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	Mean difference (95% CI) Caregiver QOL: Short-Form 12 Health Survey Questionnaire – physical component 52 weeks	-1.0 (-6.1 to 4.0)	NR	NR	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	Mean difference (95% CI) Caregiver QOL: Short-Form 12 Health Survey Questionnaire – mental component 52 weeks	-1.7 (-6.9 to 3.4)	NR	NR	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	Mean difference (95% CI) Caregiver work: Resource utilization in Dementia - Basic Activities of Daily Living care by primary carer (hours per day) subscale 52 weeks	0.1 (-0.8 to 1.0)	NR	NR	NS
Voight-Radloff 2011[46] (22021760) Community Occupational Therapy in Dementia Program vs. usual care (one session home consultation) Medium 26-52 weeks Explanatory Germany	Mean difference (95% CI) Caregiver work: Resource utilization in Dementia - Instrumental Activities of Daily Living -care by primary carer (hours per day) subscale 52 weeks	0.5 (-0.6 to 1.6)	NR	NR	NS
Wang 2011[47] (21752121) Family Mutual Support Program in Dementia Care (FMSP-DC) vs. usual care Medium	Mean (SD) baseline Mean (SD) 6 months	NR	68.2 (11.9) baseline 55.2 (15.0) 6 months	68.8 (16.7) baseline 65.0 (18.1) 6 months	<0.001

Study (PMID) Comparison Caregiver Type RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Explanatory USA	Caregiver burden: Family Caregiving Burden Inventory (FCBI) 6 months				
Wang 2011[47] (21752121) Family Mutual Support Program in Dementia Care (FMSP-DC) vs. usual care Medium Explanatory USA	Mean (SD) baseline Mean (SD) 6 months Caregiver quality of life: World Health Organization Quality of Life Scale (Brief H.K. version) (WHOQOL-BREF) 6 months	NR	65.9 (13.0) baseline 78.8 (19.0) 6 months	67.0 (13.5) baseline 68.9 (15.7) 6 months	<0.001
Wang 2011[47] (21752121) Family Mutual Support Program in Dementia Care (FMSP-DC) vs. usual care Medium Explanatory USA	Mean (SD) baseline Mean (SD) 6 months Caregiver social support: Six-item Social Support Questionnaire (SSQ6) – number of support persons subscale 6 months	NR	3.1 (1.0) baseline 4.4 (2.0) 6 months	2.9 (1.1) baseline 2.9 (1.3) 6 months	NS
Wang 2011[47] (21752121) Family Mutual Support Program in Dementia Care (FMSP-DC) vs. usual care Medium Explanatory USA	Mean (SD) baseline Mean (SD) 6 months Caregiver social support: Six-item Social Support Questionnaire (SSQ6) – satisfaction subscale 6 months	NR	5.3 (1.8) baseline 6.2 (3.1) 6 months	5.5 (1.1) baseline 5.6 (2.1) 6 months	NS
Gitlin 2010[49] (20662955) Advancing Caregiver Training (ACT) vs. no treatment control Medium Explanatory USA	Adjusted mean difference (95% CI) Cohen's D Caregiver upset with PLWD problem behaviors 4 months	-0.93 (-1.76 to -0.10) 0.30	NR	NR	0.03
Gitlin 2010[49] (20662955) Advancing Caregiver Training (ACT) vs. no treatment control Medium Explanatory USA	Adjusted mean difference (95% CI) Cohen's D Caregiver confidence managing PLWD problem behaviors 4 months	0.33 (0.08 to 0.58) 0.30	NR	NR	0.01
Gitlin 2010[49] (20662955) Advancing Caregiver Training (ACT) vs. no treatment control Medium Explanatory USA	Adjusted mean difference (95% CI) Caregiver skills: task simplification strategies 4 months	0.06 (-0.03 to 0.15)	NR	NR	0.21
Gitlin 2010[49] (20662955) Advancing Caregiver Training (ACT) vs. no treatment control Medium Explanatory USA	Adjusted mean difference (95% CI) Caregiver burden: Zarit Caregiver Burden Interview (ZBI) 4 months	-1.37 (-2.75 to 0.01)	NR	NR	0.05
Gitlin 2010[49] (20662955) Advancing Caregiver Training (ACT) vs. no treatment control Medium Explanatory USA	Percentage with CES-D score > 8 Caregiver depressive symptoms: Centers for Epidemiologic Study Depression Scale (CES-D) 4 months	NR	53.0	67.8	0.02 for chi-square test
Gitlin 2010[49] (20662955) Advancing Caregiver Training (ACT) vs. no treatment control Medium Explanatory USA	Adjusted mean difference (95% CI) Cohen's D Caregiver affect: 4 months	0.46 (0.27-0.65) 0.58	NR	NR	0.004
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean change score (SD) Caregiver burden: Zarit caregiver burden interview 10 months	NR	-8.1 (17.3)	2.1 (16.5)	.0083
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of	Mean (SD) Caregiver quality of life: Spanish SF-36 physical functioning	NR	80.1 (20.7)	68.8 (25.6)	0.0310

Study (PMID) **Comparison** **Caregiver Type** **RoB** **Category*** **Country**	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
PLWD care vs. usual care Medium Explanatory Spain	subscale 10 months				
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean (SD) Caregiver quality of life: Spanish SF-36 physical role subscale 10 months	NR	84.7 (34.6)	56.8 (47.0)	0.0074
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean (SD) Caregiver quality of life: Spanish SF-36 bodily pain subscale 10 months	NR	74.0 (18.7)	61.7 (26.9)	0.0157
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean (SD) Caregiver quality of life: Spanish SF-36 General Health subscale 10 months	NR	53.4 (18.0)	40.1 (15.7)	0.0011
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean (SD) Caregiver quality of life: Spanish SF-36 Vitality 10 months	NR	53.8 (15.9)	38.9 (17.9)	0.0002
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean (SD) Caregiver quality of life: Spanish SF-36 Social Functioning 10 months	NR	71.0 (23.4)	58.9 (27.7)	0.0488
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean (SD) Caregiver quality of life: Spanish SF-36 Emotional Role 10 months	NR	73.5 (41.0)	47.4 (48.2)	0.0160
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean (SD) Caregiver quality of life: Spanish SF-36 Mental Health 10 months	NR	63.0 (9.2)	60.9 (8.3)	0.3197
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean (SD) Caregiver mental health status: General Health Questionnaire (GHQ-28) 4 months	NR	4.7 (7.2)	6.3 (6.6)	0.0340
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care	Mean (SD) Caregiver mental health status: General Health Questionnaire (GHQ-28) 10 months	NR	2.2 (4.0)	7.8 (7.6)	0.0004

Study (PMID) Comparison Caregiver Type RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Medium Explanatory Spain					
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Frequency (percent) Caregiver healthcare and social resources use: number of visits 4 months	NR	0 visits: 34/44 (77%) 1-2 visits: 10/44 (23%)	0 visits: 29/38 (77%) 1-2 visits: 9/38 (23%)	NR (NS)
Martin-Carrasco 2009[54] (18949763) Psychoedcuational Intervention Program to teach strategies for confronting problems of PLWD care vs. usual care Medium Explanatory Spain	Mean (SD) Caregiver healthcare and social resources use: time spent on medical care 4 months	NR	24.6 (19.6)	14.5 (10.1)	NR
Gallagher-Thompson 2008[56] (25067886) Coping with Caregiving (CWC) vs. minimal telephone-based control condition (TSC) Medium Explanatory	Beta (SE) for linear regression model Caregiver depressive symptoms: CESD Center for Epidemiological Studies Depression scale (CESD) 6 months	-2.135 (1.073)	NR	NR	ANOVA p=.048
Gallagher-Thompson 2008[56] (25067886) Coping with Caregiving (CWC) vs. minimal telephone-based control condition (TSC) Medium Explanatory	Beta (SE) for linear regression model Caregiver perceived psychological stress: Perceived Stress Scale (PSS-10) 6 months	-1.530 (0.760)	NR	NR	ANOVA p=.046
Gallagher-Thompson 2008[56] (25067886) Coping with Caregiving (CWC) vs. minimal telephone-based control condition (TSC) Medium Explanatory	Beta (SE) for linear regression model Caregiver bother of PLWD neuropsychiatric symptoms: Subscale of Revised Memory and Behavior Problem Checklist (RMBPC-CB) 6 months	-0.250 (0.092)	NR	NR	ANOVA p=.007
Graff 2006[60] (17114212) Community based occupational therapy program vs. Waitlist for occupational therapy Medium Explanatory	Adjusted Mean difference (95% CI) Caregiver competence: Sense of Competence Questionnaire (SCQ) 6 weeks	11.0 (9.2; 12.8) 1.2 2.5 (2.3 to 2.7) NNT	NR	NR	<0.0001
Graff 2006[60] (17114212) Graff 2007[89] (17895439) Community based occupational therapy program vs. Waitlist for occupational therapy Medium Explanatory	Adjusted treatment difference (95% CI) Effect size Mean (SD) Caregiver quality of life: Dementia Quality of Life Instrument 6 weeks	0.7 (0.5 to 0.9) 1.2 (effect size)	4.0 (0.6)	3.4 (0.7)	< 0.0001
Graff 2006[60] (17114212) Graff 2007[89] (17895439) Community based occupational therapy program vs. Waitlist for occupational therapy Medium Explanatory	Adjusted treatment difference (95% CI) Effect size Mean (SD) Caregiver depression: Center for Epidemiologic Studies Depression Scale CES-D 6 weeks	7.6 (5.3 to 9.7) 1.3 effect size	5.8 (4.8)	12.6 (8.5)	< 0.0001
Farran 2004[62] (41552352) Caregiver skill building (CSB) vs. Information and support group (ISO) Medium Explanatory USA	Regression coefficient (SE) Caregiver depression: Center for Epidemiological Studies of Depression scale (CES-D) 18 months	0.034 (0.032)	NR	NR	0.707
Farran 2004[62] (41552352) Caregiver skill building (CSB) vs. Information and support group (ISO) Medium Explanatory USA	Regression coefficient (SE) Caregiver skills: Behavior Management Skill-Revised (BMS-R) 18 months	-0.006 (0.010)	NR	NR	0.538
Gitlin 2001[93] (11220813) Home Environmental Intervention vs. usual care	Adjusted mean difference (95% CI) Mean (SD) baseline	.03 (-.03; .08)	.81 (.33) baseline .93 (.18) 3 months	.80 (.34) baseline .90 (.21) 3 months	0.375

Study (PMID) Comparison Caregiver Type RoB Category* Country	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Medium Explanatory USA	Mean (SD) 3 month Caregiver self-efficacy: managing ADL dependency 3 months				
Gitlin 2001[93] (11220813) Home Environmental Intervention vs. usual care Medium Explanatory USA	Adjusted mean difference (95% CI) Mean (SD) baseline Mean (SD) 3 month Caregiver self-efficacy: managing IADL dependency 3 months	.01 (-.03; .05)	.87 (.30) baseline .96 (.15) 3 months	.87 (.26) baseline .95 (.14) 3 months	0.704
Gitlin 2001[93] (11220813) Home Environmental Intervention vs. usual care Medium Explanatory USA	Adjusted mean difference (95% CI) Mean (SD) baseline Mean (SD) 3 month Caregiver self-efficacy: managing behaviors 3 months	.03 (-.03; .10)	.77 (.27) baseline .84 (.24) 3 months	.74 (.32) baseline .80 (.27) 3 months	0.314
Gitlin 2001[93] (11220813) Home Environmental Intervention vs. usual care Medium Explanatory USA	Adjusted mean difference (95% CI) Mean (SD) baseline Mean (SD) 3 month Caregiver upset: managing ADL dependency 3 months	-.06 (-.16; .03)	.26 (.35) baseline .25 (.34) 3 months	.29 (.36) baseline .34 (.37) 3 months	0.156
Gitlin 2001[93] (11220813) Home Environmental Intervention vs. usual care Medium Explanatory USA	Adjusted mean difference (95% CI) Mean (SD) baseline Mean (SD) 3 month Caregiver upset: managing IADL dependency 3 months	-.02 (-.10; .07)	.17 (.30) baseline .17 (.29) 3 months	.22 (.33) baseline .22 (.32) 3 months	0.663
Gitlin 2001[93] (11220813) Home Environmental Intervention vs. usual care Medium Explanatory USA	Adjusted mean difference (95% CI) Mean (SD) baseline Mean (SD) 3 month Caregiver upset: managing behaviors 3 months	-0.02 (-0.09; .05)	.48 (.27) .43 (.31)	.47 (.30) .45 (.29)	0.501

Abbreviations: ADL= Activities of Daily Living; CI= Confidence Interval; IADL= Instrumental Activities of Daily Living; MMSE= Mini-Mental State Examination; NR=Not Reported; PMID=PubMed Identification Number; QOL-AD= the Quality of Life in Alzheimer's; SD= Standard Deviation; SE= Standard Error

Appendix Table E.6. Summary of strength of evidence for PLWD outcomes: Psychosocial Interventions for Caregiver Well-being

Outcome Comparison	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Depression Usual care	6-52 weeks	4 RCTs (n=592)	1 found benefit 3 found no difference	Medium	Inconsistent	Indirect	Imprecise	Insufficient
Depression Attention control	52 weeks	1 RCT n=330	1 found benefit 0 found no difference	Medium	Unknown	Indirect	Imprecise	Insufficient
Function Usual care	6-12 weeks	3 RCTs (n=545)	2 found benefit 1 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Function Usual care	6-12 months	3 RCTs (n=540)	0 found benefit 3 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Function Attention control	4-12 months	2 RCTs (n=490)	1 found benefit 1 found no difference	Medium	Consistent	Direct	Imprecise	Insufficient
Neuropsychiatric symptoms Usual care	3-6 months	4 RCTs (n=740)	1 found benefit 3 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Neuropsychiatric symptoms Attention control	4-6 months	2 RCTs (n=227)	2 found benefit 0 found no difference	Medium	Consistent	Direct	Imprecise	Insufficient

Neuropsychiatric symptoms Attention control	12-18 months	3 RCTs (n=916)	0 found benefit 3 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Quality of life Usual care	6 weeks	1 RCT (n=135)	1 found benefit 0 found no difference	Medium	Unknown	Indirect	Imprecise	Insufficient
Quality of life Usual care	6-24 months	5 RCTs (n=936)	0 found benefit 5 found no difference	Medium	Inconsistent	Indirect	Imprecise	Insufficient
Quality of life Attention control	4-12 months	2 RCTs (n=490)	1 found benefit 1 found no difference	Medium	Consistent	Indirect	Imprecise	Insufficient
Social support Usual care	6 months	1 RCT (n=108)	0 found benefit 1 found no difference	Medium	Unknown	Direct	Imprecise	Insufficient
Social support Attention control	6 months	1 RCT (n=250)	0 found benefit 1 found no difference	Medium	Unknown	Direct	Imprecise	Insufficient
Health care usage Usual care	4-24 months	4 RCTs (n=652)	1 found benefit 3 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Health care usage Attention control	6 months	1 RCT (n=250)	0 found benefit 1 found no difference	Medium	Unknown	Direct	Imprecise	Insufficient
Harms – adverse events Usual care	52 weeks	1 RCT (n=141)	0 found benefit 1 found no difference	Medium	Unknown	Direct	Imprecise	Insufficient
Institutionalization Usual care	6-12 months	2 RCTs (n=288)	1 found benefit 1 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Institutionalization Attention control	6-18 months	2 RCT (n=545)	0 found benefit 2 found no difference	Medium	Unknown	Direct	Imprecise	Insufficient

Abbreviations: n=Number; RCT= Randomized Controlled Trial

Appendix Table E.7. Summary of strength of evidence for caregiver outcomes: Psychosocial Interventions

Outcome Comparison	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Anxiety Attention control	24-52 weeks	2 RCT N=358	0 found benefit 2 found no difference	Medium	Consistent	Direct	Imprecise	Insufficient
Anxiety Usual care	6 weeks	1 RCT n=170	1 found benefit 0 found no difference	Medium	Unknown	Direct	Imprecise	Insufficient
Anxiety Usual care	2 years	1 RCT n=260	0 found benefit 1 found no difference	Low	Unknown	Direct	Imprecise	Insufficient
Burden of care Attention control	8-24 weeks	5 RCT N= 725	3 found benefit 2 found no difference	Medium	Consistent	Direct	Imprecise	Insufficient
Burden of care Usual care	6-16 weeks	3 RCT N=680	0 found benefit 3 found no difference	Medium	Consistent	Direct	Imprecise	Insufficient
Burden of care Usual care	24-52 weeks	5 RCT N=561	2 found benefit 3 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Depressive symptoms Attention control	8-24 weeks	7 RCT n= 976	6 found benefit 1 found no difference	Medium	Consistent	Direct	Imprecise	Insufficient
Depressive symptoms Attention control	52-72 weeks	3 RCT n=916	0 found benefit 3 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Depressive symptoms Usual care	6-24 weeks	5 RCT N=852	2 found benefit 3 found no difference	Medium	Consistent	Direct	Imprecise	Insufficient
Depressive symptoms Usual care	52-104 weeks	5 RCT N=1073	2 found benefit 3 found no difference	Medium	Inconsistent	Indirect	Imprecise	Insufficient
Caregiving bother/distress/affect Attention control	4-12 months	5 RCT N=952	3 found benefit 2 found no difference Have means SD	Medium	Inconsistent	Direct	Imprecise	Insufficient
Caregiving bother/distress/affect Usual care	6-24 weeks	4 RCT N=702	1 found benefit 3 found no difference	Medium	Consistent	Direct	Imprecise	Insufficient

Outcome Comparison	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Health care usage Attention control	3-6 months	2 RCT n=359	1 found benefit 1 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Health care usage Usual care	4-24 months	2 RCT n=251	0 found benefit 2 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Caregiving knowledge Usual care	24 weeks	1 RCT n=167	1 found benefit 0 found no difference	Medium	Unknown	Direct	Imprecise	Insufficient
Quality of life Attention control	8 weeks	1 RCT n=132	1 found benefit 0 found no difference	Medium	Unknown	Direct	Imprecise	Insufficient
Quality of life Attention control	24-52 weeks	2 RCT n=541	0 found benefit 2 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Quality of life Usual care	6-24 weeks	7 RCT n=843	4 found benefit 3 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Quality of life Usual care	9 months to 2 years	4 RCT N=652	1 found benefit 3 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Relationship with PLWD Attention control	20-52 weeks	3 RCT n=652	1 found benefit 2 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Caregiving confidence Attention control	20-24 weeks	3 RCT N=428	2 found benefit 1 found no difference	Medium	Consistent	Direct	Imprecise	Insufficient
Caregiving confidence Usual care	12-24 weeks	3 RCT N=582	1 found benefit 2 found no difference	Medium	Consistent	Direct	Imprecise	Insufficient
Caregiving skill Attention control	6-18 months	2 RCT N=545	0 found benefit 2 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Caregiving skill Usual care	6-16 weeks	2 RCT N=407	1 found benefit 1 found no difference	Medium	Consistent	Direct	Imprecise	Insufficient
Caregiving skill Usual care	24-52 weeks	3 RCT N=444	0 found benefit 3 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Stress Attention	6 months	1 RCT N=184	1 found benefit 0 found no difference	Medium	Unknown	Direct	Imprecise	Insufficient
Stress Usual care	6-52 weeks	3 RCT n=486	0 found benefit 3 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Social support Attention control	6 months	1 RCT N=250	1 found benefit 0 found no difference	Medium	Unknown	Direct	Imprecise	Insufficient
Social support Usual care	12-24 weeks	2 RCT n=188	0 found benefit 2 found no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient
Caregiving coping Usual care	24 weeks	1 RCT n=167	1 found benefit 0 found no difference	Medium	Unknown	Direct	Imprecise	Insufficient

Abbreviations: n=Number; RCT= Randomized Controlled Trial

Evidence Map: Psychosocial Interventions for Caregiver Well-being

Appendix Table E.8. Characteristics of evidence map studies: Psychosocial Interventions for Caregiver Well-being

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Meichsner, 2019[95] (31384663) Germany Small Sample	CBT intervention delivered via internet, weekly message exchanges with therapist, 8 weeks	No treatment	Community 2 x 3 RCT Caregivers	Dementia, unspecified	N=37 Age: yes Sex: yes Race: no Education: no	NR	N=37 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: yes Living with PLWD: yes	NA	NA	Post intervention, 3 months post intervention	NA	CES-D CGS Burden of care Emotional wellbeing
Orgeta, 2019[96] (31609689) England Pilot	Weekly individual behavioral activation intervention delivered at home, 8 weeks, 1-hour sessions	Treatment as usual	Community RCT Caregiver-PLWD Dyads	Diagnosis of dementia of any type, defined by an MMSE score of ≥18	N=63 Age: yes Sex: yes Race: yes Education: yes	Household status	N=63 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Health Status: yes	NA	NA	3 months after start of treatment, 6 months after start of treatment	CSDD BADLS DEMQOL (self and proxy) EQ-5D (self and proxy) NPI	SF-12 HADS EQ-5D
Ta Park, 2019[97] (31609689) (Embase 629157769)[98] United States Pilot	Weekly group sessions of Vietnamese-language cognitive-behavioral skills evidence-based program, 4 weeks, 120-minute sessions	Received educational materials on dementia	Community RCT Caregivers	Dementia or neurocognitive disorder, memory loss confirmed by Montreal Cognitive Assessment if in doubt	NR	NR	N=60 Sex: yes Race: yes Education: yes Relation to PLWD: Yes	Living with PLWD: yes Employment Status: yes	NA	NA	3 months post enrollment in study	NR	CES-D RMBPC (Conditional Bother Subscale)
Terracciano 2019[9] (31866419) United States High ROB	Powerful Tools for Caregivers educational program Weekly 2-hours classes for 6 weeks	Waitlist control	Community-based RCT N=60 informal caregivers	Dementia diagnosis BPSD symptoms (assessed with RMBPC)	N=60 Age: yes Sex: yes Race: no Education: no	NR	N=60 Age: yes Sex: yes Race: yes Education: no Relation to PLWD: yes	Duration: yes Living with PLWD: no Employment Status: yes	NA	NA	6 weeks	RMBPC CMAI	ZBI CES-D NPI Caregiver satisfaction
Uyar 2019[10] (no PMID) Turkey High ROB	Dementia Care and Support Program Multicomponent intervention 8 sessions over 16 weeks	Waitlist control	Community-based RCT N=61 informal caregivers	Dementia diagnosis Physician-diagnosed	NR	NR	N=61 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: no Living with PLWD: no Employment Status: yes	NA	NA	16 weeks	QOL-AD NPI-S	ZBI SF-36 BDI Beck Anxiety Inventory
Wawrziczny 2019[11] (29665714)	Individualized psychoeducatio	Usual support	Community Quasi-	Physician diagnosed Alzheimer's, mixed,	N=102 Age: yes Sex: no	Household characteristics SES	N=102 Age: yes Sex: yes	Duration: yes Employment: yes	NA	NA	7 weeks	NR	Caregiving self-esteem, distress

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
France High ROB	n for 7 weeks, 90 min sessions		experimental Caregivers	Lewy body, or frontotemporal dementias	Race: no Education: no		Race: no Education: yes Relation to PLWD: yes						Self-efficacy Depression Impact on finances Self-rated health
Whitlatch 2019[99] (29171296) US High ROB	Psychoeducation Support, Health, Activities, Resources, and Education (SHARE) Program Dyadic counseling for early stage dementia 6 sessions	Education One 90-minute session	Home-based setting RCT N=128 dyads	Dementia diagnosis	N=128 Age: yes Sex: yes Race: no Education: yes	NR	N=128 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: yes Living with PLWD: yes Employment Status: yes Training: no	NA	NA	2 months	NR	Preferences for Care Tasks Scale Service Availability Measure Dyadic Relationship Scale Care-related Agreement Scale Emotional-Intimacy Disruptive Behavior Scale Dementia Quality of Life
Yoo, 2019[100] (30938110) Korea Small Sample	Psycho-educational intervention, 4 in-person sessions delivered over 8-10 weeks, 60 minutes sessions, 1st session delivered to group, subsequent sessions individual	No treatment	Community Multicenter RCT Caregivers	Possible and probable Alzheimer's disease per NINCDS-ADRDA and DSM-V criteria, a CDR score of 0.5-2.0 and an MMSE score of 10-26, with BPSD within last 6 months to one year	NR	NR	N=76 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	NR	NA	NA	2 weeks post intervention	NA	ZBI (Korean), GDS Philadelphia Geriatric Center Morale Scale (PGCMS) CGA-NPI (burden) Positive Affect and Negative Affect Schedule (PANAS), Self-Compassion Scale (SCS)
Boots 2018[12] (30006327) (27142676)[101]	8-week, blended care self-management	Waitlist control	Community-based RCT N=81	Dementia diagnosis	NR	NR	N=81 Age: yes Sex: yes Race: no	Living with PLWD: yes	NA	NA	8 weeks	NR	Caregiver Self-Efficacy Scale CESD

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
(29258980)[102] Netherlands High ROB	Partner in Balance program Group modified mindfulness-based cognitive therapy, 7 2-hour sessions over 10 weeks		informal caregivers				Education: yes Relation to PLWD: yes						Pearlin Mastery Scale Investigation Choice Experiments for the Preferences of Older People HADS
De Oliveira, 2018[103] (30035341) Brazil Small Sample	Activity-based intervention (TAP) delivered face-to-face to dementia PLWD and their caregivers, 8 one-hour sessions over a 3-month period	Psychoeducation intervention delivered face-to-face to dementia PLWD and their caregivers, 8 sessions over a 3-month period	Community RCT Caregiver-PLWD dyads	Diagnosis of dementia by physician, MMSE score <24, and presence of at least three types of neuropsychiatric symptoms	N=21 Age: yes Sex: yes Race: no Education: yes	NR	N=21 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	NR	NA	NA	Post intervention	NPI-C	ZBI
Kales, 2018[104] (29747583) United States Pilot	Use of WeCareAdvisor tool (for assessment, management, and tracking of BPSD) for one month, with weekly check-in calls of 20 minutes max	No Treatment	Community RCT Caregivers	Clinical diagnosis of dementia or MMSE<24	N=57 Age: yes Sex: yes Race: yes Education: no	NR	N=57 Age: yes Sex: yes Race: yes Education: yes Relationship: yes	NR	NA	NA	Post intervention	Functional Dependence	Confidence in Using Activities, Caregiver Distress (NPI-Q) Caregiver Stress CES-D ZBI Negative Communication Scale
Meichsner, 2018[105] (30597537) Germany Pilot	Telephone-based CBT intervention including grief module delivered via 12 50-minute individual therapy sessions over six months	Written information on dementia and caregiving	Community RCT Caregivers	Diagnosis of dementia	N=273 Age: yes Sex: yes Race: no Education: no	NR	N=273 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	Duration: yes Living with PLWD: yes	NA	NA	Post intervention, six months post intervention	NR	Caregiver Grief Scale (coping)
Novelli, 2018[106]	Activity-based intervention	Usual care	Community RCT	Previous diagnosis of dementia per	N=30 Age: yes	NR	N=30 Age: yes	NR	NA	NA	Post Intervention	NPI (frequency,	NPI Distress ZBI

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Brazil Pilot	(TAP), 8 sessions in the home over 4-month period		Caregiver-PLWD dyads	NIAAA criteria and able to perform at least 2 basic ADLs, with presence of ≥ 2 BPSD in last 30 days	Sex: yes Race: no Education: yes		Sex: yes Race: no Education: yes Relation to PLWD: yes					severity, and carer distress related to behaviors), Quality of Life Scale	Quality of Life Scale
Spalding-Wilson 2018[14] (30258974) US High ROB	Two day-intervention using techniques aimed at fostering self-care for caregivers and improving communication between caregivers	Waitlist	Community-based RCT N=104 informal caregivers	Dementia diagnosis	N=104 Age: no Sex: no Race: no Education: no	NR	N=104 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: no	Duration: yes Living with PLWD: yes	NA	NA	1, 3, 6 months	NR	PSS CBI BDI-II Beck Anxiety Inventory
Van Knippenberg, 2018[107] (30126766) Netherlands Pilot	Experience sampling method (ESM) self-monitoring 3 days/week for 6 weeks, with personalized face-to-face feedback received every 2 weeks OR ESM self-monitoring 3 days/week for 6 weeks with no ESM feedback (semi-structured well-being interview instead)	Usual Care	Community RCT Caregivers	Dementia of any subtype or stage	NR	NR	N=76 Age: yes Sex: yes Race: no Education: yes Relation to PLWD	Living with PLWD: yes	NA	NA	Post intervention, 2 months post intervention	NEO Five Factor Inventory (neuroticism) Utrecht Coping List NPI	Short Sense of Competence Questionnaire Pearlin Mastery Scale CES-D PSS HADS Affect (positive, negative)
Wilz 2018[15] (29190357) (Embase 626130265)[108] (Embase 626123635)[109]	Tele.TAnDem Intervention Telephone-based CBT for family caregivers 12 50-minute sessions	Usual care	Community-based RCT N=273 informal caregivers	Dementia diagnosis	N=273 Age: yes Sex: yes Race: no Education: no	NR	N=273 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: yes Living with PLWD: yes Employment Status: no Training: no	NA	NA	6 months	NR	CESD BDI Emotional wellbeing Gießen Body Complaints List

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Germany High ROB													BEHAVE-AD coping item
Callahan 2017[16] (27893087) US High ROB	Collaborative care and occupational therapy 24 sessions over 2 years	Usual care	Home-based setting RCT N=180 dyads	Dementia diagnosis	N=180 Age: yes Sex: yes Race: yes Education: yes	NR	N=180 Age: yes Sex: no Race: no Education: no Relation to PLWD: yes	NR	NA	NA	24 months	NR	ADCS ADL SPPB
Lok, 2017[110] Turkey Pilot	"First You Should Get Stronger" program delivered to individuals weekly, 7 weeks, 45-minute sessions	No Treatment	Community RCT Caregivers	Diagnosis of dementia per DSM V criteria	N=40 Age: yes Gender: yes Race: no Education: No	NR	N=40 Age: yes Sex: yes Race: no Education: yes Relationship: no	Duration	NA	NA	Post intervention	NR	IC: Zarit Burden Interview, Health Life Style Behavior Scale II
O'Connor, 2017[111] Australia Pilot	Activity-based intervention (TAP), 8 home visits over 4-month period	Three phone calls to caregivers over 4-month period on dementia education	Community RCT Caregiver-PLWD dyads	Diagnosis of frontotemporal dementia according to current diagnostic criteria, presence of behavioral disturbances over the past month as rated by the carer, score of >3.31 on Informant Questionnaire on Cognitive Decline for the Elderly, and able to perform at least 2 basic ADLs	N=20 Age: yes Sex: yes Race: no Education: yes	no	N=-20 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Living with PLWD: yes	NA	NA	Post Intervention	NPI-C (frequency, severity, and carer distress related to behaviors), DAD (ADLs and IADLs), EruoQol5-D	Vigilance Items (carer time feeling "on duty" and "doing things" for PLWD)
Supiano, 2017[112] United States Small Sample	Weekly Complicated Grief Group Therapy (CGGT), 120-minute sessions, 16 weeks, with weekly homework on grief status and emotions	Weekly phone calls, 30 minutes duration, discussing caregiver's grief status and emotions	Community Randomized attention control Caregivers	Dementia, unspecified	NR	NR	N=35 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	NR	NA	NA	Weekly throughout trial, post intervention	NR	Brief Grief Questionnaire (BGQ) Inventory of Complicated Grief-revised (ICG-r) Clinical Global Impressions – Severity Scale (CGI-S)

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
													Clinical Global Impressions-Improvement Scale (CGI-I)
Whitlatch 2017[17] (29171296) US High ROB	Psychoeducation Support, Health, Activities, Resources, and Education (SHARE) Program Dyadic counseling for early stage dementia 6 sessions	Education One 90-minute session	Home-based setting RCT N=128 dyads	Dementia diagnosis	N=128 Age: yes Sex: yes Race: yes Education: yes	NR	N=128 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes Living with PLWD: yes Employment Status: yes Training: no	NA	NA	2 months	NR	Preferences for Care Tasks Scale Service Availability Measure Dyadic Relationship Scale Care-related Agreement Scale Emotional-Intimacy Disruptive Behavior Scale Dementia Quality of Life
Nunez-Naveira, 2016[113] Denmark, Poland, Spain Pilot	UnderstAID application--with information, skills training, social network forum, and daily reminders--made available via mobile device and/or PC for three months with periodic check-ins by research staff	No Treatment	Community, RCT Caregivers	Diagnosis of dementia by a specialist or neurologist per criteria of CMBD-10, DSM-IV, NINDSADRDA	NR	NR	N=77 Age: yes Sex: yes Race: no Education: no Relationship: yes	Duration: yes Payment: yes Health Status: yes Employment Status: yes	NA	NA	Post intervention	NR	CES-D Revised Caregiving Satisfaction Scale
Sepe-Monti, 2016[114] Italy Pilot	Six weekly group sessions of psycho-education program delivered by a psychologist, 2-hour sessions	Two group sessions providing medical information and discussing management of care recipient	Community Multicenter RCT Caregivers	Probable or possible AD according to NINCDS-ADRDA criteria	N=381 Age: yes Sex: yes Race: no Education: no	NR	N=164 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Living with PLWD: yes	NA	NA	Two weeks post intervention, six months post intervention	NR	Coping Orientations to Problems Experienced-New Italian Version (COPE-NIV) Caregiver

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
		behaviors, 2-hour sessions, one session in week two of trial, one session in week four; informational leaflet provided											Burden Inventory (CBI) NPI NPI-Distress Scale SF-12 (physical and mental health) CES-D STAI-Y
Taati 2016[22] (no PMID) Iran High ROB	Support group for family caregivers 8 ~2-hour sessions	Nonspecified control	Community-based setting RCT N=80 informal caregivers	Dementia diagnosis	NR	NR	N=80 Age: no Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: no Employment Status: yes Training: no	NA	NA	8 weeks	NR	DASS-21 (depression, anxiety, stress level)
Zauszniewski, 2016[115] (27500286) (26735507)[116] United States Pilot	40-minute individual resourcefulness training with daily journaling or recording as practice/reinforcement methods for four weeks, with random assignment to choice of method vs. assignment of method	Journaling or recording without learning training skills	Community Modified partially randomized preference trial Caregivers	Dementia, any form	N=138 Age: yes Sex: yes Race: no Education: no	NR	N=138 Age: yes Sex: yes Race: yes Education: yes Relationship: no	Duration: yes Living with PLWD: yes Health Status: yes	NA	NA	Post intervention, 6 weeks post intervention	NR	PSS DCS ESC
Au, 2015[117] (25848237) China Small Sample	Individual psychoeducation by telephone for 4 weeks, 30 minutes sessions, followed by 8 biweekly telephone sessions, 15-20 minutes each, of behavioral activation	Individual psychoeducation by telephone for 4 weeks, 30-minute sessions, followed by 8 biweekly telephone sessions , 15-20 minutes each, of general discussion of	Community RCT Caregivers	Alzheimer's diagnosis for at least 3 months	N=59 Age: yes Sex: yes Race: no Education: no	NR	N=62 Age: yes Sex: yes Race: no Education: no Relationship: yes	Duration: yes Living with PLWD: yes	NA	NA	4 weeks (i.e., after first arm), 6 months (i.e., after second arm)	NR	CES-D RAS

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
		psychoeducation and related information											
Au 2015[118] (no PMID) Hong Kong High ROB	Psychoeducation with telephone-assisted behavioral activation intervention 8 biweekly sessions	Psychoeducation only	Community-based setting RCT N=96 informal caregivers	Dementia diagnosis	NR	NR	N=96 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	Duration: yes Employment Status: no Training: no	NA	NA	4 months	NR	CES-D
Blom 2015[23] (no PMID) (23305463)[119] (25648589)[120] Netherlands High ROB	Mastery of Dementia Intervention Problem solving, relaxation, cognitive restructuring, communication 8 lessons + booster session	Education via e-bulletins	Home-based setting RCT N=251 dyads	Dementia diagnosis	NR	NR	N=251 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: no Living with PLWD: yes Employment Status: no Training: no	NA	NA	3, 6 months	NR	CES-D HADS-A
Chen, 2015[121] (25515800) Taiwan Small Sample	Biweekly in-person education sessions about problem-solving skills, dementia, social resources, and emotional support, six sessions over 3 months (session length not specified)	Biweekly phone calls for usual clinical management (phone call length not specified	Community or Clinic RCT Caregivers	Dementia, unspecified	N=unclear Age: yes Sex: yes Race: no Education: no	NR	N=46 Age: yes Sex: yes Race: no Education: yes Relationship: yes	Living with PLWD: yes	NA	NA	2 weeks post intervention	NR	WCCL-R Caregiver Burden Inventory, RMBPC
Chiu 2015[24] (25615434) Canada High ROB	Problem-solving technique-based intervention 3 1-hour sessions over 3-4 weeks	Nonspecified control	Home-based setting RCT N=56 informal caregivers	Dementia diagnosis	NR	NR	N=56 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	Duration: no Employment Status: yes Training: no	NA	NA	4 weeks	NR	ZBI Pearlin Self-Mastery and Competency Scales PSS
Cristancho-Lacroix, 2015[122] (25967983)	Web-based psycho-educational	Usual care only	Day care center geriatric unit	Alzheimer's diagnosis per DSM-IV criteria	N=49 Age: no Sex: no	NR	N=49 Age: yes Sex: yes	Living with PLWD: yes Health status: yes	NA	NA	Post intervention, 3	NR	RSCS RMBPC

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
(25263541)[123] France Small Sample	program delivered in 15-30-minute weekly sessions for 12 weeks		RCT Caregivers		Race: no Education: no		Race: no Education: yes Relationship: yes				months post intervention		ZBI NHP
Gallagher-Thompson 2015[25] (25590939) US High ROB	Psychoeducation Fotonovela for reducing stress and depression in Latino caregivers	Usual care with basic information	Home-based setting RCT N=147 dyads	Dementia diagnosis	N=147 Age: yes Sex: no Race: yes Education: yes	NR	N=147 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes Living with PLWD: yes Employment Status: yes Training: no	NA	NA	4, 6 months	NR	CES-D RMBPC Reaction
Gaugler, 2015[124] (25751083) United States Pilot	Individual psychosocial intervention (other family members or care decision makers present per participant discretion), six sessions, weekly for three weeks, then monthly for 3 months, 60-120-minute sessions	No Treatment	Community RCT Caregivers	Dementia	N=36 Age: yes Sex: yes Race: yes Education: yes	NR	N=36 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Employment Status: yes	NA	NA	Post intervention, 4 months post intervention	NR	ZBI CES-D GDS NPI-Q Role overload PSS
Kamkhagi, 2015[125] (no PMID) Brazil Small Sample	Psychological intervention delivered via weekly group sessions, 90-minute sessions, 14 weeks	Non-psychologically-oriented intervention delivered via weekly group sessions, 90-minute sessions, 14 weeks	Community RCT Caregivers	Mild or moderate Alzheimer's disease	NR	NR	N=37 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Living with PLWD: yes	NA	NA	Post intervention	NR	ZBI BDI WHO-QoL Scale
Losada 2015[26] (21061414) Spain High ROB	1. CBT 2. ACT (Acceptance and Commitment Therapy) to reduce depression in caregivers	3. Minimal support control	Community-based setting RCT N=135 informal caregivers	Dementia diagnosis	NR	NR	N=135 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: yes Employment Status: yes Training: yes	NA	NA	2 months	Barthel Index RMBPC	CES-D Profile of Mood States

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
	8 weekly 90-minute sessions												
Paun, 2015[126] (24510968) United States Pilot	12 weekly group sessions of chronic grief management intervention, 60-90-minute sessions	No treatment (Two check-in calls at 1.5 months and 4.5 months)	Long-term care facilities Pre-test/multiple post-test quasi-experimental design Caregiver	Diagnosis of AD or a related dementia	NR	NR	N=93 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	NR	NA	NA	Post intervention, 3 months post intervention	NR	FPCR (Family Perception of Caregiver Role – role stress) MMCGI (grief in caregivers of persons with AD) CES-D
Aboulafia-Brakha, 2014[127] (no PMID) Brazil Small Sample	Weekly 90-minute group sessions of psychoeducation and cognitive behavioral therapy, or weekly 60-minute group sessions of psychoeducation alone, 8 weeks	No Control Group	Community Semi-Random Comparative Trial Caregivers	Clinical diagnosis of possible or probable Alzheimer's disease in the moderate or severe stage, with diagnosis and staging based on the DSM-IV, the FAST, and the MMSE (Portuguese version)	NR	NR	N=35 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	Duration: yes Living with PLWD: yes Employment Status: yes	NA	NA	Post intervention	NR	PSS ZBI BDI STAI-S STAI-T Portuguese version
Arango-Lasprilla 2014[29] (24550547) Spain High ROB	Group-based cognitive behavioral intervention for caregiver mental health	Educational control	Community-based setting RCT N=69 informal caregivers	Dementia diagnosis	NR	NR	N=69 Age: yes Sex: yes Race: yes Education: no Relation to PLWD: yes	Duration: yes Employment Status: no Training: no	NA	NA	8 weeks 3 months	NA	PHQ-9 ZBI Satisfaction with Life Scale PSS
Dowling, 2014[128] (24113564) United States Small Sample	Weekly, one-on-one, positive affect skill-building intervention sessions delivered in person or via video-conference, 5 weeks, 1-hour sessions	Weekly, one-one one, sessions delivered in person or via video-conference consisting of a thematic interview, 5 weeks, 1-hour sessions	Community Randomized attention control Caregivers	Frontotemporal dementia (FTD)	NR	NR	N=26 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes Living with PLWD: yes	NA	NA	One-week post intervention, One-month post intervention	NR	DES CES-D PSS NPI ZBI

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Gonzalez, 2014[129] (25328754) United States Pilot	Weekly group resourcefulness trainings delivered for 6 weeks, 2 hours per training	Usual Care	Community RCT Caregivers	Probably diagnosis of AC using the NINCDS/ADRD criteria for probable AC	N=102 Age: yes Sex: yes Race: yes Education: no	NR	N=102 Age: yes Sex: yes Race: yes Education: yes Relationship: yes	Health status: yes	NA	NA	Within one-week post intervention, 12 weeks post intervention	RMBPC	STAI CESD CRS
Passoni 2014[32] (24614271) Italy High ROB	1. Group-based cognitive behavioral intervention for caregiver mental health 2. Manual only	Control	Community-based setting RCT N=100 informal caregivers	Dementia diagnosis	N=100 Age: yes Sex: yes Race: no Education: no	NR	N=100 Age: yes Sex: yes Race: no Education: no Relation to PLWD: no	Duration: no Employment Status: no Training: no	NA	NA	6 months	NA	Anxiety and Depression Scale-Reduced Form Caregiver Need Assessment Family Strain Questionnaire
Bruvik 2013[33] (24348500) Norway High ROB	Tailored psychosocial support intervention for depression	Usual care	Home-based setting RCT N=230 dyads	Dementia diagnosis	N=230 Age: yes Sex: yes Race: no Education: yes	NR	N=230 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: yes Living with PLWD: yes Employment Status: yes Training: no	NA	NA	12 months	CSDD	GDS
Huang 2013[34] (23933422) Taiwan High ROB	Training program for caregivers for skills managing behavioral problems	Written instructions and telephone followup	Home-based setting RCT N=129 dyads	Dementia diagnosis	N=129 Age: yes Sex: yes Race: no Education: no	NR	N=129 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: yes Employment Status: no Training: no	NA	NA	3, 6 months	CMAI	Agitation Management Self-efficacy Scale Preparedness and Competence Scales
Judge 2013[35] (22899427) Judge 2011 (19808841)[130] Judge 2011 (no PMID)[131] US High ROB	ANSWERS Intervention (Acquiring New Skills While Enhancing Remaining Strengths) Education and cognitive rehabilitation skills	Educational pamphlets	Home-based setting RCT N=128 dyads	Dementia diagnosis	N=128 Age: yes Sex: yes Race: yes Education: yes	NR	N=128 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: no Employment Status: yes Training: no	NA	NA	11, 19 weeks	NA	Pearlin Caregiver Mastery scales Depression Anxiety QOL Self-Esteem
Kajiyama 2013[36] (23461355)	iCare Stress Management e-Training Program	Information only	Home-based setting RCT	Dementia diagnosis	N=150 Age: yes Sex: no	NR	N=150 Age: yes Sex: yes Race: no	Duration: yes Employment Status: no Training: no	NA	NA	3 months	NA	CES-D PSS RMBPC

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
US High ROB			N=150 dyads		Race: no Education: no		Education: yes Relation to PLWD: yes						Bother PQOL
Kuo 2013[37] (22778053) (27653753)[132] Kuo 2014 (no PMID)[133] Taiwan High ROB	Training program to improve QOL and decrease depression 2 2-3-hour sessions 1 week apart	Attention control	Home-based setting RCT N=129 informal caregivers	Dementia diagnosis	NR	NR	N=129 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: yes Employment Status: no Training: no	NA	NA	2 weeks 3, 6 months	NA	HRQOL CES-D
Kwok, 2013[134] (24072965) China Small Sample	Psychoeducation for caregivers by telephone, twelve 30-minute weekly sessions, plus DVD containing educational information about dementia caregiving	DVD containing educational information about dementia caregiving	Community RCT Caregivers	Clinical diagnosis of dementia of any stage	N: no Age: no Sex: yes Race: no Education: no	NR	N=42 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	NR	NA	NA	Post intervention	NR	ZBI Revised Scale for Caregiving Self-efficacy
Moore 2013[38] (23916631) US High ROB	Pleasant Events Program Behavioral Activation therapy for improving physical and mental health in caregivers 6 weeks	Educational manual	Community-based setting RCT N=100 dyads	Dementia diagnosis	N=100 Age: no Sex: no Race: no Education: no	NR	N=100 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: no	Duration: yes Employment Status: no Training: no	NA	NA	6 weeks 12 months	NA	CES-D Health status Social Support Scale PANAS
Joling 2012[39] (22303473) (22876304)[135] (24053631)[136] (18208607)[137] Netherlands High ROB	Family Meeting Intervention for depression and anxiety in caregivers Four sessions every 2-3 months	Usual care	Home-based setting RCT N=192 caregivers	Dementia diagnosis	N=192 Age: yes Sex: yes Race: no Education: no	NR	N=192 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: no Living with PLWD: yes Employment Status: no Training: no	NA	NA	3, 6, 9, 12 months	NA	CES-D HADS-A Caregiver Reaction Assessment SF-12
Chu 2011[41] (20847363) Taiwan High ROB	Support group for caregiver burden and depression 12 weeks	Usual care	Home-based setting RCT N=85 dyads	Dementia diagnosis	NR	NR	N=85 Age: no Sex: yes Race: no Education: no	Duration: no Living with PLWD: yes Employment Status:	NA	NA	3, 4 months	NA	BDI-II CBI

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							Relation to PLWD: yes	no Training: no					
Davis, 2011[138] (20842759) United States Small Sample	Psychosocial intervention delivered by telephone, 10 contacts over 3 months: initial call and 7 weekly follow-up calls (60 minutes each), and 2 bimonthly termination calls (35-45 minutes each)	No Treatment	Community RCT Caregivers	Diagnosis of dementia	N=53 Age: yes Sex: no Race: no Education: no	NR	N=53 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	NR	NA	NA	Post intervention	NR	CES-D ZBI SF-36
Losada 2011[44] (21061414) Spain High ROB	CBT for caregiver behavioral activation and modifying dysfunctional thoughts 12 sessions	Usual care	Community-based setting RCT N=170 dyads	Dementia diagnosis	N=170 Age: yes Sex: no Race: no Education: no	NR	N=170 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	Duration: yes Employment Status: no Training: no	NA	NA	3 months	RMBPC	CES-D Dysfunctional Thoughts about Caregiving Questionnaire Leisure Time Satisfaction
Spijker 2011[45] (21358385) (19500421)[139] (23290200)[140] Netherlands High ROB	Systematic Care Program for Dementia	Usual care	Community health centers Cluster RCT	PLWD with suspected dementia and their caregivers Exclusion criteria	N=155 Intervention group140 Control group Age: yes Sex: yes Education: yes Race % majority: yes	Household characteristics: yes	Age: yes Sex: yes Race % majority: yes Education: yes Relation to PLWD: yes	Living with PLWD: yes	Education: yes	NR	12 months	PLWD institutionalization NPI	Sense of competence Depression QoL Distress
Wilz 2011[48] (no PMID) (26311735)[141] (27792398)[142] (28428730) Germany High ROB	CBT for goal-attainment and treatment compliance 7 60-minute sessions over 3 months	1. Attention control 2. Usual care	Community-based setting RCT N=229 dyads	Dementia diagnosis	N=229 Age: yes Sex: no Race: no Education: no	NR	N=229 Age: yes Sex: no Race: no Education: no Relation to PLWD: no	Duration: yes Employment Status: no Training: no	NA	NA	3, 6 months	NA	Goal Attainment Scaling
Au, 2010[143] (no PMID) China Small Sample	Weekly CBT group intervention, 13 weeks, 2-hour sessions	No Treatment	Community RCT Caregivers	Presence of Alzheimer's Disease	NR	NR	N=37 Age: yes Sex: no Race: no Education: yes Relation to PLWD: yes	Living with PLWD, Employment: yes	NA	NA	Post intervention	NR	CES-D Revised Scale for Caregiving Self-Efficacy Chinese Way

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
													of Coping Questionnaire
Gallagher-Thompson, 2010[144] (359062574) United States Pilot	CBT skill training program delivered via DVD, 2.5 hours in length	General educational DVD program on dementia, 2.0 hours in length	Community RCT Caregivers	Significant memory lost or deterioration in cognitive abilities	N=68 Age: yes Sex: no Race: no Education: yes	NR	N=76 Age: yes Sex: yes Race: no Education: yes Relationship: yes	Health status: yes	NA	NA	Post intervention	NR	CES-D Positive Affect subscale RMBPC
Gitlin 2010[145] (20810376) US High ROB	COPE (Care of Persons with Dementia in their Environments) biobehavioral intervention 12 home or phone contacts over 4 months	Attention control	Home-based setting RCT N=237 dyads	Dementia diagnosis	N=237 Age: yes Sex: yes Race: yes Education: no	NR	N=237 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes Employment Status: no Training: no	NA	NA	4, 9 months	Functional Independence QOL-AD Agitated Behavior in Dementia	Perceived Change Index Caregiver confidence
Kurz 2010[51] (19946869) Germany High ROB	Psychoeducation 7 90-minute biweekly sessions + boosters over 15 months	One session	Home-based setting RCT N=292 dyads	Dementia diagnosis	N=292 Age: yes Sex: yes Race: yes Education: no	NR	N=292 Age: yes Sex: yes Race: yes Education: no Relation to PLWD: yes	NR	NA	NA	5, 15 months	MMSE NPI ADCS-ADL	MADRS SF-12 Time spent caregiving Resource use QOL
Williams 2010[52] (20978227) US High ROB	Psychoeducation video on coping skills for caregivers Telephone coaching 2 10-minute modules per week for 5 weeks	Waitlist	Home-based setting RCT N=116 informal caregivers	Dementia diagnosis	NR	NR	N=116 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes Living with PLWD: yes Employment Status: no Training: no	NA	NA	3, 6 months	NA	PSS PSQI STAI STAXI CES-D
Gavrilova 2009[53] (18814197) Russia High ROB	Psychoeducation 10/66 intervention basic education and training for managing problem behaviors 5 weekly 30-minute sessions	Usual care	Community-based setting RCT N=60 dyads	Dementia diagnosis	N=60 Age: yes Sex: yes Race: no Education: no	NR	N=60 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	Duration: yes Employment Status: no Training: no	NA	NA	6 months	NA	ZBI SRQ 20 WHOQOL-BREF NPI-Q DEMQOL

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Dias 2008[146] (18523642) India Pilot	Support and guidance from Home Care Advisors team	Caregivers received only education and information on dementia; Intervention delayed for 6 months	Home-based RTC	PLWD diagnosed with mild to moderate dementia and their home caregivers Exclusion criteria	N= 33 intervention group 26 control group Age: yes Sex: yes Education: yes Race % majority: N	Household characteristics: yes Availability of paid help: yes Income: yes	Age: yes Sex: yes Rae % majority: no Education: yes Relation to PLWD: yes	NR	NR	Training: yes	6 months	Activities of daily living NPI	Caregiver mental health Caregiver burden
Gitlin, 2008[147] (18310553) (20847903)[148] (19420314)[149] United States Pilot	Activity-based intervention (TAP), 6 home visits and two 15-minute phone calls over 4 months	Tailored activity intervention administered upon conclusion of main trial (6 home visits and two 15-minutes phone calls over 4 months)	Community RCT Caregiver-PLWD dyads	Diagnosis of dementia by physician or MMSE score <24	N=60 Age: yes Sex: yes Race: yes Education: yes	NR	N=60 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Health status: yes	NA	NA	Post intervention	CSDD Quality of Life-AD Behavioral occurrences	ZBI Subjective burden Objective burden CES-D
Tremont, 2008[150] (20228893) (18838742)[151] Pilot	Psychosocial telephone intervention delivered on set schedule, completing 23 calls over one year, calls ranged from 15-60 minutes, totaling approximately 12 hours	Standard Care	Community RCT Caregivers	Formal dementia diagnosis per DSM-IV criteria and CDR score of 1 or 2	N=60 Age: yes Sex: no Race: no Education: no	NR	N=60 Age: yes Sex: no Race: no Education: yes Relation to PLWD: no	Duration: yes Living with PLWD: yes Health Status: yes	NA	NA	Post intervention	NR	ZBI RMBPC GDS Self-Efficacy Scale SF-36
Gant, 2007[152] (17545139) United States Pilot	Psychosocial intervention delivered via 10-session video series with workbook and 12 weekly telephone coaching sessions (phone call length not specified)	Education intervention delivered via booklet and 7 bi-weekly check-in calls (phone call length not specified)	Community RCT Caregivers	Diagnosis of dementia secondary to: Alzheimer's disease, Parkinson's disease, cerebrovascular disease, Huntington's disease, Korsakoff's disease, multiple sclerosis, or other	N=32 Age: yes Sex: no Race: no Education: no	NR	N=32 Age: yes Sex: yes Race: no Education: yes Relationship: yes	Living with PLWD: yes Employment status: yes	NA	NA	Post intervention	NR	RMBPC RSCSE PNAS Target complaints (upset, sad, frustrated, and irritated)
Glueckauf, 2007[153] (no PMID)	Weekly cognitive-behavioral	No treatment	Community RCT Caregivers	Medical diagnosis of Alzheimer's disease or another	N=24 Age: yes Sex: yes	NR	N=24 Age: yes Sex: yes	Duration: yes	NA	NA	One-week post intervention	NR	Caregiver Appraisal Inventory CAI

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 United States Small Sample	intervention delivered via at-home video with telephone follow-up: 7 weeks of 45-minute group phone sessions, followed by 5 weeks of one-hour individual phone sessions, 12 weeks			type of progressive dementia	Race: yes Education: no		Race: yes Education: yes Relation to PLWD: yes						Caregiver Self-Efficacy CES-D
Marquez-Gonzalez 2007[57] (18074249) (22899425)[154] Spain High ROB	Cognitive behavioral intervention for caregiver coping 8 weekly 2-hour sessions	Waitlist	Community-based setting RCT N=74 informal caregivers	Dementia diagnosis	NR	NR	N=74 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: yes Employment Status: no Training: no	NA	NA	8 weeks	MBPC (proxy)	CES-D Dysfunctional Thoughts about Caregiving Questionnaire
Ulstein 2007[58] (17986818) Norway High ROB	Psychosocial intervention for education about dementia and structured problem-solving 3-hour education program + 6 2-hour group meetings over 1 year	Usual care	Community-based setting RCT N=180 dyads	Dementia diagnosis	N=180 Age: no Sex: yes Race: no Education: no	NR	N=180 Age: no Sex: yes Race: no Education: no Relation to PLWD: yes	NR	NA	NA	1 year	NPI	Relative Stress Scale
Gonyea 2006[59] (17169938) US High ROB	Behavioral intervention to reduce caregiver distress, burden, and PLWD symptom severity 5 90-minute weekly sessions, 16-20 hours total training	Education only	Community-based setting RCT N=80 informal caregivers	Dementia diagnosis	NR	NR	N=80 Age: yes Sex: yes Race: yes Education: no Relation to PLWD: yes	Duration: yes Employment Status: no Training: no	NA	NA	6 weeks	NPI	ZBI

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Beauchamp 2005[61] (no PMID) US High ROB	Multimedia support program delivered via internet	Waitlist	Community-based setting RCT N=299 informal caregivers	Dementia diagnosis	NR	NR	N=299 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes Employment Status: no Training: no	NA	NA	1 month	NA	CES-D STAI CSS Positive Aspects of Caregiving
Akkerman, 2004[155] (15106393) United States Small Sample	Weekly cognitive-behavioral group intervention, 9 weeks, 2-hour meetings	No Treatment	Community RCT Caregivers	Diagnosis of Alzheimer's	NR	NR	N=38 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes	NA	NA	Post intervention, 6 weeks post intervention	NR	HAMA BAI
Nobili, 2004[156] (15249851) Italy Pilot	60-minute home visit from a psychologist, separate 90-minute home visit from occupational therapist	Standard counseling via help line, information about services and supports	Community RCT Caregiver-PLWD Dyads	Clinical diagnosis of dementia made by a neurologist, geriatrician, or psychiatrist	N=69 Age: yes Sex: yes Race: no Education: yes	NR	N=69 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: yes Living with PLWD: yes Employment Status: yes	NA	NA	6 months post intervention, 12 months post intervention	ADLs SBI-C (problem behaviors)	RSS
Burgio 2003[63] (12937335) (16625937)[157] US High ROB	Skills training group workshop + 16 home-based treatment sessions over 12 months	Educational materials and telephone support	Home-based setting RCT N=118 dyads	Dementia diagnosis	N=118 Age: yes Sex: yes Race: yes Education: yes	NR	N=118 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes Employment Status: yes Training: no	NA	NA	6 months	MMSE RMBPC (proxy)	Positive Aspects of Caregiving RMBPC bother Lubben Social Network Index Leisure Time Satisfaction CES-D Desire to Institutionalize
Burns 2003[64] (12937333) (19290751)[158] US High ROB	REACH PLWD behavior management and caregiver stress management	Targeted educational materials	Home-based setting RCT N=167 dyads	Dementia diagnosis	N=167 Age: yes Sex: yes Race: yes Education: yes	NR	N=167 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes Employment Status: yes Training: no	NA	NA	2 years	RMBPC	General wellbeing scale CES-D

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Coon 2003[65] (14570964) US High ROB	Psychoeducation skill training for 1. anger or 2. depression management over 3-4 months	Waitlist	Home-based setting RCT N=169 dyads	Dementia diagnosis	N=169 Age: no Sex: no Race: no Education: no	NR	N=169 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	Duration: yes Employment Status: no Training: no	NA	NA	4, 7 months	NA	STAXI Multiple Affect Adjective Checklist Hostility and Depression subscales Ways of Coping Checklist Positive Coping subscales BDI Caregiving Self Efficacy Scale
Gitlin 2003[67] (12937332) (15860476)[159] (17595426)[160] (17563191)[161] US High ROB	REACH Home Environmental Skill-Building Program 5 home-based sessions + 1 telephone session	Usual care	Home-based setting RCT N=255 dyads	Dementia diagnosis	N=255 Age: yes Sex: yes Race: no Education: no	NR	N=255 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes Employment Status: no Training: no	NA	NA	6 months	NA	RMBPC Upset Caregiving Mastery Index Task Management Strategy Index
Hebert 2003[68] (12496309) (15841829)[162] Canada High ROB	Psychoeducation Group Program on stress appraisal and coping 15 2-hour weekly sessions	Usual care	Home-based setting RCT N=158 dyads	Dementia diagnosis	NR	NR	N=158 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: yes Living with PLWD: yes Employment Status: yes Training: no	NA	NA	4 months	RMBPC	RMBPC reaction ZBI STAI Bradburn Revised Affective Scale Inventory of Socially Supportive Behavior Ilfeld Psychiatric Symptoms Index
Huang, 2003[163] Taiwan Pilot	Two-session in-home caregiver training, sessions separated by one week, 2-3-	Written educational materials with social telephone phone calls once a week for	Community RCT Caregivers	Diagnosis of dementia by psychiatrist or neurologist	N=59 Age: yes Sex: yes Race: no Education: yes	NR	N=59 Age: yes Sex: yes Race: no Education: yes	NR	NA	NA	Three weeks after experimental group completed two-session	Cohen-Mansfield Agitation Inventory (CMAI;	Agitation Management Self-Efficacy Scale (AMSS)

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	hour sessions; training accompanied by follow-up phone calls once a week for two weeks; accompanied by further weekly follow-up consultation calls beginning three weeks after completion of two-session program	two weeks; accompanied by weekly follow-up social phone calls beginning three weeks after experimental group completed two-session program					Relation to PLWD: yes				training program; again three months after training completion	problematic behaviors)	
Martin-Cook, 2003[164] (14682086) United States Pilot	Weekly group psychoeducational intervention, 4 weeks, 2-hour sessions	Standard Care	Community RCT Caregivers	Diagnosis of dementing illness with behavioral disturbance	NR	NR	N=37 Age: no Sex: no Race: no Education: no Relationship: no	NR	NA	NA	Two weeks post intervention, 10 weeks post intervention	NR	Caregiver Resentment Scale CES-D NPI
Fung 2002[69] (12037799) Hong Kong High ROB	Support group for family caregivers 12 1-hour sessions	Usual care	Community-based setting RCT N=52 dyads	Dementia diagnosis	NR	NR	N=52 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: yes Employment Status: yes Training: no	NA	NA	3 months	NA	NPI-D WHOQOL-BREF Mental health service use
Garand, 2002[165] (12143075) United States Pilot	Psychoeducational nursing intervention delivered through two in-home visits, 3 hours each, followed by twice weekly phone calls for 6 months (phone call length not specified)	Psychological support, traditional dementia information, and referral to community-based services, delivered through two in-home visits, 3 hours each, followed by twice weekly phone calls for 6 months	Community RCT Caregivers	Dementia, diagnosed or undiagnosed	N=39 Age: yes Sex: yes Race: yes Education: no	NR	N=39 Age: yes Sex: yes Race: yes Education: yes IC Relation to PLWD: yes	Health Status: yes Employment Status, Training: yes	NA	NA	One week after in-home phase, again after 6 months of biweekly phone calls	NR	Total mood disturbance

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
		(phone call length not specified)											
Stolley, 2002[70] (11954669) US High ROB	Psychoeducation based on progressively lowered stress theory	Basic dementia education	Community RCT Caregivers	Physician-diagnosed dementia; 66% AD	NR	NR	N=241 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes	NA	NA	12 months	NA	ZBI Mastery
Wright 2001[71] (11885210) US High ROB	Nurse education and counseling program Home visits and phone calls	Attention control	Community-based setting RCT N=93 informal caregivers	Dementia diagnosis	N=93 Age: yes Sex: yes Race: no Education: no	NR	N=93 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes Living with PLWD: yes Employment Status: no Training: no	NA	NA	2, 6, 12 weeks 6, 12 months	Blessed Dementia Rating Scale CMAI	Caregiving Hassle Scale CES-D Multilevel Assessment Inventory
Marriott, 2000[166] (10974962) United Kingdom Small Sample	Cognitive-behavioral family intervention, individual sessions every two weeks, 14 sessions (length of sessions unspecified)	In-depth interview of caregiver OR no interview	Community RCT Caregivers	Satisfaction of DSM-III-R criteria for primary degenerative dementia of the Alzheimer type	N=42 Age: yes Sex: yes Race: no Education: no	NR	N=42 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	Duration: yes Living with PLWD: yes	NA	NA	Post intervention, three months post intervention	ADLs CSDD	GHQ (caseness/psychiatric morbidity) BDI
Steffen, 2000[167] (no PMID) United States Pilot	Weekly 30-minute psychoeducational videos--viewed either at home with 20-minute weekly telephone sessions or in a class setting with a trained facilitator--with accompanying workbook, 8 weeks, 90-minute classroom sessions	No Treatment	Community RCT Caregivers	Diagnosis of Alzheimer's disease, multi-infarct dementia or some other dementing illness	NR	NR	N=33 Age: yes Sex: yes Race: yes Education: yes Relationship: yes	NR	NA	NA	Post intervention	NR	CgAI BDI Revised Care-Giving Self-Efficacy Scale
Buckwalter 1999[72]	Psychoeducation for managing	NR	Community-based	Dementia diagnosis	N=245 Age: no	NR	N=245 Age: yes	Duration: yes Employment Status:	NA	NA	6, 12 months	NA	POMS GDRS

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
(10222636) (12464756)[168] US High ROB	problem behaviors Information, case management referrals, service provision, support groups		setting RCT N=245 dyads		Sex: yes Race: no Education: no		Sex: yes Race: yes Education: yes Relation to PLWD: yes	yes Training: yes					
Chang 1999[73] (10337848) (15471059)[169] USA High ROB	Cognitive-behavioral intervention for PLWD and care-giver	Attention only placebo telephone calls	Homebased RCT	PLWD diagnosed with dementia MMSE<21 Significant eating and dressing problems Home caregivers	N=34 Intervention group 31 Control group Age: yes Sex: no Education: yes Race % majority: yes	NR	Age: yes Sex: yes Race % majority: yes Education: yes Relation to PLWD: yes	Duration: yes Living with PLWD: yes Training: yes	NR	NR	12 weeks	MMSE	Depression Burden Satisfaction Anxiety
Ostwald 1999[74] (10396888) US High ROB	Psychoeducation group intervention for caregiver burden and depression 7 weekly 2-hour sessions	Waitlist	Community-based setting RCT N=117 dyads	Dementia diagnosis	N=117 Age: yes Sex: yes Race: no Education: yes	PLWD SES: yes	N=117 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: no	Duration: no Employment Status: no Training: no	NA	NA	5 months	RMBPC	ZBI CES-D
McCurry, 1998[170] (9520929) United States Pilot	Weekly small group behavioral treatment sessions, 6 weeks (session length not specified) OR weekly individual behavioral treatment, 4 weeks (session length not specified)	No Treatment	Community RCT Caregivers	Diagnosis of senile dementia	N=36 Age: yes Sex: yes Race: no Education: no	NR	N=36 Age: yes Sex: yes Race: yes Education: yes Relationship: yes	Living with PLWD: yes	NA	NA	Post intervention, 3 months post intervention	NR	CES-D SCB RMBPC
Moniz-Cook, 1998[171] (no PMID) Pilot	Advice pamphlets plus home-based individualized intervention delivered after dementia	Advice pamphlets plus usual care (i.e., referred to local psychogeriatric community	Community RCT Caregiver-PLWD Dyads	Probable diagnosis of Alzheimer's disease, multi-infarct dementia, or frontal lobe dementia per neuropsychological	N=30 Age: yes Sex: yes Race: no Education: no	Household characteristics	N=30 Age: no Sex: no Race: no Education: no Relation to PLWD: no	NR	NA	NA	6 months after diagnosis (caregivers), 18 months after diagnosis	Memory impairment RBMT	GHQ BDI HADS

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	diagnosis, six to 12 hours in duration, four to fourteen weeks	team upon diagnosis)		profiles and ICD-10 operational criteria for diagnosing dementia							(PLWD and caregivers)		
Brodaty, 1997[172] (9520929) Australia Pilot	Caregiver training program delivered daily for 10 days in residential setting immediately upon enrollment in study, followed by telephone check-ins at decreasing time intervals over the next 12 months OR same treatment and follow-up delivered 6 months after study enrollment	No Treatment (PLWD memory retraining only, delivered to all PLWD in study)	Community RCT Caregivers	Diagnosis of Dementia	N=96 Age: yes Sex: yes Race: no Education: no	NR	N=96 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	Living with PLWD: yes	NA	NA	3 months post-intervention, 6 months post-intervention, 12 months post-intervention, and annually thereafter until conclusion of 8-year study	Nursing home admission, time until death	NR
Teri, 1997[173] (9224439) United States Small Sample	Behavior therapy focused on increasing pleasant events OR behavior therapy focused on problem solving situations of concern, both treatments administered weekly for 9 weeks, 60-minute sessions	Typical therapeutic care weekly for 9 weeks, 60-minute sessions OR no treatment (waitlist)	Community RCT Caregiver-PLWD dyads	Probable Alzheimer's disease per NINCDS-ADRDA criteria	N=88 Age: yes Sex: yes Race: no Education: yes	NR	N=88 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	NR	NA	NA	Post intervention, six months post intervention	HDRS CSDD BDI Record of Independent Living (RIL)	HDRS ZBI
Gendron, 1996[174] (26250550) Pilot	Weekly cognitive-behavioral skills training group intervention, 8	Weekly support group emphasizing information and social exchange	Community RCT Caregivers	Diagnosis of dementia	NR	NR	N=35 Age: yes Sex: yes Race: no Education: yes	Duration: yes Living with PLWD: yes Health Status: yes	NA	NA	Post intervention, 3-month follow-up, 6 month follow up	NR	Hopkins Symptom Checklist (distress) Automatic Thoughts

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	weeks, 90-minute sessions	8 weeks, 90-minute sessions					Relation to PLWD: yes						Questionnaire (depressive thinking) ZBI RMBPC
Hebert, 1994[175] (24087060) (25107702)[176] Canada Small Sample	Weekly structured support group sessions for 8 weeks, 2-hour sessions	Referral to informal monthly meetings of the Alzheimer's Society	Community RCT Caregivers	Dementia confirmed by DSM-IIIR criteria	NR	NR	N=45 Age: yes Sex: yes Race: no Education: yes Relationship: yes	Living with PLWD: yes Employment status: yes	NA	NA	Post intervention, 6 months post intervention	SMAF	ZBI BSI RMBPC
Tappen, 1994[177] United States Small Sample	Group interventions of (a) skill training or (b) mental stimulation delivered 5 days a week, 20 weeks, 2.5 hours per session	No treatment	Nursing home RCT PLWD	Diagnosis of dementia with six or more errors out of 10 items on the Short Portable Mental Status Questionnaire	N=63 Age: yes Gender: yes Race: no Education: no	NR	NA	NA	NA	NA	Post intervention	Physical Self-Maintenance Scale Performance Test of ADLs	NA

Abbreviations: BDI= Beck Depression Inventory; CES-D=C Center for Epidemiologic Studies-Depression Scale; char=characteristics; CMAI= Cohen-Mansfield Agitation Inventory; FC=formal caregiver; GDRS= Geriatric Depression Rating Scale; IC=informal caregiver; MCS-12=Mental Health Composite, 12-item Short-Form Health Survey; MBPC= Memory Behavior Problem Checklist; MMSE= Mini Mental State Examination; N=number; NA=Not Applicable; NPI=Neuropsychiatric Inventory; NPI-D=Neuropsychiatric Inventory-Caregiver Distress; NR=Not Reported; PCS-12=Physical Health Composite, 12-item Short-Form Health Survey; POMS= The Profile of Moods States; PMID=PubMed Identification Number; PSS=Perceived Stress Scale; PLWD=Persons with Dementia; RCT=Risk of Bias; RoB=Risk of Bias; RMBPC=Revised Memory Behavior Problem Checklist; RS=Reporting Status; SES=socioeconomic status; STAI= Spielberger State-Trait Anxiety Inventory; STAXI=Spielberger State-Trait Anger Inventory; WHOQOL-BREF= World Health Organization Quality of Life Instruments; ZBI=Zarit Burden Interview

Social Support

Appendix Table E.9. Risk of bias assessment: social support

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Huis 2019[178] (32130142)	6 weeks 12 weeks	Medium 14%	Low	Medium	High	Low	Medium	Netherlands Organization for Health Research and Development program Tussen Weten en Doen	High
Van Mierlo 2015[179] (25872457)	6 months 12 months	Medium 6 months: 12% High 12 months: 33%	Medium	High	Medium	Medium	X	Government	High
Wang 2012[180] (22554214)	28 weeks	Low 7.6%	Medium	Low	Low	Low	Medium	NR	Medium
Logsdon 2010[181] (20693265)	2 months	Low 4%	Medium	Low	Medium	High	X	Government	High

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Charlesworth 2008[182] (18284895) Charlesworth 2008[183] (18505757) Wilson 2009[184] (19101921)	6 months 15 months 24 months	Medium 6 months: 10% 15 months: 16% High 24 months: 21%	Low	Medium	High	Low	X	Government	High
Winter 2006[185] (17267370)	6 months	Low 8.7%	Medium	High	High	Medium	X	Non-profit	High
Mahoney 2003[186] (12937334) Mahoney 2001[187] (11346473)	6 months 12 months 18 months	Low 6 months: 8% Medium 12 months: 14% 18 months:18%	Low	Low	Medium (6 months) High (12 and 18 months)	Medium	Medium	Government	Medium (6 months) High (12 and 18 months)
Pillemer 2002[188] (NA)	6 months	High 22%	X	X	X	X	X	Government	High
Goodman 1990[189] (2354800) Goodman 1990[189] (2284602)	NR	High 34%	X	X	X	X	X	NR	High

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Appendix Table E.10. Characteristics of included studies: social support

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Wang 2012[180] (22554214) China Medium Explanatory	In person, peer-led mutual support group for caregivers; bi-weekly 90-minute sessions for 24 weeks (12 total sessions)	Usual care (conventional family services)	Dementia resource and respite centers RCT Multisite 78 Informal Caregivers	All dementia types and severities (primarily AD and cerebrovascular). Dementia diagnosis based on DSM-IV criteria	N=78 81% Age 61+ 53% Female Race NR Education NR	NR	N=78 65% Age 31-70 62% Female 73% Secondary School or Higher Race NR 37% Spouse	Duration: Yes Employment Status: Yes	NA	NA	28 weeks	NA	NPI-D WHOQOL-BREF(HK Family Supports Services Index
Mahoney 2003[186] (12937334) US Medium Explanatory Mahoney 2001[187] (11346473)	Automated telephone support system for caregivers which included a weekly automated conversation, a personal voice mailbox, telephone support group, and an activity-respite module; available 22 hours a day for 12 months	Usual care	Community-based recruitment from health and social agencies. RCT Single site 100 Informal Caregivers	Diagnosis of probable AD or MMSE ≤ 23, with two IADL impairments and one AD-related disturbing behavior	N=100 77 years 48% Female Race NR 70% High School Diploma or Higher	NR	N=100 63 years 78% Female 79% White 82% High School Diploma or Higher 54% Spouse	Employment Status: Yes	NA	NA	6 months	NA	CES-D STAI

*High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: AD=Alzheimer's Disease**;** CES-D= Center for Epidemiologic Studies Depression Scale; char=characteristics; DSM-IV= Diagnostic and Statistical Manual of Mental Disorders 4th edition; FC=formal caregiver; IADL=Instrumental Activities of Daily Living; IC=informal caregiver; MMSE=Mini-mental State Exam; N=number; NA=Not Applicable; NPI-D=Neuropsychiatric Inventory Caregiver Distress; NR=Not Reported; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RCT=Randomized Controlled Trial; RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status;; STAI= State-Trait Anxiety Inventory; WHOQOL-BREF(HK)= World Health Organization Quality of Life Instruments (Hong Kong Version)

Appendix Table E.11. Caregiver outcomes summary low and medium risk of bias studies: social support

Study (PMID) Comparison Caregiver Type RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Wang 2012[180] (22554214) In-person support group vs. Usual care Informal Medium Explanatory	Mean (SD) NPI-D Total Score 28 weeks	NR	37.47 (9.68)	43.88 (13.56)	p=0.005

Study (PMID) Comparison Caregiver Type RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Wang 2012[180] (22554214) In-person support group vs. Usual care Informal Medium Explanatory	Mean (SD) WHOQOL-BREF(HK) Total Score 28 weeks	NR	114.02 (13.98)	88.19 (7.56)	p=0.001
Wang 2012[180] (22554214) In-person support group vs. Usual care Informal Medium Explanatory	Mean (SD) Mental Health Services Utilization, Family Supports Services Index 28 weeks	No difference between groups in utilization of mental health services.	NR	NR	NR
Mahoney 2003[186] (12937334) Automated support vs. Usual care Informal Medium Explanatory Mahoney 2001[187] (11346473)	Mean (SD) CES-D 6 months	No difference between groups.	12.3 (9.1)	14.9 (11.7)	NR
Mahoney 2003[186] (12937334) Automated support vs. Usual care Informal Medium Explanatory Mahoney 2001[187] (11346473)	Mean (SD) STAI 6 months	No difference between groups.	19.8 (5.7)	20.6 (7.7)	NR

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: CES-D= Center for Epidemiologic Studies Depression Scale; NA=Not Applicable; NPI-D=Neuropsychiatric Inventory Caregiver Distress; NR=Not Reported; PMID=PubMed Identification Number; SD=Standard Deviation; STAI= State-Trait Anxiety Inventory; WHOQOL-BREF(HK)= World Health Organization Quality of Life Instruments (Hong Kong Version)

Appendix Table E.12. Summary of strength of evidence for caregiver outcomes: social support

Comparison Caregiver Type Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
In-person support vs. Usual care Informal All Outcomes	28 weeks	1 RCT (n=78)	Insufficient evidence to draw conclusions about all outcomes.	Moderate	Unknown	Direct	Imprecise	Insufficient
Automated support vs. Usual care Informal All Outcomes	6 months	1 RCT (n=100)	Insufficient evidence to draw conclusions about all outcomes.	Moderate	Unknown	Direct	Imprecise	Insufficient

Abbreviations: n=number; RCT=Randomized Controlled Trial

Evidence Map: Social Support for Caregivers Appendix Table E.13.

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Huis 2020[178] (32130142) Netherlands High ROB	Email contacts with a specialist dementia nurse and informational videos and e-bulletins vs. informational videos and e-bulletins vs. e-bulletins		Community 3-arm RCT N=81 informal caregivers	AD Vascular dementia Frontotemporal dementia Dementia with Lewy bodies Mixed dementia Dementia type not known PLWD lives at home and has minimum weekly contact with informal caregiver who is partner or family member	N=81 Age: yes Sex: yes Race: no Education: no	Household Characteristics: yes	N=81 Age: yes Sex: yes Education: yes Relation to PLWD: yes	Living with PLWD: yes	NA	NA	6 weeks, 12 weeks	Disruptive behavior (RMBPC)	Self-efficacy (TRUST) Dyadic relationship quality (DRS)
Gustafson 2019[190] (31256126) US Pilot study	Dementia–Comprehensive Health Enhancement Support System (D-CHESS) website access for 6 months	Caregiving book	Community-based (intervention at home) RCT; single site 31 informal caregivers	AD, all severities	N=31 Age: yes Sex: no Race: no Education: no	NR	N=31 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Payment: yes	NA	NA	6 months	NA	Caregiver Burden (composite) Family Conflict (Aneshensel Scale) Satisfaction with Decision Scale MOS Social Support Survey UCLA Loneliness Scale Generalized Anxiety Disorder Scale PHQ Coping Competence (Lawton Scale)
Metcalfe 2019[191] (31111516)	Online information and support program for	Waitlist control	Community-based memory clinics	AD or behavioral variant frontotemporal degeneration onset	N=61 Age: yes Sex: yes	NR	N=61 Age: yes Sex: yes Race: no	Duration: yes Employment Status: yes	NA	NA	12 weeks	NA	RSCE PSS Burden Scale for Family

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Multinational Pilot study	caregivers of individuals with young onset dementia; access for 12 weeks		(intervention at home) RCT; multisite 61 informal caregivers	before the age of 65	Race: no Education: no		Education: yes Relation to PLWD: yes						Caregivers EQ-5D-5L
Van Mierlo 2015[179] (25872457) Netherlands High ROB	DEMentia-specific dynamic interactive social chart (DEM-DISC) providing information on support, coping, dementia, and other topics; accessible to both carers and case managers	No intervention	Community-based setting (intervention at home) Cluster RCT; multisite 27 clusters 73 informal caregivers	Dementia (not specified)	N=73 Age: yes Sex: yes Race: no Education: no	NR	N=73 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Living with PLWD: yes Payment: yes Health Status: yes	NA	NA	6 months 12 months	QOL-AD EQ-5D	Camberwell Assessment of Needs for the Elderly NPI-Distress Short Sense of Competence Questionnaire
Torkamani 2014[192] (24643137) UK Pilot Study	Computerized social support platform provided information, social networking, and educational materials	No intervention	Hospital outpatients RCT, multisite 60 PLWD-informal caregiver dyads	Dementia with BI score 35 or greater and MMSE score from 9 to 21	N=60 Age: yes Sex: no Race: no Education: no	NR	N=60 Age: yes Sex: no Race: no Education: no Relation to PLWD: no	NR	NA	NA	3 months 6 months	NPI MMSE MDRS BDRS CDR RMBPC GDS BI Lawton ADL	ZBI BDI Zung Depression Self-rating Scale EQ-5D Quality of Life Scale
Logsdon 2010[181] (20693265) US High ROB	Early-stage memory loss support group for PLWD-caregiver dyad; 90-minute sessions weekly for 9 weeks	Waitlist control	Community-based setting RCT; single site 142 PLWD-informal caregiver dyads	Dementia diagnosis with MMSE score 18 or higher	N=142 Age: yes Sex: yes Race: yes Education: yes	NR	N=142 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	NR	NA	NA	9 weeks	QOL-AD SF-36 GDS RMBPC	GDS Family Assessment Measure, Communication PSS
van der Roest 2010[193] (20455122) Netherlands Pilot Study	DEMentia-specific dynamic interactive social chart (DEM-DISC) providing information on support, coping,	No intervention	Community-based setting (intervention at home) CCT; single site 29 informal caregivers	Dementia (not specified)	N=29 Age: yes Sex: yes Race: no Education: no	NR	N=29 Age: yes Sex: no Race: no Education: yes Relation to PLWD: yes	Health status: yes	NA	NA	2 months	Camberwell Assessment of Need for the Elderly QOL-AD	Short Sense of Competence Questionnaire Pearlin Mastery Scale

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	dementia, and other topics												
Charlesworth 2008[182] (18284895) High ROB UK Charlesworth 2008[183] (18505757) Wilson 2009 (19101921)	Befriending volunteers to provide emotional support to informal caregivers; weekly contact for 6 months	Usual care	Community-based setting RCT; single site 236 informal caregivers	Primary progressive dementia	N=236 Age: yes Sex: no Race: no Education: no	NR	N=236 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Employment: yes	NA	NA	6 months 15 months 24 months	NA	HADS-Depression EuroQoL Positive and negative affectivity scale HADS-Anxiety MSPSS
Winter 2006[185] (17267370) US High ROB	Telephone-based support groups; 1 hour weekly for 6 months	No intervention	Community-based setting (intervention at home) RCT; single site 106 female caregivers	AD and related dementias	N=106 Age: yes Sex: yes Race: no Education: no	NR	N=106 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes	NA	NA	6 months	NA	CES-D ZBI Gain Through Group Involvement Scale
Pillemer 2002[188] (NA) US High ROB	One-on-one in person peer support for new informal caregivers; weekly 2-hour sessions for 8 weeks	No intervention	Community-based setting (intervention at home) RCT; single site 147 informal caregivers	AD	N=147 Age: yes Sex: yes Race: no Education: no	NR	N=147 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Living with PLWD: yes	NA	NA	6 months	NA	CES-D Index of Disruptive Behaviors (Caregiving Stress)
Goodman 1990[189] (2354800) US High ROB Goodman 1990[189] (2284602)	Telephone support network; 2 calls a week for 12 weeks	Telephone-accessed taped lectures on AD and care management accessed anytime over 12 weeks	81 informal caregivers	AD and other dementias	N=81 No Sex: no Race: no Education: no	NR	N=81 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Health Status: yes Employment status: yes	NA	NA	12 weeks	MPBC	ZBI Perceived Social Support and Social Conflict Mental Health Index

Abbreviations: AD=Alzheimer's disease; ADL=Activities of Daily Living; BDI=Beck Depression Inventory; BDRS= Blessed Dementia Rating Scale; BI=Barthel Index; CDR=Clinical Dementia Rating; CES-D= Center for Epidemiologic Studies Depression Scale; char=characteristics; EQ-5D=EuroQol-5D; EQ-5D-5L=5-level EuroQoL-5D; EM=Evidence Map; FC=formal caregiver; GDS=Geriatric Depression Scale; HADS=Hospital Anxiety and Depression Scale; IC=informal caregiver; MDRS=Mattis Dementia Rating Scale; MOS=Medical Outcomes Survey; MMSE=Mini-mental Scale Exam; MPBC= Memory and Behavior Problem Checklist; MSPSS=Multidimensional Scale of Perceived Social Support; N=number; NA=Not Applicable; NPI=Neuropsychiatric Inventory; NR=Not Reported; PHQ=Patient Health Questionnaire; PMID=PubMed Identification Number; PSS=Perceived Stress Scale; PLWD=Persons with Dementia; QoL-AD= Quality of Life in Alzheimer's Disease; RCT=Randomized Controlled Trial; RS=Reporting Status; RMBPC= Revised Memory and Behavior Problem Checklist; ROB=Risk of Bias; RSCE=Revised Scale for Care-giving Self-Efficacy; SES=socioeconomic status; SF-36; 36-Item Short Form Survey; ZBI=Zarit Burden Interview

Lifestyle Interventions

Appendix Table E.14. Risk of bias assessment: lifestyle interventions

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Salamizadeh 2017[194] (28670585)	3 weeks	Medium 10%	Medium	High	High	Low	X	NR	High
Farran 2016[195] (28752016) Faran 2016[196] (29147683) Cothran 2017[197] (28956706)	12 months	High 27%	X	X	X	X	X	Government	High
Mahdavi 2016[198] (28499566)	5 weeks	Medium 11%	Medium	Medium	High	Medium	X	NR	High
Lowery 2014[199] (24338799) D'Amico 2016[200] (26489776)	12 weeks	Medium 11%	Medium	Low	High	High	X	Government	High
Whitebird 2013[201]	2 months 6 months	Low 2 months: 8% Medium 6 months:10%	Medium	Low	Low	Medium	Medium	Government	Medium
Connell 2009[202] (21709757)	6 months 12 months	Medium 17%	Medium	High	High	Low	X	Government	High
King 2002 (11773209) Castro 2002[203] (12021419)	12 months	Medium 15%	Low	Low	High	Low	X	Government	High

X indicates that domain was not assessed due to high risk of bias.
Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Appendix Table E.15. Characteristics of included studies: lifestyle interventions

Study (PMID) **Country** **RoB*** **Type**	**Intervention** **Intervention Focus** **Theoretical Model** **Delivery Person** **Intervention Target Recipient** **Mode** **Components** **Frequency** **Duration**	**Comparison** **Target** **Mode** **Components** **Frequency** **Duration**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics** **Dementia Types** **Dementia Severity** **Diagnostic Criteria** **Age of Diagnosis**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Whitebird 2013[201] (23070934) US Medium Explanatory	Group mindfulness-based stress reduction for informal caregivers; one 2.5-hour session/week for 8 weeks and a 5-hour retreat with CDs and written materials	Group community caregiver education and support for informal caregivers; one 2.5-hour session/week for 8 weeks, a 5-hour retreat, and telephone support calls	Community-based setting RCT, single site 78 family caregivers	Memory loss consistent with dementia	N=78 Age NR Sex NR Race NR Education NR	NR	N=78 57 years 89% Female 99% White 56% College or Graduation Education 74% Adult child	Duration: yes Employment status: yes	NA	NA	2 months 6 months	NA	PSS CES-D STAI Montgomery Borgatta Caregiver Burden Scale Medical Outcomes Study Social Support MCS-12 PCS-12

*High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: CES-D=Center for Epidemiologic Studies-Depression Scale; char=characteristics; FC=formal caregiver; IC=informal caregiver; MCS-12=Mental Health Composite, 12-item Short-Form Health Survey; N=number; NR=Not Reported; PCS-12=Physical Health Composite, 12-item Short-Form Health Survey; PMID=PubMed Identification Number; PSS=Perceived Stress Scale; PLWD=Persons with Dementia; RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status; ; MCS-12=Mental Health Composite, 12-item Short-Form Health Survey; NA=Not Applicable; NR=Not Reported; PCS-12=Physical Health Composite, 12-item Short-Form Health Survey; PMID=PubMed Identification Number; PSS=Perceived Stress Scale; PLWD=Persons with Dementia; RoB=Risk of Bias; RCT=Randomized Controlled Trial; RoB=Risk of Bias; STAI=State-Trait Anxiety Inventory

Appendix Table E.16. Caregiver outcomes summary low and medium risk of bias studies: lifestyle interventions

Study (PMID) **Comparison** **Caregiver Type** **RoB** **Category***	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Whitebird 2013[201] (23070934) Mindfulness-based stress reduction vs. Education and support Informal caregivers Medium Explanatory	PSS Mean (SD) 2 months 6 months	Cohen's *d* 2 months: -0.61 6 months: -0.47	2 months: 15.2 (5.8) 6 months: 14.0 (4.5)	2 months: 19.3 (7.6) 6 months: 16.7 (7.2)	2 months: 0.007 6 months: 0.07 Group x Time: 0.01
Whitebird 2013[201] (23070934) Mindfulness-based stress reduction vs. Education and support Informal caregivers Medium Explanatory	CES-D Mean (SD) 2 months 6 months	Cohen's *d* 2 months: -0.66 6 months: -0.39	2 months: 10.6 (8.4) 6 months: 10.5 (6.5)	2 months: 17.1 (11.2) 6 months: 13.7 (9.5)	2 months: 0.005 6 months: 0.16 Group x Time: 0.07
Whitebird 2013[201] (23070934) Mindfulness-based stress reduction vs. Education and support Informal caregivers Medium Explanatory	STAI Mean (SD) 2 months 6 months	Cohen's *d* 2 months: -0.59 6 months: -0.52	2 months: 34.2 (10.7) 6 months: 34.6 (10.4)	2 months: 41.7 (14.4) 6 months: 41.1 (14.2)	2 months: 0.01 6 months: 0.02 Group x Time: 0.98

Study (PMID) **Comparison** **Caregiver Type** **RoB** **Category***	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
Whitebird 2013[201] (23070934) Mindfulness-based stress reduction vs. Education and support Informal caregivers Medium Explanatory	Montgomery Borgatta Caregiver Burden Scale, Objective Burden Mean (SD) 2 months 6 months	Cohen's *d* 2 months: 0.11 6 months: -0.11	2 months: 23.8 (3.6) 6 months: 22.1 (5.1)	2 months: 23.3 (5.0_ 6 months: 22.6 (5.2)	2 months: 0.58 6 months: 0.67 Group x Time: 0.63
Whitebird 2013[201] (23070934) Mindfulness-based stress reduction vs. Education and support Informal caregivers Medium Explanatory	Montgomery Borgatta Caregiver Burden Scale, Subjective Demand Burden Mean (SD) 2 months 6 months	Cohen's *d* 2 months: -0.25 6 months: -0.42	2 months: 12.0 (3.2) 6 months: 11.0 (3.5)	2 months: 12.8 (3.5) 6 months: 12.4 (3.0)	2 months: 0.24 6 months:0.09 Group x Time: 0.80
Whitebird 2013[201] (23070934) Mindfulness-based stress reduction vs. Education and support Informal caregivers Medium Explanatory	Montgomery Borgatta Caregiver Burden Scale, Subjective Stress Burden Mean (SD) 2 months 6 months	Cohen's *d* 2 months: -0.23 6 months: -0.20	2 months: 15.0 (2.3) 6 months: 14.0 (3.5)	2 months: 15.6 (2.9) 6 months:14.7 (3.6)	2 months: 0.32 6 months:0.26 Group x Time: 0.68
Whitebird 2013[201] (23070934) Mindfulness-based stress reduction vs. Education and support Informal caregivers Medium Explanatory	Medical Outcomes Study Social Support Mean (SD) 2 months 6 months	Cohen's *d* 2 months: 0.11 6 months: 0.06	2 months: 71.1 (21.1) 6 months: 74.2 (21.0)	2 months: 68.8 (21.8) 6 months: 73.0 (21.4)	2 months: 0.66 6 months: 0.84 Group x Time: 0.51
Whitebird 2013[201] (23070934) Mindfulness-based stress reduction vs. Education and support Informal caregivers Medium Explanatory	MCS-12 Mean (SD) 2 months 6 months	Cohen's *d* 2 months: 0.66 6 months: 0.54	2 months: 47.4 (9.2) 6 months: 49.7 (7.9)	2 months: 40.8 (10.6) 6 months: 44.6 (10.9)	2 months: 0.007 6 months: 0.04 Group x Time: <0.001
Whitebird 2013[201] (23070934) Mindfulness-based stress reduction vs. Education and support Informal caregivers Medium Explanatory	PCS-12 Mean (SD) 2 months 6 months	Cohen's *d* 2 months: 0.19 6 months: 0.23	2 months: 49.9 (9.1) 6 months: 51.0 (9.1)	2 months: 48.1 (9.7) 6 months: 48.7 (11.0)	2 months: 0.36 6 months: 0.26 Group x Time: 0.35

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: CES-D=Center for Epidemiologic Studies - Depression Scale; NA=Not Applicable; MCS-12=Mental Health Composite, 12-item Short-Form Health Survey; NR=Not Reported; PCS-12=Physical Health Composite, 12-item Short-Form Health Survey; PMID=PubMed Identification Number; PSS=Perceived Stress Scale; RoB=Risk of Bias; SD=Standard Deviation; STAI=State-Trait Anxiety Inventory

Appendix Table E.17. Summary of strength of evidence for caregiver outcomes: lifestyle interventions

Comparison **Caregiver Type** **Outcome**	**Timing**	**# Studies/ Design (n analyzed)**	**Finding or Summary Statistic**	**Study Limitations**	**Consistency**	**Directness**	**Precision**	**Overall Grade/ Conclusion**
Mindfulness-based stress reduction vs. Education and support Informal caregivers All Outcomes	2 months 6 months	1 RCT (n=78)	Insufficient evidence to draw conclusions about the effect of mindfulness-based stress reduction on informal caregivers.	Moderate	Unknown	Direct	Imprecise	Insufficient

Abbreviations: n=number; RCT=randomized controlled trial

Evidence Map: Lifestyle Interventions

Appendix Table E.18. Characteristics of evidence map studies: lifestyle interventions

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Kor 2019[204] (30922609) China Pilot Study	Group modified mindfulness-based cognitive therapy, 7 2-hour sessions over 10 weeks	Usual care with brief education on dementia care (7 group sessions)	Community-based setting RCT; single site 36 informal caregivers	Dementia diagnosis	N=36 Age: no Sex: no Race: no Education: no	NR	N=36 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: yes Employment Status: yes Training: yes	NA	NA	10 weeks 3 months	NA	PSS ZBI CED-S HADS-A Brief Resilience Scale SF-12 Five Facets Mindfulness Questionnaire Short Form
Richards 2018[205] (29653492) US Sample Size	Visual arts education group (producing different artistic work each week with increasing difficulty) for PLWD-informal caregiver dyads; 1 session/week for 8 weeks	Discussion and slide shows about art and painting for PLWD-informal caregiver dyads; 1 session/week for 8 weeks	Community-based setting RCT; single site 35 PLWD-informal caregiver pairs	Mild to moderate AD and related dementias, MMSE 12 to 26	N=35 Age: yes Sex: yes Race: no Education: no	NR	N=35 Age: yes Sex: yes Race: no Education: no Relation to PLWD: no	NR	NA	NA	8 weeks 6 months	Rosenberg Self-Esteem Scale QOL-AD ADL (FAQ)	ZBI Rosenberg Self-Esteem Scale QOL-AD
Salamizadeh 2017[194] (28670585) Iran High ROB	Spiritual care education; 5 educational sessions, 45 to 60 minutes	Usual care	Community-based setting Quasi-experimental 60 informal caregivers	AD diagnosis	N=60 Age: no Sex: no Race: no Education: no	NR	N=60 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes	NA	NA	3 weeks	NA	GSE-10
Waelde 2017[206] (28263398) US Sample Size	Group stress mindfulness and mantra training for female informal caregivers; 10 sessions over 12 weeks	Telephone psychoeducation and telephone supports, biweekly 10-15-minute calls over 12 weeks	Community-based setting RCT; single site 31 informal caregivers	AD or other dementia	N=31 Age: no Sex: no Race: no Education: no	NR	N=31 Age: yes Sex: yes Race: yes Relation to PLWD: no	Living with PLWD: yes Employment: yes	NA	NA	12 weeks	MMSE	Satisfaction with Life Scale CES-D Self-Efficacy for Controlling Upsetting Thoughts, Revised Scale for Caregiving Self-Efficacy

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Brown 2016[207] (26211415) US Sample Size	Group mindfulness-based stress reduction for informal caregivers; 1.5 to 2 hours/week for 8 weeks	Group social support for informal caregivers; 1.5 to 2 hours/week for 8 weeks	Community-based setting RCT, single site 38 informal caregivers	Early stage AD or other dementia, FAST stage 5 or lower	N=38 Age: no Sex: no Race: no Education: no	NR	N=211 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes	NA	NA	3 months	NA	PSS Acceptance and Action Questionnaire II Profile of Mood States SF-36 ZBI Mortality Scale, Family Care Inventory
Farran 2016[195] (28752016) US High ROB Faran 2016[196] (29147683) Cothran 2017[197] (28956706)	Telephone-based intervention to support and encourage informal caregivers to participate in moderate vigorous physical activity, including goal-setting; regular phone calls over 12 months	Caregiver skill building to provide information, support, and problem-solving to caregivers; regular phone calls over 12 months	Community-based setting with intervention received at home RCT; single site 211 Informal Caregivers	AD or related dementia	N=211 Age: yes Sex: yes Race: no Education: no	NR	N=211 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Living with PLWD: yes Health status: yes Employment Status: yes	NA	NA	12 months	NA	2-minute Step Test 30s Chair Stand Test Caregiver Burden (PADL/IADL) PSS
Hirano 2016[208] (26289496) Japan Pilot Study	Informal caregiver selected leisure activity, 3 times/week for 30 minutes for 24 weeks	Usual care	Community-based setting RCT; single site 54 informal caregivers	AD, DSM-IV criteria	N=54 Age: yes Sex: yes Race: no Education: no	NR	N=54 Age: yes Sex: yes Race: no Education: no Relation to PLWD: no	Living with PLWD: yes Health status: yes	NA	NA	12 months	MMSE NPI	ZBI
Mahdavi 2016[198] (28499566) Iran High ROB	Spiritual group therapy for informal caregivers based on Iranian culture/Islam; weekly 45 to 60-minute sessions for 5 weeks	1. Caregiver discussion group; weekly 45 to 60-minute sessions for 5 weeks 2. No intervention	Community-based setting RCT; single site 100 Informal Caregivers	Diagnosis of AD	N=100 Age: yes Sex: no Race: yes Education: no	NR	N=100 Age: Yes Sex: no Race: yes Education: no Relation to PLWD: yes	NR	NA	NA	5 weeks	NA	Caregiver Strain Index
Danucalov 2015 (26685923)	Yoga and compassion	Waitlist control	Community-based	Diagnosis of AD	N=53 Age: no	NR	N=53 Sex: yes	NR	NA	NA	8 weeks	NA	WHOQOL-Bref

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Danucalov 2013 (368865412) Brazil Sample Size	meditation; in-person and at home; three 75 min sessions/week for 8 weeks		setting RCT; single site 53 informal caregivers		Sex: no Race: yes Education: no		Age: yes Race: no Education: no Relation to PLWD: no						Subjective Vitality Scales Mindfulness Attention Awareness Scale Self-Compassion Sale
Leach 2015[209] (25952550) Australia Pilot Study Leach 2014[210] (24044373) Leach 2016[211] (27227995)	Transcendental meditation; 14-hour program over 12 weeks with face to face 12-week follow-up	Waitlist control	Community-based setting RCT; single site 17 informal caregivers	Diagnosis of dementia	N=17 Age: no Sex: no Race: yes Education: no	NR	N-17 Sex: yes Age: yes Race: no Education: no Relation to PLWD: yes	Duration: yes Health Status: yes	NA	NA	12 weeks 24 weeks	NA	AQoL-8D WebNeuro Test Battery
Lowery 2014[199] (24338799) UK High ROB D'Amico 2016[200] (26489776)	Individually tailored, progressively intensive walking regimen for PLWD and informal caregiver dyad, 20–30 min at least 5 times/week for 12 weeks	Usual care	Community-based setting with intervention at home RCT; single site 131 PLWD-informal caregiver dyads	Clinical diagnosis of dementia with ICD-10 Diagnostic Criteria for Research and NPI minimum score of 2 and frequency of 2 (hallucinations and delusions excluded)	N=131 Age: yes Sex: yes Race: yes Education: yes	NR	N=131 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	NR	NA	NA	12 weeks	NPI DemQOL-Proxy Change of Domiciliary Status Mortality	ZBI NPI Caregiver Distress GHQ
Lavretsky 2013[212] (22407663) US Pilot Study	Kirtan Kriya yogic meditation, 12 min/day for 8 weeks	Relation, 12 min/day for 8 weeks	RCT, single site	Dementia based on DSM-IV-R without major depression (screened by HAM-D-24)	N=39 Age: no Sex: no Race: no Education: no	NR	N=39 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: yes Health Status: yes	NA	NA	8 weeks	NA	SF-36 HAM-D MMSE Cumulative Illness Rating Scale CVLT II TMT A TMT B
Hirano 2010 (20850878) Japan Sample Size	Regular exercise for informal caregivers with moderate intensity, 3 times a week for 12 weeks	No exercise	Community-based setting RCT; single site 36 informal caregivers	AD according to DSM-IV criteria	N=36 Age: no Sex: no Race: no Education: no	NR	N=36 Age: yes Sex: yes Race: no Education: no Relation to PLWD: no	Health status: yes Living with PLWD: yes	NA	NA	12 weeks	NPI MMSE	ZBI VAS

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Carbpnneau 2011[213] (20598758) Canada Sample Size	Adapted leisure education program for informal caregiver-PLWD dyads; 4 to 6 in person sessions with telephone follow-ups	Usual care	Community and nursing home RCT; single site 49 PLWD-informal caregiver dyads	Not specified	N=49 Age: no Sex: no Race: no Education: no	NR	N=49 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Health status: yes	NA	NA	8 weeks 12 weeks	NA	General Well-being Scale Elder Care Scale Self-Efficacy
Oken 2010[214] (20929380) US Pilot Study	Mindfulness-based cognitive therapy, one 90-minute session in-person/week with at home implementation for 7 weeks	1. Educational class based on Powerful Tools for caregivers with weekly assignments, one 90-minute session/week for 7 weeks 2. Respite only, 3 hours of respite/week for 7 weeks	Community-based RCT; single site 31 informal caregivers	Progressive dementia	N=31 Age: no Sex: no Race: no Education: no	NR	N=31 Age: yes Sex: yes Race: no Education: No Relation to PLWD: yes	NR	NA	NA	8 weeks	NPI	RMBPC Caregiver Appraisal Tool PSS CESD General Perceived Self-Efficacy Scale PSQI Epworth Sleep Questionnaire Global Impression of Change
Connell 2009[202] (21709757) US High ROB	Telephone-based exercise counseling and goal-setting for female spouse caregivers with exercise workbooks and videos; 14 calls over 6 months	No intervention	Community-based setting with intervention at home RCT; single site 157 female spouse caregivers	No specified	N=157 Age: no Sex: no Race: no Education: no	NR	N=157 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Health status: yes Employment status: yes	NA	NA	6 months 12 months	NA	MOS Short-Form General Health Survey RMBPC (Caregiver Burden) CES-D
Wilz 2008[215] (18381838) Germany Pilot study	Assisted vacations (participating in positive activities, improving utilization of support, psychoeducation) based on the	Waitlist control	Hotel or rehabilitation centers Quasi experimental 29 caregiving wives	Medical diagnosis of dementia	N=29 Age: yes Sex: yes Race: no Education: no	NR	N=29 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	Living with PLWD: yes	NA	NA	3 months	NA	Giessen Subjective Complaints List BDI

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
	needs of the caregiver and PLWD; 1 week in a hotel or rehabilitation clinic												
King 2002 (11773209) Castro 2002[203] (12021419) US High ROB	Home-based, telephone supervised moderate intensity exercise training for female caregivers, 30-40-minute sessions 4 times/week for 12 months, 15 telephone contacts over 12 months	Telephone-based nutrition education, 15 telephone contacts over 12 months	Community-based setting with intervention at home RCT; single site 100 female caregivers	AD or another form of dementia	N=100 Age: yes Sex: no Race: no Education: no	NR	N=100 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: yes Employment Status: yes	NA	NA	12 months	NA	Screen for Caregiver Burden TMAS BDI PSS Interpersonal Social Evaluation List RMBPC (Caregiver Burden) PSQI

Abbreviations: AD=Alzheimer's Disease; AQoL-8D= Validity and Reliability of the Assessment of Quality of Life; BDI=Beck Depression Inventory; CES-D=Center for Epidemiologic Studies Depression Scale; char=characteristics; CVLT II=California Verbal Learning Test, 2nd edition; DemQOL-Proxy=Dementia Quality of Life-Proxy; EM=Evidence Map; FAQ=Functional Activities Questionnaire; FC=formal caregiver; GHQ=General Health Questionnaire; GSE-10= General Self-Efficacy Scale; HAM-D=Hamilton Depression Rating Scale; HADS-Anxiety= Hospital Anxiety and Depression Scale-Anxiety; IADL=Instrumental Activities of Daily Living; IC=informal caregiver; MMSE=Mini-mental State Exam; MOS=Medical Outcomes Survey; N=number; NA=Not Applicable; NPI= Neuropsychiatric Inventory; NR=Not Reported; PADL=Personal Activities of Daily Living; PMID=PubMed Identification Number; PSS=Perceived Stress Scale; PSQI=Pittsburgh Sleep Quality Index; PLWD=Persons with Dementia; QoL-AD= Quality of Life in Alzheimer's Disease; RCT=Randomized Controlled Trial; RMBPC=Revised Memory and Behavior Problems Checklist; ROB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status; SF-12= 12-Item Short Form Health Survey; SF-36= 36-Item Short Form Survey; TMAS=Taylor Manifest Anxiety Scale; TMT=Trail Making Test; VAS=Visual Analogue Scale; WHOQOL-Bref=World Health Organization Quality of Life Instruments; ZBI=Zarit Burden Interview

Respite Care

Appendix Table E.19. Risk of bias assessment: respite care vs. usual care

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Vandepitte 2019[216] (31243801) Vandepitte 2016[217] (27912740)	6 months	High 24.7%	X	X	X	X	X	Foundation	High
Zarit 1998[218] (9750575) Kim 2012[219] (21322030)	3 months 12 months	High 3 months: 42.7% 12 months:65.9%	X	X	X	X	X	Government	High
Lawton 1989[220] (NA)	12 months	High 46%	X	X	X	X	X	Foundation	High

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: NR=Not Reported; PMID=PubMed Identification Number; NA=Not Applicable

Evidence Map: Respite Care

Appendix Table E.20. Characteristics of evidence map studies: respite care vs. usual care

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Vandepitte 2019[216] (31243801) Belgium High ROB Vandepitte 2016[217] (27912740)	In-home respite care for informal caregivers with support diary for additional caregiver support; 5 to 14 days of 24-hour care for PLWD from trained employee	Usual care	Community-setting with in home care Quasi experimental 198 Informal Caregiver-PLWD Dyads	Not specified	N=198 Age: yes Sex: yes Race: no Education: yes	NR	N=198 Sex: yes Race: no Education: yes Relation to PLWD: yes	Living with PLWD: yes Employment Status: yes	NA	NA	6 months	RMBPC	ZBI EQ-5D-5 L Desire-to-Institutionalize scale
Zarit 1998[218] (9750575) US High ROB Kim 2012[219] (21322030)	Adult day care; at least 2 times/week for 12 months	Usual care (no intervention)	Community-based adult day care Quasi experimental 566 informal caregivers	Not specified	N=566 Age: yes Sex: yes Race: no Education: no	NR	N=566 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	NR	NA	NA	3 months 12 months	PADL IADL	Involvement in Caregiving CES-D Positive and Negative Affect Schedule Role Captivity
Lawton 1989[220] (NA) US High ROB	Respite program with options for in-home respite services, adult day care, and institutional respite care (limited to 21 days); any combination of services (caregiver discretion) over 12 months	Usual care with list of local services	In-home, adult care, and/or nursing home RCT; Single site 632 Informal caregivers	Not specified	N=632 Age: yes Sex: yes Race: no Education: yes	Household Characteristics: Yes	N=632 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Employment Status: yes	NA	NA	12 months	NA	Multilevel Assessment Instrument CES-D The Affect Balance Scale

Abbreviations: CES-D=Center for Epidemiologic Studies Depression Scale; char=characteristics; EM=Evidence Map EQ-5D-5l= 5-level EQ-5D version; FC=formal caregiver; IADL=Instrumental Activities of Daily Living; IC=informal caregiver; N=number; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; PADL=Performance Activities of Daily Living; PLWD=Persons with Dementia; RCT=Randomized Controlled Trial; RMBPC=Revised Memory and Behavior Checklist; ROB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status; ZBI=Zarit Burden Interview

Multicomponent Intervention

Appendix Table E.21. Risk of bias assessment: multicomponent interventions for informal caregivers

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Overall Rating
Luchsinger 2018[221xxxx] (30084133)	6 months	Low 6 months: 5%	Medium	Medium	Medium	Low	Medium	Medium
Berwig 2017[222] (29233097)	6 months	Low 6 months: 12%	Low	Medium	Medium	Low	Low	Medium
Berwig 2017[222] (29233097)	9 months	High 9 months: 33%	Low	Medium	Medium	Low	Low	High
Brijoux 2016[223] (27839534)	16 weeks	Medium 16 weeks: 17%	Low	High	Medium	Low	Low	High
Koivisto 2016[224] (26177825)	36 months	High 36 months: 45%	Low	NA	NA	NA	NA	High
Baglio 2015[225] (24788581)	32 weeks	Medium 32 weeks: 17%	Low	Medium	High	Low	Low	High
Prick 2015[226] (26004290)	3 months	Low 3 months: 11%	Low	Low	Medium	Medium	Low	Low
Prick 2015[226] (26004290)	6 months	Medium 6 months: 21%	Low	Low	Medium	Medium	Low	Medium
Gaugler 2013[227] (23339050)	12 months	High Unclear	Low	NA	NA	NA	NA	High
Martindale-Adams 2013[228] (24617278)	12 months	Medium months: 11%	Medium	High	Medium	Low	Low	High
Mittleman 2008[229] (18978250)	24 months	Low 24 months: 2%	Low	Low	High	Medium	Medium	Medium
Signe 2008[55] (18269429)	6 months 12 months	NA	High	NA	NA	NA	NA	High
Belle 2006[230] (17116917)	6 months	Low 6 months: 9%	Low	Medium	High	Low	Low	Medium
Ducharme 2005[231] (16024406)	6 months	High 6 months: 34%	Medium	NA	NA	NA	NA	High
Mittleman 2004[232] (14722336)	4 months	Low 4 months:9%	Low	Low	High	Low	Medium	Medium
Mittleman 2004[232] (14722336)	12 months	High 12 months: 35%	Low	NA	NA	NA	NA	High

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Overall Rating
Mittleman 2004[232] (14722336)	24 months	High 24 months: 53%	Low	NA	NA	NA	NA	High
Mittleman 2004[232] (14722336)	36 months	High 36 months: 67%	Low	NA	NA	NA	NA	High
Mittleman 2004[232] (14722336)	48 months	High 46 months: 74%	Low	NA	NA	NA	NA	High
Eisdorfer 2003[233] (12937331)	18 months	High 18 months: 32%	Low	NA	NA	NA	NA	High
Teri 2003[234] (14559955)	3 months	Low 3 months: 9%	Low	Medium	Medium	Low	Low	Medium
Teri 2003[234] (14559955)	6 months	Low 6 months: 18%	Low	Medium	Medium	Low	Low	Medium
Teri 2003[234] (14559955)	12 months	Medium 12 months: 25%	Low	Medium	Medium	Low	Low	Medium
Teri 2003[234] (14559955)	18 months	High 18 months: 37%	Low	NA	NA	NA	NA	High
Teri 2003[234] (14559955)	24 months	High 24 months: 42%	Low	NA	NA	NA	NA	High
Mittelman 1993[235] (8314099)	12 months	Low 12 months: 2%	Medium	High	High	Low	Medium	High
Mohide 1990[236] (2184186)	6 months	Medium 6 months:30%	Low	High	Medium	Low	Low	High

* High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: char=characteristics; FC=formal caregiver; IC=informal caregiver; CMAI-SF=Cohen-Mansfield Agitation Inventory-Short-Form; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RoB=Risk of Bias; RS=Reporting Status; RUDAS=Rowland Universal Dementia Assessment Scale

Appendix Table E.22. Characteristics of included studies: multicomponent interventions for informal caregivers

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Teri 2003[234] (14559955) US Low Explanatory	Dyad, trained home health care facilitated 12-hour training sessions with PLWD, PLWD caregiver exercise and behavioral management techniques (RDAD) (2 sessions per week for 3 weeks, 1 session per week for 4 weeks, followed by biweekly sessions for 4 weeks.) 12 weeks	Routine medical care in community.	In-person, in-home visits at homes of community dwelling PLWD and PLWD caregivers. RCT 153 PLWD	National Institute of Neurological and Communicative Diseases and Stroke/Alzheimer Disease and Related Disorders Association criteria for Alzheimer disease. Dementia diagnosis for an average of 4.3 years.	N=153 78 years 41% female 89% white 13 years education	Detailed Race Information: yes	N=153 70 years 70% female 87% white 13 years education 80% spouse	Living Status: yes	NA	NA	12 weeks	Physical role functioning scores (SF-36) SIP Mobility Cornell Depression in Dementia Restricted Activity (number of days reported)	NA
Prick 2015[226] (26004290) (28120631)[237] (27099480)[238] (25336121)[239] Netherlands Medium Explanatory	During three months, a personal coach visited PLWD/PLWD caregiver dyads for eight one-hour-long home visits. The first month the dyads were visited weekly, followed by biweekly home visits over the next eight weeks. 12 weeks	Monthly mailed bulletins and phone calls.	Community-dwelling PLWD living with their caregivers. RCT 111 PLWD	Diagnosis of dementia, age 55+ years, living at home with a caregiver, no use of antidepressants, no psychotic symptoms, MMSE score < 14, receiving more than two days respite care in a day care facility.	N=111 77 years 41% Female Race NR Education 4.01 (0-6 scale)	None	N=111 72 years 72% female Education 4.08 (0-6 scale) 90.1% spouse	Living with PLWD: yes	NA	NA	12 weeks	NA	Family caregiver mood Self-Perceived Pressure from Family Care (Dutch version) RMBPC (Dutch version)
Belle 2006[230] (17116917)	12 in-home and telephone Structured sessions	Mailed packet of educational materials and	PLWD caregiver living with	Alzheimer disease or related disorders. MMSE > 0	N=642 77 years 60% female	SES: yes Prior disability: yes	N=642 60 years 83% female 35% white	Duration: yes Living with PLWD: yes	NA	NA	6 months		Prevalence of clinical depression for caregivers

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
(20122038)[240] (28295134)[241] (21357811)[242, 243] (24652899)[244] (20056684)[245] (27294873)[246] (23983230)[247] (16920998)[248] (14518801)[249] US Medium Explanatory	involving preliminary talk, information booklet, structured telephone-based support groups, and structured evaluation of each support group session. 6 months	provided 2 brief (<15 minute) telephone "check-in" calls at 3 months and 5 months after randomization 6 months	or sharing cooking facilities with PLWD relative with diagnosed Alzheimer disease or related disorders providing care least 4 hours per day for at least the past 6 months. RCT 642 PLWD		Education < 12 years	Household characteristics: yes Detailed race: yes	Education 57% > 12 years 43% spouse	Employment status: yes					(CES-D score ≥15)
Berwig 2017[222] (NCT01690117) Germany Medium Explanatory	12 individual two-weekly sessions (9 at home with the informal caregiver and 3 via telephone) and combined five modules. 6 months.	Mailed packet of educational materials and provided 2 brief (<15 minute) telephone "check-in" calls at 3 months and 5 months after randomization 6 months	Community/in-home dwelling PLWD and caregivers. RCT 92 PLWD	AD or related disorders. MMSE > 0	N=92 73 years 72% female Race NR Education NR	NR	Education 13 years 89% spouse	92 living with PLWD	NA	NA	6 months	NA	Benefit caregiver depression (PHQ4) Benefit quality of life (SF-12)
Mittelman 2004[232] (14722336) (15121650)[250] (17101889)[251] (17804831)[252] (16616406)[253] (19139247)[254] (16420138)[255] (18179495)[256] (21543959)[257] (15197285)[258] US Medium Explanatory	Counseling sessions (in-person, family, and telephone) for caregivers vs. usual care with home-based phone interviews; Pearlin stress process model	Usual care for 4 months	Spouse caregivers living at home with patient RCT 371 PLWD	AD or related disorders.	N=371 Age: NR 90% White Sex NR Education :NR	Detailed race information: yes	N=371 71 years 60% female 90% white	371 spouse caregivers living at home with patient.	NA	NA	4 months	NA	Benefit caregiver stress perceptions Benefit caregiver depression

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Mittelman 2008[229] (18978250) (21071943)[259] (19705599)[260] Multinational Medium Explanatory	Counseling sessions (in-person, family, and telephone) for caregivers vs. usual care; five sessions individual and family counselling w/in first 3 months, continuous ad hoc telephone counselling Donepezil for all patients Pearlin stress process model	No control.	Community-based spouse caregivers living at home with patient RCT 158 PLWD	AD or related disorders. mild to moderate dementia at enrollment	N=158 Age: NR Sex NR Race NR Education NR	None	N=158 Age: NR Sex NR Race NR Education NR	None	NA	NA	6 months	NA	Depressive symptoms Beck Depression Inventory (revised).
Luchsinger 2018[221] (14722336) US Medium Explanatory	Counseling sessions (in-person, family, and telephone) for caregivers vs. usual care 6 planned visits of similar duration in 6 months and ad hoc contacts. Pearlin stress process model	No control.	Community-based spouse caregivers living at home with patient RCT 221 PLWD	AD or related disorders.	N=221 58 years 82% female Race NR Education NR	None	N=221 58 years 32% spouses. Race NR Education 12 years	Employment Status: yes	NA	NA	4 months	NA	Depressive symptoms, GDS Caregiver burden ZBI

* High risk of bias studies included in evidence map. This table includes low and medium risk of bias studies only.

Abbreviations: char=characteristics; FC=formal caregiver; IC=informal caregiver; CES-D=Center for Epidemiologic Studies Depression Scale; CMAI-SF=Cohen-Mansfield Agitation Inventory-Short-Form; GDS=Geriatric Depression Scale; MMSE=Mini-Mental State Exam; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; PHQ-4=Patient Health Questionnaire-4; PLWD=Persons with Dementia; RCT=Randomized Controlled Trial; RoB=Risk of Bias; RS=Reporting Status; RUDAS=Rowland Universal Dementia Assessment Scale; RMBPC= Revised Memory and Behavior Problem Checklist; SF-12= 12-Item Short Form Health Survey; SF-36= 36-Item Short Form Survey; SIP=Sickness Impact Profile; ZBI=Zarit Burden Interview

Appendix Table E.23. Caregiver outcomes summary low and medium risk of bias studies: multicomponent interventions for informal caregivers

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Belle 2006 [230] (17116917) 12 in-home and telephone Structured sessions involving preliminary talk, information booklet, structured telephone-based	Prevalence of clinical depression for caregivers (CES-D score ≥15) n/N (%) 6 months	Overall prevalence of clinical depression at 6 month follow-up was significantly greater among caregivers in the control group than among those in the intervention group	12.6%	22.7%	0.001

Study (PMID) **Comparison** **RoB** **Category***	**Outcome** **Timing**	**Summary Finding**	**Intervention**	**Comparator**	**p-value**
support groups, and structured evaluation of each support group session vs Mailed packet of educational materials and provided 2 brief (<15 minute) telephone "check-in" calls at 3 months and 5 months after randomization Medium Explanatory					
Belle 2006 224 (17116917) 12 in-home and telephone Structured sessions involving preliminary talk, information booklet, structured telephone-based support groups, and structured evaluation of each support group session vs Mailed packet of educational materials and provided 2 brief (<15 minute) telephone "check-in" calls at 3 months and 5 months after randomization Medium Explanatory	Burden (modified Zarit Burden) Mean (CI) 6 months	No difference	3 (-15, 21)	4.2 (-16.9, 25.7)	NR
Berwig 2017 [222] (NCT01690117) 12 individual two-weekly sessions (9 at home with the informal caregiver and 3 via telephone) and combined five modules vs. Mailed packet of educational materials and provided 2 brief (<15 minute) telephone "check-in" calls at 3 months and 5 months after randomization Medium Explanatory	ZBI Mean change from baseline (SD) 9 months	Cohen's d=0.623. Informal caregivers' burden increased in both groups, but much more strongly in the control group	2.67 (8.86)	8.10 (8.58)	0.017
Berwig 2017 [222] (NCT01690117) 12 individual two-weekly sessions (9 at home with the informal caregiver and 3 via telephone) and combined five modules vs. Mailed packet of educational materials and provided 2 brief (<15 minute) telephone "check-in" calls at 3 months and 5 months after randomization Medium Explanatory	PHQ-15 Mean change from baseline (SD) 9 months	Cohen's d=0.502	-0.601 (3.999)	1.098 (2.773)	0.057
Berwig 2017 [222] (NCT01690117) 12 individual two-weekly sessions (9 at home with the informal caregiver and 3 via telephone) and combined five modules vs. Mailed packet of educational materials and provided 2 brief (<15 minute) telephone "check-in" calls at 3 months and 5 months after randomization Medium Explanatory	SF-12 Psychological Mean change from baseline (SD) 9 months	Cohen's d=0.902	3.868 (10.662)	-4.618 (8.157)	0.001
Luchsinger 2018[221] (14722336) NYUCI vs. REACH-OUT	GDS Mean (SD) 6 months	There was no difference between groups There was no significant change from baseline in either group	REACH-OUT 9.8 (7.2)	NYUCI 9.6 (7.1)	NR

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Medium Explanatory					
Luchsinger 2018[221](14722336) NYUCI vs. REACH-OUT Medium Explanatory	ZCBS Mean (SD) 6 months	There was no difference between groups There was a decrease in the ZCBS for REACH-OUT (5.2 points (2.2–8.1), p<.001) and the NYUCI (4.6 points, (1.7–7.5, p=.002).	REACH-OUT 35.5 (18.0)	NYUCI 36.2 (15.9)	NR
Teri 2003 [234] (14559955) Reducing Disability in Alzheimer Disease (RDAD) vs. Routine Medical Care (RMC) Low Pragmatic	SF-36 Mean (SD) 12 weeks	Significant difference between groups	72.1 (33.0)	50.7 (39.1)	<0.001
Teri 2003 [234] (14559955) Reducing Disability in Alzheimer Disease (RDAD) vs. Routine Medical Care (RMC) Low Explanatory	SIP Mobility Mean (SD) 12 weeks	No significant difference between groups	16.0 (17.1)	15.2 (17.1)	0.17
Teri 2003 [234] (14559955) Reducing Disability in Alzheimer Disease (RDAD) vs. Routine Medical Care (RMC) Low Explanatory	Cornell Depression in Dementia Scale Mean (SD) 12 weeks	Significant difference between groups	5.2 (3.6)	6.2 (3.8)	0.02
Teri 2003 [234] (14559955) Reducing Disability in Alzheimer Disease (RDAD) vs. Routine Medical Care (RMC) Low Explanatory	Restricted Activity (number of days reported) Mean (SD) 12 weeks	Significant difference between groups	0.1 (0.4)	0.6 (2.5)	<0.001
Prick 2015 [226] (26004290) During three months, a personal coach visited PLWD/PLWD caregiver dyads for eight one-hour-long home visits. The first month the dyads were visited weekly, followed by biweekly home visits over the next eight weeks vs. Monthly mailed bulletins and phone calls Medium Explanatory	Family caregiver mood (Dutch version CES-D) Mean (SD) 12 weeks	All analyses showed no benefits of the intervention over time on any of the outcomes	13.71 (8.18)	10.94 (8.42)	0.08
Prick 2015 [226] (26004290) During three months, a personal coach visited PLWD/PLWD caregiver dyads for eight one-hour-long home visits. The first month the dyads were visited weekly, followed by biweekly home visits over the next eight weeks vs. Monthly mailed bulletins and phone calls Medium Explanatory	Dutch Self-Perceived Pressure from Family Care (SPICC) 12 weeks	All analyses showed no benefits of the intervention over time on any of the outcomes	5.67 (2.36)	5.85 (2.13)	0.45
Prick 2015 [226] (26004290) During three months, a personal coach visited PLWD/PLWD caregiver dyads for eight one-hour-long home visits. The first month the dyads were visited weekly, followed by biweekly home visits over the next eight weeks vs. Monthly mailed bulletins and phone calls Medium Explanatory	Dutch version of Revised Memory and Behavior Problem Checklist (RMBPC) 12 weeks	All analyses showed no benefits of the intervention over time on any of the outcomes	13.06 (10.38)	12.13 (8.55)	0.82

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Mittelman 2008 [229] (18978250) Five sessions of individual and family counselling within 3 months of enrollment and continuous availability of ad hoc telephone counselling and drug treatment vs. drug alone. Medium Explanatory	Beck Depression Inventory (BDI) (revised) Regression coefficients 6 months	The predicted BDI scores decreased for treatment caregivers and increased for control caregivers.	NR	NR	NR
Mittelman 2004 [232] (14722336) Counseling sessions (in-person, family, and telephone) for caregivers vs. usual care Medium Explanatory	MBPC Regression coefficients 4 months	Intervention did not affect the frequency of patient behavioral problems, it did significantly reduce caregivers' reaction ratings	NR	NR	NR

*Explanatory studies are listed first, followed by pragmatic studies.
Abbreviations: ZBI: Zarit Burden Inventory; GDS: Geriatric Depression Scale; ZCBS: Zarit Caregiver Burden Scale; MBPC: Memory and Behavior Problems Checklist

Appendix Table E.24. Summary of strength of evidence for caregiver outcomes: multicomponent interventions for informal caregivers

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Health in PLWD and informal caregiver Combined exercise & support vs. monthly phone calls & mailed bulletins	12 weeks	1 RCT (n=153)	1 showed benefit	Medium	Inconsistent	Direct	Imprecise	Insufficient
Depression Counseling sessions (in-person, family, and phone) for caregivers vs. usual care	4-6 months	1 RCT (n=371	1 showed benefit	Medium	Unknown	Direct	Imprecise	Insufficient
Caregiver stress perception Counseling sessions (in-person, family, and phone) for caregivers vs. usual care	4-6 months	1 RCT (n=158)	1 showed benefit	Medium	Unknown	Direct	Imprecise	Insufficient
Depression Education, group discussion, in-home and phone support sessions, and caregiver feedback vs usual care**	6 months	3 RCT (n=895)	2 showed benefit 1 showed no difference	Medium	Consistent	Direct	Imprecise	Low REACH II
Caregiver stress, burden Education, group discussion, in-home and phone support sessions, and caregiver feedback vs usual care**	6 months	3 RCT (n=895)	1 showed benefit 2 showed no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient

Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Evidence Map: Multicomponent for informal caregivers

Appendix Table E.25. Characteristics of evidence map studies: multicomponent interventions for informal caregivers

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Mazurek, 2019[261] (30666097) Poland Small sample	Meeting Centres Support Programme (MCSP) Integrated group support activities (cognitive stimulation, activity groups, music therapy, psychomotor therapy, family support groups, psychoeducation, counseling)	Usual care	Persons with mild-to-moderately severe dementia, living at home, and a with a caregiver prepared to participate	Mild-to-moderate dementia (Global Deterioration Scale / GDS)	N=42 Age: yes Sex: yes Race: no Education: yes	Household characteristics	N=42 Age: yes Sex: yes Race: yes Education: yes	NR	NA	NA	6 months	NR	caregiver unmet needs
Zhang, 2019[262] (31466807) China Pilot	6 bi-weekly self-management support sessions; education,	Education material	Community-based Quasi-experimental Caregiver	85% AD, 15% other subtypes	N=41 Age: yes Sex: yes Race: no Education: yes	None	N=41 Age: yes Sex: yes Race: no Education: yes Relationship:yes	Health status Employment	NA	NA	36 weeks	NPI IADL DAD	SF-36 Self-efficacy
Brijoux 2016[223] (27839534) Germany High RoB	Qualified family companions provided support to the caregiver	Caregivers were supported by conventional care companions	Community-dwelling RCT 76 families	Clinical diagnosis of dementia (all severity)	N=73 Age: yes Sex: yes Race: no Education: no	None	N=73 Age: yes Sex: yes Race: no Education: no Relationship: yes	NR	NA	NA	16 weeks	NR	HRQOL Burden reduction Better networking to get support
Koivisto 2016[224] (26177825) Finland	Psychosocial interventions, including education, counseling and social support	Annual follow-up	Community-based – 3 clinics RCT	Patients diagnosed with mild AD CDR of 0.5 0r 1.0 Free of interfering comorbidities Family caregiver present	N=54 Intervention group 76 Control group Age: yes Sex: yes Education: yes Race % majority: no	Comorbidities: Y	N=54 Intervention group 76 Control group Age: yes Sex: yes Education: yes Race % majority: no Relation to PLWD: yes	Employment:	NA	NA	2 years 36 months of follow-up	Admission to nursing home CDR-SOB CERAD-NB MMSE NPI BDI QoL	QoL GHQ Sense of coherence BDI

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Baglio, 2015[225] (24788581) Italy High RoB	Multidimensional Stimulation group Therapy (MST) to improve cognition, behavior, and motor functioning in PWA with informal caregivers.	No comparison	Memory Clinic Outpatients RCT PLWD	Right-handed persons diagnosed with AD with MRI evidence of AD pathophysiological processes and MMSE score 15-24 and Clinical Dementia Rating scale score of 1-2, age 65-85 years, school attendance range 5-17 years	NR	NR	NR	NR	NA	NA	10 weeks (pathophysiological outcomes only)	BPSD, language, physiological brain activation	NR
Marshall, 2015[263] (no PMID) UK Pilot	Living Well with Dementia group intervention lasting for 10 weekly sessions delivered by nurses from a memory clinic	Waitlist-control	NHS hospital or community settings or PLWD home RCT	AD, vascular, or Lewy body diagnosed within previous 18 months MMSE 18+	N=58 Age: yes Sex: yes Race: yes Education: yes	Household characteristics	N=58 Age: yes Sex: yes Race: yes Education: yes Relationship: no	NR	NA	NA	10 weeks	QOL-AD CSDD	None
Czaja 2013[264] (23831174) US Pilot	Technology-based multi-component psychosocial intervention was delivered in-home and via videophone technology over 5 months.	Attention control caregiver group Caregiver received information only	Community-dwelling 3-arm RCT 110 CG	Physician diagnosis of AD or other type of dementia with MMSE score<24 and at least one limitation in ADL or two in IADL	N=93 Age: yes Sex: no Race: no Education: yes	None	N=93 Age: yes Sex: yes Race: yes Education: no Relationship: yes	Duration: yes	NA	NA	5 months	NR	CESD RMBPC Positive aspects of caregiving. Social Support
Gaugler, 2013[227] (23339050) (26238226)[265] (25628299)[266] (29562359)[267] (30009268)[268] US High RoB	Individual and family counseling, support group referral, and ad hoc consultation for adult children of PLWD	Contact-control	Community/ independent living to residential setting Adult children of PLWD N=107	NR	NR	NR	N=107 Age: yes Sex: yes Race: yes Education: yes Relationship: no	Employment	NA	NA	2 years	Residential care placement	caregiver subjective health social support

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Martindale-Adams 2013[228] (24617278) US	Telephone support and periodic group meetings for caregivers	Printed materials for support	Community-based RCT	Veteran patients diagnosed with dementia or dementia patients with veteran caregivers MMSE of 23 or less At least one ADL or 2 IADL limitations Exclusion criteria	N=77 intervention group 77 control group Age: yes Sex: yes Education: yes Race % majority: no	Not reported	Age: yes Sex: yes Education: yes Race % majority: yes Relation to PLWD: yes	Duration Income Employment	NA	NA	1 year	No reported	Bother Burden Depression General well-being
Signe, 2008[55] (18269429) Sweden High ROB	Psychosocial intervention & conversation group, 5 weeks	Control group (comparison NR)	In-home Quasi-experimental Caregiver	Dementia unspecified	N=150 Age: yes Sex: yes Race: no Education: no	Household characteristics	N=155 Age: yes Sex: yes Race: no Education: no Relationship: yes	Employment	NA	NA	6 month and 12 month measures	NR	Caregiver Burden Scale CASI Nottingham Health Profile
Finkel, 2007[269] (17463195) US Pilot	Technology-based psychoeducational intervention for family caregivers of dementia patients	Information-only	NR RCT Caregivers	Diagnosis AD or other type of dementia and MMSE score 23 (excluding scores of zero).	N=46 Age: yes Sex: yes Race: yes Education: yes	None	N=46 Age: yes Sex: yes Race: yes Education: yes Relationship: yes	None	NA	NA	6 months	NR	CED-S RMBPC
Ducharme 2005[231] (16024406) Canada High RoB	90 minutes of weekly sessions (10 weeks) for women CG comprising of a psychoeducational program focusing on cognitive appraisal of stress, perception of control over a situation and problem solving, reframing, and stress symptoms management.	Comparison program offered by an Alzheimer Society Control: No program	Long term care and residential centers 3-arm RCT 137 caregivers	Diagnosed with irreversible dementia	N=unclear Age: yes Sex: yes Race: no Education: no	None	N=unclear Age: yes Sex: yes Race: no Education: no Relationship: yes	NR	NA	NA	10 weeks 3 months	NR	PDI Caregiver Overload SAM CAMI Competence in dealing with healthcare

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Eisdorfer 2003[233] (12937331) US High RoB	SET: 60-90 minutes structural family therapy sessions for 12 months, with weekly sessions for the first 4 months, biweekly sessions for the subsequent 2 months, and monthly sessions for the final 6 months of treatment. SET+CTIS: CTIS is an information network that utilizes computer–telephone technology facilitating linkages of the caregivers with both their family and with supportive resources outside of the home.	Telephone-based, minimal support condition; biweekly calls for the first 6 months and monthly calls during the next 7–12 months. The duration of the calls ranged from 5 min to 15 min and consisted of active listening and empathic comments when appropriate.	Community-dwelling 3-arm RCT 225 CG	Medical diagnosis of AD or other type of dementia with MMSE score<24 and at least one limitation in ADL or two in IADL	N=148 Age: yes Sex: yes Race: yes Education: **no**	None	N=148 Age: yes Sex: yes Race: yes Education: yes Relationship: yes	Duration: yes	NA	NA	6 months 18 months	NR	CESD RMBPC Satisfaction with social support MMSE ADL IADL
Mittelman 1993[235] (8314099) US	Individual and family counseling, support group and ad hoc consultation	Routine support	Community-based RCT	Patients with a clinical diagnosis of AD Spouse is primary caregiver Additional family support locally Exclusion criteria	N=103 Intervention group 103 control group Age: yes Sex: yes (inferred) Education: no Race % majority: no	Patient income	N=103 Intervention group 103 control group Age: yes Sex: yes Education: yes Race % majority: yes Relation to PLWD: yes	Duration Employment status Religion	NA	NA	12 months	Admission to nursing home Predictors of nursing home placement regression analysis	Not reported

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PLWD Dementia Characteristics**	**PLWD Non-Disease Char** **PLWD N** **PLWD Age (mean)** **PLWD Sex (% female)** **PLWD Race (% majority)** **PLWD Education (mean years)**	**PLWD Non-Disease Char Reporting Status (RS)** **PLWD SES** **PLWD Prior Disability** **PLWD Household Characteristics** **PLWD Health Insurance** **PLWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PLWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PLWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PLWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Mohide, 1990[236] (2184186) Canada High ROB	Caregiver Support Program (CSP): caregiver-focused health care, education about dementia and caregiving, assistance with problem solving, regularly scheduled in-home respite, self-help family caregiver support group	Conventional community nursing care	In-home RCT Caregiver	Moderate to severe dementia	N=30 Age: yes Sex: yes Race: no Education: no	SES	N=30 Age: yes Sex: yes Race: no Education: no	Duration	NA	NA	6 months	NR	CES-D Self-Anchoring Striving Scale Caregiver Quality of Life Inventory

Abbreviations: AD= Alzheimer's disease; ADL=Activities of Daily Living; AES=Apathy Evaluation Scale; APADEM-NH=Apathy Scale for Institutionalized Patients with Dementia Nursing Home; AWS== Revised Algase Wandering Scale–Nursing Home version; BARS=Brief Agitation Rating Scale; BPSD=Behavioral and Psychological Symptoms of Dementia; CDR=Clinical Dementia Rating; CES-D= Center for Epidemiological Studies of Depression scale; CMAI-SF=Cohen-Mansfield Agitation Inventory-Short Form; CSDD=Cornell Scale for Depression in Dementia; DSM=Diagnostic and Statistical Manual; EM=Evidence Map; FC=Formal Caregiver; GDS=Global Deterioration Scale; GDS-SF= Geriatric Depression Scale Short Form; IC= Informal Caregiver; MMSE=Mini-mental State Examination; N=number; N= number; NA=Not Applicable; NIA=National Institute on Aging; NPI=Neuropsychiatric Inventory; NR=Not Reported; OERS=Observed Emotion Rating Scale; PMID=PubMed Identification Number; PLWD=People with dementia; QoL-AD=Quality of Life in Alzheimer's Disease; QUALID=Quality of Life in Late Dementia; RCT= Randomized controlled trial; RMBPC= Revised Memory and Behavior Problems Checklist; ROB= Risk of bias; RS= Reporting status; SES= Socioeconomic status

Other Interventions for Informal Caregiver Well-being

Appendix Table E.26. Risk of bias assessment: other interventions for informal caregiver well-being

Study (PMID)	**Outcome Timing**	**Attrition Bias** **Attrition %**	**Selection Bias**	**Detection Bias**	**Performance Bias**	**Reporting Bias**	**Fidelity Bias**	**Funder**	**Overall Rating**
Jutten, 2018[270] (30631337) Jutten 2017[271] (28827242)	2.5 months 15 months	High 2.5 months: 16% 12 months: 57%	High	X	X	X	X	Government and Nonprofit	High
Stern 2008[272] (19064472)	8 weeks	Medium NR	Medium	High	Medium	High	X	Government	High
Simpson 2006[273] (16734920)	6 months 12 months	High 12 months: 39%	X	X	X	X	X	Government	High

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Evidence Map: Other Interventions for Informal Caregiver Well-Being

Appendix Table E.27. Characteristics of evidence map studies: other interventions for informal caregiver well-being

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Jutten, 2018[270] (30631337) Netherlands High ROB Jutten 2017[271] (28827242)	Mixed virtual reality simulator (simulate experience of dementia)	No virtual reality	Community-based Quasi-experimental caregivers	Dementia unspecified	N=201 Age: yes Sex: yes Race: no Education: no	Duration	N=201 Age: yes Sex: yes Race: yes Education: no Relation to PLWD: yes	Living with PLWD: yes	NA	NA	2.5 and 15 months	NA	Empathy Hospital Anxiety and Depression Scale Caregiver Reaction Assessment Relationship Quality Index
Lord 2017[274] (28243460) UK Pilot Study	DECIDE decision aid for informal caregivers about place of care for PLWD; one 45-minute session with a decision coach	Usual care	Community-based memory clinics RCT, single site 41 informal caregivers	Moderate or severe dementia MMSE < 20	N=41 Age: no Sex: no Race: no Education: no	NR	N=41 Age: yes Sex: yes Race: yes Education: no Relation to PLWD: yes	Living with PLWD: yes	NA	NA	10 weeks	NA	Decisional Conflict Scale Hospital Anxiety and Depression Scale
Stirling 2012[275] (22429384) Australia Pilot Study	Decision aid about community services, including respite care, for informal caregivers; mailed directly to caregivers and completed over a week	Waitlist control	Community-based setting with in-home decision aid RCT; single site 31 informal caregivers	Not specified	N=31 Age: no Sex: no Race: no Education: no	NR	N=31 Age: yes Sex: yes Race: yes Education: yes Relation to PLWD: yes	Duration: Yes	NA	NA	2 weeks 3 months	NA	Modified Caregiver Strain Index Decisional Conflict Scale Control Preference Scale
Rose 2009[276] (19427574) US Pilot Study	At home AlphaStim® cranial electrical stimulation Alzheimer's disease or multi-infarct dementia for spouse caregivers; 60 minutes per day for 4 weeks	Sham	Rural community setting, intervention at home RCT; single site 39 spouse caregivers	AD or multi-infarct dementia	N=39 Age: yes Sex: no Race: no Education: no	NR	N=39 Age: yes Sex: yes Race: no Education: yes Relation to PLWD: yes	Duration: Yes	NA	NA	2 weeks 4 weeks	NA	PSQI General Sleep Disturbance Scale Geriatric Depression Scale Philadelphia Geriatric Center Caregiving

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
													Appraisal Scales
Stern 2008[272] (19064472) US High ROB	Family caregiver psychoeducational support meetings for PLWD driving cessation; 4 weekly 2-hour meetings	1. Written educational information and resource list for PLWD driving cessation. 2. No intervention (waitlist control)	Community-based setting Cluster RCT 14 sites 66 informal caregivers	Caregiver's report of MCI, AD, or other dementia	N=66 Age: no Sex: no Race: no Education: no	NR	N=66 Age: yes Sex: yes Race: no Education: no Relation to PLWD: yes	NR	NA	NA	8 weeks	NA	Brief COPE Scale Self-Efficacy Questionnaire
Simpson 2006[273] (16734920) UK High ROB	Carer held record folder with sections for carer/family, professional feedback, and a carer diary; held at home and maintained for 12 months	Usual Care	Community-based mental health care and at home CCT 84 informal caregiver-PLWD dyads	Not specified	N=84 Age: no Sex: no Race: no Education: no	NR	N=84 Age: no Sex: no Race: no Education: no Relation to PLWD: no	NR	NA	NA	6 months 12 months	Crichton Behavioral Scale Global Deterioration Scale	Dementia Knowledge Questionnaire Caregiver Strain Index GHQ SF-36 Locus of Control Scale

Abbreviations: AD=Alzheimer's disease; CCT=Controlled Clinical Trial; char=characteristics; COPE=Coping Orientation to Problems Experienced; EM=Evidence Map; FC=formal caregiver; GHQ=General Health Questionnaire; IC=informal caregiver; MCI=Mild Cognitive Impairment; MMSE=Mini Mental State Exam; N=number; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; PSQI= Pittsburgh Sleep Quality Index; PLWD=Persons with Dementia; RCT=Randomized Controlled Trial; ROB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status; SF-36=36-item Short Form Survey

Care Interventions for Formal Caregiver Staff Well-Being Evidence Map: Formal Caregiver Staff

Appendix Table E.28. Characteristics of evidence map studies: care interventions for formal caregiver staff well-being

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PLWD Dementia Characteristics	PLWD Non-Disease Char PLWD N PLWD Age (mean) PLWD Sex (% female) PLWD Race (% majority) PLWD Education (mean years)	PLWD Non-Disease Char Reporting Status (RS) PLWD SES PLWD Prior Disability PLWD Household Characteristics PLWD Health Insurance PLWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PLWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PLWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PLWD Outcomes	Caregiver Outcomes IC: FC:
Barbosa, 2015[277] (25237132) (263994850)[278] Portugal Pilot	8 weekly sessions of 60 minutes psychoeducation plus 30 minutes relaxation and stress management strategies	Education only	Aged-care residential facilities Cluster RCT 4 facilities	Dementia unspecified (private, non-profit institutions with staff to resident ratio 1:2 or 1:3)	NR	NR	NA	NA	N=58 Age: yes Sex: yes Race: no Education: yes	Length of service	10 weeks	NR	Perceived stress scale MBI Intrinsic satisfaction with job
Visser, 2008[279] (18297478) (17191270) [280] Australia Pilot	8-week staff education plus peer support group	Waitlist Education only	Aged-care facility Cluster RCT 3 facilities	Residents selected by staff for displaying agitation; dementia unspecified	N=76 Age: yes Sex: yes Race: no Education: no	NR	NA	NA	N=52 Age: yes Sex: yes Race: no Education: no	NR	6 months	ADRQL CMAI	The Staff Attitudes Questionnaire MBI, third edition
Mackenzie, 2003[281] (14569646) Canada Pilot	4 module training and education to decrease formal caregiver stress and burn-out	Usual care activities	Dementia care units Quasi-experimental 2 care units	NR	NR	NR	NA	NA	N=41 Age: yes Sex: yes Race: no Education: yes	Position	3-month post-intervention	NR	Inventory of Geriatric Nursing Self-Efficacy MBI Satisfaction with teamwork

Abbreviations: ADRQL= Alzheimer's Disease Related Quality of Life; char=characteristics; CMAI= Cohen-Mansfield Agitation Inventory; FC=formal caregiver; IC=informal caregiver; MBI= Maslach Burnout Inventory; N=number; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; PLWD=Persons with Dementia; RCT=randomized controlled trial; RS=Reporting Status; SES=socioeconomic status

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Appendix F. Care Delivery Interventions Consultation

Appendix Table F.1. Risk of bias assessment: Consultation services

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Overall Rating
Fortinsky 2009[1] (19347683)	12 months	Medium 12 months: 10.7%	Medium	Medium	Low	Medium	Medium	Medium
Borbasi 2011[2] (21692400)	12 months	X	High	X	X	X	X	High
McSweeney 2012[3] (22344753)	15 weeks	Medium 11%	Low	Low	High	Low	High	High
Opie 2002[4] (11802224)	4 weeks	Low	Medium 3%	High	High	Low	Medium	High
Orrell 2007[5] (17394129)	20 weeks	Medium 19%	Medium	Low	Medium	Low	High	High

Abbreviations: PMID=PubMed Identification Number

Appendix Table F.2. Characteristics of included studies: Consultation services

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Fortinsky 2009[1] (19347683) US Medium Explanatory	Intervention group family caregivers received the dementia care consultation intervention per protocol as well as educational materials about dementia and community resources over 12 months period	Educational materials	Community-based in-home Cluster RCT 26 practice sites	Diagnosed with AD or other dementia. With following ICD-9 codes: arteriosclerotic dementia (290.40,290.41,290.42,290.43); senile dementia (290.00,290.20,290.21,290.30); pre-senile dementia (290.10,290.11,290.12,290.13); memory loss, mild (310.10); or AD (331.00).	N=84 66% Female 82 years Race NR Education NR	None	NA	N=84 72% Female 61 years Race NR Education NR	NA	NA	12 months	Nursing home admission;	IC: 2 measures of self-efficacy Caregiver Burden CES-D HSC measures of symptom severity CSC PBS

*High risk of bias studies included in evidence map

Abbreviations: AD=Alzheimer's disease; char=characteristics; CES-D=Center for Epidemiological Studies Depression Inventory; FC=formal caregiver; CSC=Cognitive Status Scale; IC=informal caregiver; ICD=International Classification of Diseases; HSC=Hopkins Symptoms Checklist; PBS= Problematic Behavior Scale; PMID=PubMed Identification Number; PWD=Persons with Dementia; RCT=Randomized Controlled Trial; RoB=Risk of Bias; RS=Reporting Status

Appendix Table F.3. PWD outcomes summary low and medium risk of bias studies: Consultation services

Study (PMID) Comparison RoB Category	Outcome Timing	Intervention		Comparator		p-value
		Before	After 12 months	Before	After 12 months	
Fortinsky 2009[1] (19347683) Consultation vs Control Medium Exploratory	Adjusted Odds Ratio (95% CI) Nursing home admission 12 months	NR	0.4 (0.14, 1.18)	NR	1.0	p=0.10

Abbreviations: CES-D=Center for Epidemiological Studies Depression Inventory; CI=Confidence Interval; NR=Not Reported; PMID=PubMed Identification Number; RoB=Risk of Bias

Appendix Table F.4. Informal caregiver outcomes summary low and medium risk of bias studies: Consultation services

Study (PMID) Comparison RoB Category	Outcome Timing	Intervention		Comparator		p-value
		Before	After 12 months	Before	After 12 months	

Fortinsky 2009[1] (19347683) Consultation vs Control Medium Exploratory	Adjusted Mean (95% CI) Symptom management self-efficacy score 12 months	33.52 (27.77–39.26)	33.88 (28.04–39-73)	33.51 (27.31–39.71)	34.21 (27.92–40.49)	p=0.89
Fortinsky 2009[1] (19347683) Consultation vs Control Medium Exploratory	Adjusted Mean (95% CI) Support service self-efficacy 12 months	27.96 (25.17–30.75)	31.95 (28.90–35.00)	24.63 (20.95–28.31)	27.92 (24.17–31.66)	P=0.80
Fortinsky 2009[1] (19347683) Consultation vs Control Medium Exploratory	Adjusted Mean (95% CI) CES-D score 12 months	12.13 (8.90–15.35)	9.80 (6.24–13.36)	15.10 (10.77–19.43)	15.00 (10.51–19.49)	p=0.41
Fortinsky 2009[1] (19347683) Consultation vs Control Medium Exploratory	Adjusted Mean (95% CI) Zarit burden score 12 months	30.42 (26.30–34.53)	26.18 (21.81–30.55)	36.02 (30.71–41.33)	30.57 (25.03–36.10)	p=0.73
Fortinsky 2009[1] (19347683) Consultation vs Control Medium Exploratory	Adjusted Mean (95% CI) Hopkins symptom checklist score 12 months	2.33 (1.57–3.09)	2.92 (2.10–3.74)	3.23 (2.31–4.17)	3.74 (2.78–4.70)	p=0.87

Abbreviations: CES-D=Center for Epidemiological Studies Depression Inventory; CI=Confidence Interval; NR=Not Reported; PMID=PubMed Identification Number; RoB=Risk of Bias

Appendix Table F.5. Summary of strength of evidence for PWD outcomes: Consultation services

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Consultation vs Control Nursing home admission	12 months	1 RCT (n=84)	Nursing home admissions showed no difference between the comparison groups.	Moderate	Unknown	Direct	Imprecise	Insufficient

Abbreviations: CES-D=Center for Epidemiological Studies Depression Inventory; n=Number; RCT=Randomized Controlled Trial

Appendix Table F.6. Summary of strength of evidence for caregiver outcomes: Consultation services

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Consultation vs Control Symptom management self-efficacy score	12 months	1 RCT (n=84)	Symptom management self-efficacy scores were not different between the comparison groups	Moderate	Unknown	Direct	Imprecise	Insufficient
Consultation vs Control Support service self-efficacy	12 months	1 RCT (n=84)	Support service self-efficacy was not different between the comparison groups	Moderate	Unknown	Direct	Imprecise	Insufficient
Consultation vs Control CES-D score	12 months	1 RCT (n=84)	CES-D scores were not different between the comparison groups	Moderate	Unknown	Direct	Imprecise	Insufficient
Consultation vs Control Zarit burden score	12 months	1 RCT (n=84)	Zarit burden scores were not different between the comparison groups	Moderate	Unknown	Direct	Imprecise	Insufficient
Consultation vs Control Hopkins symptom checklist score	12 months	1 RCT (n=84)	Hopkins symptom checklist scores were not different between the comparison groups	Moderate	Unknown	Direct	Imprecise	Insufficient

Abbreviations: CES-D=Center for Epidemiological Studies Depression Inventory; n=Number; RCT=Randomized Controlled Trial

Evidence Map: Consultation services

Appendix Table F.9. Characteristics of evidence map studies: Consultation services

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PWD Dementia Characteristics**	**PWD Non-Disease Char** **PWD N** **PWD Age (mean)** **PWD Sex (% female)** **PWD Race (% majority)** **PWD Education (mean years)**	**PWD Non-Disease Char Reporting Status (RS)** **PWD SES** **PWD Prior Disability** **PWD Household Characteristics** **PWD Health Insurance** **PWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Borbasi 2011[2] (21692400) Australia High RoB	Dementia Outreach Service (DEMOS): comprised a multidisciplinary healthcare team to assess and manage residents experiencing cognitive deterioration as a result of dementia. Conducted for 12 months in 3 stages	NR	Residential aged care facilities Quasi-experimental	Not specified	NR	None	NR	None	N=320 Age: no Sex: yes Race: yes Education: no	NA	12 months	NR	Improved capacity and clinical skills of staff (stress, knowledge and self-confidence) Improvement in timeliness and appropriateness of referrals Satisfaction Barriers to success
McSweeney 2012[3] (22344753) Australia High RoB	Psychiatrist and psychologist's consultation regarding best-practice management of depression via psychosocial (individually tailored, psychosocial care plan) and medical care plan	Care as usual	Aged care facilities RCT; 44 PWD	MMSE cut point score of 23 and PAS Informant History≥4 PAS, Cognitive Decline Informant History and CSDD	N=44 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	15 weeks	CSDD RAID MMSE BEHAVE-AD CANE	NA
Opie 2002[4] (11802224) Australia High RoB	Multidisciplinary interventions (early and late groups) encompassing psychosocial strategies, nursing approaches, psychotropic approaches and management of pains	NA	Nursing homes Quasi-experimental	Based on CMAI, BAGS and MMSE scores	N=99 Age: yes Sex: no Race: no Education: no	None	NA	NA	NA	NA	Weekly up to 4 weeks	Restlessness Physical aggression Verbal disruption Inappropriate behavior	NA
Orrell 2007[5] (17394129) UK High RoB	1 hour per week liaison mediated personalized intervention package over 20 weeks to address the unmet needs	Care as usual	residential care homes Cluster RCT; 238 PWD	Diagnosis based on DSM-IV criteria for dementia	N=238 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	20 weeks	CANE QoL-AD MMSE CDR CAPE-BRS BI CBS CSDD RAID	CANE QoL-AD

Abbreviations: BAGS=Behavior Assessment Graphical System; BEHAVE-AD=Behavioural Pathology in Alzheimer's Disease; BI=Barthel IndexCANE=Camberwell Assessment of Need for the Elderly; CAPE-BRS=Clifton Assessment Procedures for the Elderly-Behavior Rating Scale; CBS=Challenging Behavior Scale; CDR=Clinical Dementia Rating; CMAI= Cohen-Mansfield Agitation Inventory; CSDD=Cornell Scale for Depression in Dementia; DSM=Diagnostic and Statistical Manual; EM=Evidence Map; MMSE=Mini-mental State Examination; N=number; NA=Not Applicable; NR=Not Reported; PAS=Psychogeriatric Assessment Scale; PMID=PubMed Identification Number; QoL-AD=Quality of Life in Alzheimer's Disease; RAID=Rating for Anxiety in Dementia

Case Management

Appendix Table F.10. Risk of bias assessment: case management

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Xiao, 2016[6] (25805891)	12 months	Medium 15%	Low	Medium	High	Low	Low	Government	High
MacNeil Vroomen, 2015[7] (26170035)	24 months	High 40%	Medium	X	X	X	X		High
Chien, 2011[8] (21198803)	12, 18 months	Low 2%	Low	Low	Medium	Low	High	Government University	Medium
Lam, 2010[9] (19606455)	12 months	Low 3%	Low	Medium	Medium	Low	High	Government	Medium
Brodaty, 2003[10] (12590626)	12 weeks	Medium 16%	Low	Low	High	Low	High		High
Challis, 2002[11] (11994884)	6 months	Low 0%	High	High	X	X	X		High
Eloniemi-Sulkava, 2001[12] (11890485)	2 years	Low 0%	Medium	Low	Medium	Low	Medium	Government	Medium
Weinberger, 1993[13] (8426038)	6 months	Medium 14%	Medium	High	High	Low	High		High

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Appendix Table F.11. Characteristics of included studies: case management

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Chien 2011[8] (21198803) Hong Kong Medium Explanatory	Orientation to dementia care, educational workshop, family role and strength rebuilding, community support resources, program evaluation For 6 months	Routine care Usual services provided by the dementia resources center	Community RCT N=92 dyads	Nonspecified dementia DSM-IV	N=92 Age 68 44% Female Race NR Education NR	Mean monthly household income 14,000 Hong Kong dollars	NR Age 45 66% Female Race NR Education 27% Primary or less 64% Secondary 8% Tertiary	NR	NA	NA	12, 18 months	NPI Institutionalization	Family Caregiving Burden Inventory WHOQOL-BREF Social Support Questionnaire Family Support Services Index
Lam 2010[9] (19606455) Hong Kong Medium Explanatory	Case Management model: Assessment and advice. Home-based advice and training on cognitive stimulation strategies, support sites & telephone calls For 4 months	One home visit for home safety at the beginning of the trial, no case management	Community-based RCT N=102	Nonspecified dementia Chinese Mini-Mental State Examination (CMMSE) 15+ Clinical Dementia Rating Scale 1	N=102 Age 78 58% Female Race NR Education NR	NR	N=102 Age NR 74% Female Race NR Education NR 29% Spouse or partner 51% Child	NR	NA	NA	12 months	CSDD NPI Personal Wellbeing Index-Intellectual Disability	ZBI General Health Questionnaire Personal Well-Being Index Social support use
Eloniemi-Sulkava 2001[14] (11890485) Finland Medium Explanatory	Care coordination support program 2 years	Usual care activities	Home-based RCT N=100 dyads	Alzheimer's disease Vascular dementia DSM-III	N=100 Age 79 53% Female Race NR Education NR	NR	N=100 Age 64 69% Female Race NR Education NR 56% Spouse 35% Child	NR	NA	NA	2 years	Rate of institutionalization	General Health Questionnaire

Abbreviations: char=Characteristics; CMMSE=Mini State Mental Examination Chinese version; CSDD=Cornell Scale for Depression in Dementia; DSM-III=Diagnostic and Statistical Manual of Mental Disorders-Third Ed; DSM-IV=Diagnostic and Statistical Manual of Mental Disorders-Fourth Ed; FC=Formal Caregiver; IC=Informal Caregiver; N=Number; NA=Not Applicable; NPI=Neuropsychiatric Inventory; NR=Not Reported; PMID=PubMed Identification Number; RCT=Randomized Controlled Trial; RoB-Risk of Bias; RS=Reporting Status; SES=Socioeconomic Status; WHOQOL-BREF= World Health Organization Quality of Life Measure-Brief Version; ZBI=Zarit Burden Interview

Appendix Table F.12. PWD outcomes summary for low and medium risk of bias studies: case management

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Chien, 2011[8] (21198803) Case management vs usual care Medium Explanatory	NPI 18 months	Favors intervention F(1,90) = 3.70	Baseline 81.8 (SD 9.1) 18 month 76.5 (SD 8.9)	Baseline 80.9 (SD 9.5) 18 month 82.4 (SD 11.0)	<0.01
Chien, 2011[8] (21198803) Case management vs usual care Medium Explanatory	Average number institutionalizations over previous 6 months 18 months	Favors intervention F(1,90) = 4.32	Baseline 5.1 (SD 0.9) 18 month 2.6 (SD 1.9)	Baseline 5.5 (SD 1.2) 18 month 6.0 (SD 2.9)	<0.01
Lam, 2010[9] (19606455) Medium Explanatory	Personal well-being index for intellectually disabled (PWI-ID) difference in difference 12 month	No statistical difference	(reported data must be incorrect for NS finding)	Change from baseline 1.4 (-7.1, 10.7)	NS
Lam, 2010[9] (19606455) Medium Explanatory	Cornell Scale for Depression in Dementia (CSDD) difference in difference 12 month	No statistical difference	Change from baseline -1.0 (-3.5, 1.0)	Change from baseline -1.5 (-4.0, 1.0)	NS
Lam, 2010[9] (19606455) Medium Explanatory	NPI difference in difference 12 month	No statistical difference	Change from baseline -2.0 (-18.5, 6.0)	Change from baseline -7.0 (-19.0, 0.0)	NS
Eloniemi-Sulkava, 2001[12] (11890485) Medium Explanatory	Rate of institutionalization 2 years	No statistical difference	32% placement	30% placement	NS

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number

Appendix Table F.13. Caregiver outcomes summary low and medium risk of bias studies: case management

Study (PMID) Comparison Caregiver Type RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Chien, 2011[8] (21198803) Case management vs usual care Medium Explanatory	Family caregiving burden inventory 18 months	F(1,90) = 7.09	Baseline 68.0 (SD 14.8) 18 month 45.5 (SD 10.0)	Baseline 66.9.0 (SD 14.8) 18 month 64.1 (SD 11.4)	<0.001
Chien, 2011[8] (21198803) Case management vs usual care Medium Explanatory	WHOQoL 18 months	F(1,90) = 6.81	Baseline 64.8 (SD 13.0) 18 month 82.7 (SD 13.5)	Baseline 64.8 (SD 13.0) 18 month 64.5 (SD 13.1)	<0.001
Lam, 2010[9] (19606455) Medium Explanatory	Personal well-being Index for Adult 12 month	No statistical difference	Change from baseline 2.9 (-15.0, 7.1)	Change from baseline 0.0 (-6.1, 5.0)	NS
Lam, 2010[9] (19606455) Medium Explanatory	ZBI 12 month	No statistical difference	Change from baseline 5.0 (-10.5, 12.0)	Change from baseline 3.5 (-9.3, 12.3)	NS
Lam, 2010[9] (19606455) Medium Explanatory	General Health Questionnaire 12 month	No statistical difference	Change from baseline 1.0 (-2.0, 5.5)	Change from baseline 0.0 (-2.0, 3.0)	NS

Abbreviations: NS=Not Significant; PMID=PubMed Identification Number; RoB-Risk of Bias; SD=Standard deviation; WHOQOL=World Health Organization Quality of Life Measure; ZBI=Zarit Burden Interview

Appendix Table F.14. Summary of strength of evidence for PWD outcomes: Consultation services

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Institutionalization Case management vs usual care	18-24 months	2 RCTs (n=192)	Mixed findings for institutionalization	Moderate	Unknown	Direct	Imprecise	Insufficient
NPI Case management vs usual care	12-18 months	2 RCT (n=194)	Mixed findings for NPI	Moderate	Unknown	Direct	Imprecise	Insufficient
Quality of Life Case management vs usual care	12 months	1 RCT (n=102)	No significant difference between groups	Moderate	Unknown	Direct	Imprecise	Insufficient
Depression Case management vs usual care	12 months	1 RCT (n=102)	No significant difference between groups	Moderate	Unknown	Direct	Imprecise	Insufficient

Abbreviations: N=Number; NPI=Neuropsychiatric Inventory; RCT=Randomized Controlled TriaL

Appendix Table F.15. Summary of strength of evidence for caregiver outcomes: Consultation services

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion

Quality of Life Case management vs usual care	12-18 months	2 RCTs (n=194)	Mixed findings for NPI	Moderate	Unknown	Direct	Imprecise	Insufficient
Caregiver Burden Case management vs usual care	12-18 months	2 RCT (n=194)	Mixed findings for NPI	Moderate	Unknown	Direct	Imprecise	Insufficient
Caregiver health status Case management vs usual care	12 months	1 RCT (n=102)	No significant difference between groups	Moderate	Unknown	Direct	Imprecise	Insufficient

Abbreviations: N=Number; NPI=Neuropsychiatric Inventory; RCT=Randomized Controlled TriaL

Evidence Map: Case Management

Appendix Table F.16. Characteristics of evidence map studies: Case management

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PWD Dementia Characteristics**	**PWD Non-Disease Char** **PWD N** **PWD Age (mean)** **PWD Sex (% female)** **PWD Race (% majority)** **PWD Education (mean years)**	**PWD Non-Disease Char Reporting Status (RS)** **PWD SES** **PWD Prior Disability** **PWD Household Characteristics** **PWD Health Insurance** **PWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Xiao, 2016[6] (25805891) Australia High ROB	Case manager, home visit for initial assessment, monthly telephone contact	Usual care activities	Community RCT Caregivers	Dementia unspecified, from minority groups	N=61 Age: Yes Sex: Yes Race: No Education: no	(minority groups not specified)	N=61 Age: Yes Sex: Yes % majority race: No Education: no Relationship: Yes	Duration Living with PWD Health status	NA	NA	6, 12 months	Blessed dementia score NPI QUORE	SSCQ SF-36v2
MacNeil Vroomen, 2015[7] (26170035) Netherlands High RoB	Case management: (1) provided within one care organization (ICMM), (2)case management where multiple case management organizations are present within one region (LM)	Control: group with no access to case management	Home setting Non-RCT 521 dyads		N=521 Age: Yes Sex: Yes Race: No Education: Yes	Marital status Living condition	N=521 Age: Yes Sex: Yes Race: No Education: Yes Relationship: Yes	Living condition: Yes	NA	NA	2 years	Neuropsychiatric problems: NPI	Psychological health: (GHQ-12)
Brodaty, 2003[10] (12590626) Australia High RoB	Different models of care: (1) Psychogeriatric case management (2) Psychogeriatric consultation	Control: continued to receive whatever treatment they would have had were the survey not to have taken place.	Nursing home RCT 102 PWD	Not specified	N=102 Age: Yes Sex: Yes Race: No Education: No	None	NA	NA	NA	NA	12 weeks	Depression: HAM-D; CSD; GDS & EBAS-DEP Psychopathology: (NPI) Behavior pathology: BEHAVE-AD	NA
Challis, 2002[11] (11994884) UK High ROB	Intensive case management, protected small caseloads per worker	Usual care activities	Community Matched case control 43 matched pairs	Not specified	N=86 Age: Yes Sex: Yes Race: No Education: No	SES	NR	NR	NA	NA	2 years	Unmet needs Service patterns and costs	IC: Caregiver burden
Newcomer, 1999[15] (10445896) US Pilot demonstration	Medicare demonstration of case management (high attrition over 3 years)	Higher client to case manager ratio	Community RCT Caregivers	Alzheimer's disease	N=2731 Age: Yes Sex: Yes Race: yes Education: No	None	N=2576 Age: Yes Sex: Yes Race: No Education: no Relationship: Yes	None	NA	NA	3 years (attrition 64%)	NR	Caregiver burden and depression
Weinberger, 1993[13] (8426038) Us High RoB	Social work case management	Usual care activities	Community RCT Caregivers	Progressive dementia unspecified	N=264 Age: Yes Sex: Yes Race: Yes Education: No	SES Household characteristics	N=264 Age: Yes Sex: Yes Race: Yes Education: Yes Relationship: Yes	Duration Health status Employment	NA	NA	6 months	Health utilization	NR

Abbreviations: BEHAVE-AD=Behavioral Pathology in Alzheimer's Disease; char=Characteristics; CSD=Cornell Scale for Depression; EBAS-DEP= Even Briefer Assessment for Depression; EM=Evidence Map; FC=Formal Caregiver; GDS=Geriatric Depression Scale; GHQ-12=General Health Questionnaire-12 Item; HAM-D=Hamilton Rating Scale for Depression; IC=Informal Caregiver; N=Number; NA=Not Applicable; NPI=Neuropsychiatric Inventory; NR=Not Reported; PMID=PubMed Identification Number; PWD=Persons with Dementia; QUORE=Quality of Patient's Eyes; RCT=Randomized Controlled Trial; RoB=Risk of Bias; RS=Reporting Status; SES=Socioeconomic Status; SF-36V2=Quality of Life Questionnaire; SSCQ=Sense of Competence Questionnaire

Care Protocols For PWD

Appendix Table F.17. Risk of bias assessment: care protocols for PWD

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Appelhof, 2019[16] (30799167)	18 months stepped wedge	Stepped wedge	X	X	X	X	High		High
Husebo, 2019[17] (30630722)	9 months	Medium 27%	Low	X	X	X	High	X	High
Livingston 2019[18] (30872010)	8 months	Medium 21%	Medium	Medium	Medium	Low	High	Government	High
Nakanishi 2017[19] (28857263)	6 months	Medium 15%	Low	High	Medium	Low	High	Government	High
Pieper 2016[20] (26804064)		Medium 11%	Low	Low	Low	Low	High	Nonprofit	High
McCabe, 2015[21] (25319535)	3 months	Medium 13%	Low	Medium	Medium	Low	High		High
Zwijsen, 2014[22] (24878214)	Stepped wedge		X	X	X	X	High		High
Rapp, 2013[23] (23827658)	10 months	Medium 15%	Medium	Low	High	Low	High		High
Cohen-Mansfield, 2012[24] (23059151)	2 weeks	High 46%	X	X	X	X	X		High
Kovach, 2012[25] (22998656)		Low	High 30%	X	X	X	X		High
Salva, 2011[26] (22159768)		Low	High 31%	X	X	X	X		High
Kovach, 2006[27] (16869334)	8 weeks	Medium 11%	Low	Low	High	Low	Low	Government	High

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: PMID=PubMed Identification Number

Evidence Map: Care Protocols For PWD

Appendix Table F.18. Characteristics of evidence map studies: care protocols for PWD

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Appelhof, 2019[16] (30799167) Netherlands High RoB	The care program: Involves five steps: evaluation of psychotropic drug prescription, detection, analysis, treatment, & evaluation of treatment of NPS	Control: consisted of care as usual, without the educational program and use of the care program	Young-onset dementia Special care unit RCT (stepped wedge) 274 PWD	Mild-severe dementia (All types)	N=274 Age: Yes Sex: yes Race: No Education: No	None	NA	NA	NA	NA	18 months	Agitation & aggression: CMAI (Dutch) NPS: NPI-NH (Dutch)	NA
Husebo, 2019[17] (30630722) Norway High ROB	4-month training for multicomponent guideline-based, includes communication, systematic pain management, medication review, and activities	Usual care	Nursing homes Cluster RCT 33 nursing homes, both urban (52%) and non-urban (patients per cluster average 8)	Dementia unspecified	N=545 Age: Yes Sex: yes Race: No Education: No	None	NA	NA	NR	NR	9 months	QUALIDEM QUALID EQ-VAS ADL CGIC total medication	Staff distress

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PWD Dementia Characteristics**	**PWD Non-Disease Char** **PWD N** **PWD Age (mean)** **PWD Sex (% female)** **PWD Race (% majority)** **PWD Education (mean years)**	**PWD Non-Disease Char Reporting Status (RS)** **PWD SES** **PWD Prior Disability** **PWD Household Characteristics** **PWD Health Insurance** **PWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Livingston 2019[18] (30872010) UK High RoB	MARQUE:6 sessions of manual-based intervention, followed by an implementation and supervision period (panel)	Treatment as usual	Care homes in Uk Cluster RCT 20 Care homes 404 PWD 492 CG	Clinical diagnosis of dementia	N=404 Age: Yes Sex: yes Race: yes Education: yes	None	NA	NA	N=492 Age: Yes Sex: yes Race: yes Education: yes	Length of service Training	8 months	CMAI NPI DEMQOL EQ-5D 5L CDR	MBI SCID STS
Nakanishi 2017[19] (28857263) Japan High RoB	BASE: consisted of training course; a web-based tool for ongoing monitoring and assessment for challenging behavior, and a multiagency discussion meeting.	Same as the intervention group, the care professionals' input of measures of their persons with dementia using the web-based tool at base-line. However, the web-based tool for the control group had no assessment of unmet needs nor an action plan.	Home care service providers Cluster RCT 283 PWD 45 Home care providers 98 case managers and CG	Dementia diagnosis	N=283 Age: Yes Sex: yes Race: No Education: No	None	NA	NA	NR	NR	6 months	NPI-NH Abbey Pain Scale BI SMQ	NR
Chen, 2016[28] (26584896) Taiwan Training	PRT: Basic pain education + PRT	Basic pain education alone	Dementia special care unit RCT (Cluster) 37 NRs +195 PWDs	NR	NA	NA	N=195 Age: Yes Sex: Yes Race: No Education: Yes	None	N=37 Age: Yes Sex: No Race: No Education: No	Years of experience: Yes	4 months? (Unclear) 3-month follow up	Pain reduction:	Improving the pain management performance of RNs
Pieper 2016[29] Netherlands High ROB	STA OP! Stepwise multicomponent intervention for NH healthcare professionals Training on general nursing skills, dementia management and pain	Treatment as usual	Nursing home-based Cluster RCT 21 clusters in 12 nursing homes N=288 PWD	Nonspecified advanced dementia Reisberg Global Deterioration Scale 5-7	N=288 Age yes Sex: yes Race: no Education no	NR	NA	NA	NR	NR	3, 6 months	CMAI NPI-NH CSDD Minimum Dataset Depression in Dementia Psychotropic medication use	NR
Kovach, 2015[30] (26250849) USA Feasibility study	T3 Protocol	Usual care	Long term care facility RCT 78 PWD	NR	N=127 Age: Yes Sex: Yes Race: No Education: No	None	NA	NA	NA	NA	8 weeks	Feasibility, assessments, treatment changes, nurse time, and drug costs	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
McCabe, 2015[21] (25319535) Australia High RoB	The BPSD protocol training: (1) Training & support condition: Training in the use of a BPSD -structured clinical protocol, plus external clinical support (2)Support condition: a workshop on BPSD, plus external clinical support (3) Training condition: training in the use of the structured clinical protocol alone	Care as usual	Residential care facility RCT 475 (staff=261 + PWD=214)		N=187 Age: Yes Sex: Yes Race: No Education: No	None	NA	NA	N=204 Age: Yes Sex: No Race: No Education: no	Job position: Yes Service length: Yes Dementia training: Yes	3 months	CMAI	Staff stress: Carer stress scale General strain: SDCS Self-efficacy: Staff attitude toward PWD: (ADQ)
Zwijsen, 2015[31] (25458804) Netherlands High RoB	A new care programme for challenging behaviour: care staff was educated on how to detect and reflect on signs of challenging behavior, consisting of four steps; detection, analysis, treatment & evaluation	Control (Stepped wedged Cluster)	Dementia special care Unit RCT (Stepped wedge cluster) 380?	NA	NA	NA	NA	NA	N=380 Age: Yes Sex: No Race: No Education: no	Education: Yes Job position: Yes Service length: Yes Dementia training: Yes	4 months	NA	Burnout: MBI Job satisfaction & job demands: Stress: Saliva samples Comorbid burden:
Rapp, 2013[23] 23827658) German High ROB (Protocol in German)	Guideline-based intervention includes clinical assessments, nondrug interventions, medication review to reduce agitation	Usual care	Nursing homes Cluster RCT 18 nursing homes PWD	Dementia not specified	N=304 Age: Yes Sex: Yes Race: No Education: no Marital status: no	None	NA	NA	NR	NR	10 month	CMAI Number of neuroleptics	NR
Cohen-Mansfield, 2012[32] (23059151) US High ROB	TREA decision tree protocol to assess unmet needs for agitation	Usual care	Nursing homes Cluster RCT 11 nursing homes PWD	Dementia not specified	N=125 Age: Yes Sex: Yes Race: yes Education: yes Marital status: yes	None	NA	NA	NR	NR	2 weeks	ABMI LMBS	NR
Kovach, 2012[33] (22998656) USA High RoB	Serial Trial Intervention (STI): A decision support tool-9-Step STI	5-Step STI	Nursing home Quasi 125 PWD	Moderate to severe dementia	N=125 Age: Yes Sex: Yes Race: Yes Education: No	None	NA	NA	NA	NA	6 weeks	Discomfort & agitation	NA

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants** **Randomized N**	**PWD Dementia Characteristics**	**PWD Non-Disease Char** **PWD N** **PWD Age (mean)** **PWD Sex (% female)** **PWD Race (% majority)** **PWD Education (mean years)**	**PWD Non-Disease Char Reporting Status (RS)** **PWD SES** **PWD Prior Disability** **PWD Household Characteristics** **PWD Health Insurance** **PWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Montgomery, 2011[34] (21840840) US Pilot	TCARE protocol decision algorithm assists care managers create care plans	Usual care activities	Community RCT 266 caregivers	Dementia unspecified; caregivers with high burden such that considering nursing home placement	NR	NR	N=266 Age: Yes Sex: Yes Race: No Education: Yes Relationship: yes	Health status	NA	NA	9 months	NR	Modified Montgomery Borgatta Caregiver Burden Scale; CESD; Intention to place
Salva, 2011[26] (22159768) Spain High ROB	Health and nutrition promotion, includes nutritional counseling	Usual care activities	Community Cluster RCT 11 Medical centers dyad	Mild to moderate dementia	N=946 Age: Yes Sex: Yes Race: no Education: yes		N=946 Age: no Sex: no Race :No Education: no Relationship: yes	Duration Received payment	NA	NA	1 year	CDR NPI MMSE Eating behavior scale	Zarit burden
Verkaik, 2011[35] (21495077) Netherlands Training	Introduction of a nursing guideline: Nursing team introduced nursing guideline that entails increasing individualized pleasant activities and decreasing unpleasant events.	Usual care	Nursing home RCT 100 PWD	moderately severe dementia (All types)	N=195 Age: Yes Sex: Yes Race: No Education: Yes Marital status: Yes	None	NA	NA	NA	NA	11 months	Depession; CSDD (Dutch version Mood	NA
Cohen-Mansfield, 2007[36] (17702884) US Pilot	TREA decision tree protocol to assess unmet needs for agitation	Usual care	Nursing homes Quasi-experimental PWD	Dementia not specified	N=167 Age: Yes Sex: Yes Race: yes Education: yes Marital status: yes	None	NA	NA	NR	NR	10 days	ABMI LMBS	NR
Kovach, 2006[37] (16869334) USA High RoB	STI: an innovative clinical protocol for assessment & management of unmet needs in people with late-stage dementia.	Control: Standard care	Long term care facility RCT 127 PWD	Late stage dementia	N=114 Age: Yes Sex: Yes Race: No Education: Yes	None	NA	NA	NA	NA	8 weeks	Discomfort-DAT and BEHAVE-AD scales Daily Behavior symptoms, assessment & treatment: Daily logs	NA

Abbreviations: ABMI=Agitation behavior mapping instrument; ADL=Activities of Daily Living; ADQ=Approaches to Dementia Questionnaire; BASE=Behavior Analytics and Support Enhancement; BEHAVE-AD=Behavioral pathology in Alzheimer's disease; BI=Barthel Index; BPSD=Behavioral and psychological symptoms of dementia; CDR=Clinical Dementia Rating; CESD=Center for Epidemiological Studies–Depression scale; Discomfort-DAT= Discomfort-Dementia of the Alzheimer's Type; CG=Caregiver; char=characteristics; CGIC=Clinical Global Impressions of Change; CMAI=Cohen-Mansfield Agitation Inventory; CSDD=Cornell Scale for Depression in Dementia; Discomfort-DAT= Discomfort-Dementia of the Alzheimer's Type; DEMQOL=Dementia Quality of Life; EM=Evidence Map; EQ-VAS=European Quality of Life visual analog scale; EQ-5D-5L=European quality of life five dimensions questionnaire; FC=formal caregiver; IC=informal caregiver; LMBS=Lawtons modified behavior stream; MBI=Maslach Burnout Inventory; MARQUE=Managing Agitation and Raising Quality of Life; MBI=Maslach Burnout Inventory; MMSE=Mini-Mental Status Examination; N=number; NA=Not Applicable; NPI=Neuropsychiatric Inventory; NPI-NH=Neuropsychiatric Inventory Home Version; NPI-Q=Neuropsychiatric Inventory Questionnaire; NR=Not Reported; NPS=Neuropsychiatric symptoms; PMID=PubMed Identification Number; PRT=Pain Recognition and Treatment; PWD=Persons with Dementia; QUALID=Quality of Life late-stage dementia scale; QUALIDEM=Quality of Life dementia scale; RCT=Randomized Controlled Trial; RN=Registered Nurse; RoB=Risk of Bias; RS=Reporting Status; SCID=sense of Competence in Dementia; SDCS=Strains in Dementia Care Scale; SMQ=Short Memory Questionnaire; STA OP!=Dutch Serial Trial Intervention; STI=Serial Trial Intervention; STS=Staff Tactics Scale; T3=Track and Trigger Treatment; TCARE=Tailored Caregiver Assessment and Referral; TREA=Treatment Routes for Exploring Agitation; YOD=Young-onset Dementia

Advance Care Planning

Appendix Table F.19. Risk of bias assessment: advance care planning

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Brazil 2018[38] (28786323)	6 weeks	Medium 19.3%	Low	Low	High	Low	X	Government, Foundation	High
Mitchell 2018[39] (29868778) Cohen 2019[40] (30273717)	6 months 12 months	Low 12 months: 2%	Low	Low	Low	Medium	Low	Government	Medium
Hanson 2017[41] (27893884) Hanson 2016[42] (27271683)	3 months 6 months 9 months	Low 3 months: 1% 6 months: 8.2% Medium 9 months: 15.6&	Low	Low	3 months, 9 months: Low 6 months: High	High	X	Government	High
Reinhardt 2014[43] (24835382)	3 months 6 months	Medium 3 months: 12.7% 6 months: 18.1%	Medium	Low	High	Low	X	Foundation	High

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Appendix Table F.20. Characteristics of included studies: advance care planning

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Mitchell 2018[39] (29868778) US Medium Explanatory Cohen 2019[40] (30273717)	Advanced Care Planning 12-minute video for goal-oriented care (advanced care directives, care preferences, etc)	Usual care	Nursing home-based Cluster RCT 64 nursing homes 402 PWD	Nonspecified advanced dementia Primarily AD Global Deterioration Scale 7	N=402 Age 87 80% Female 87% White Education NR	None	N=402 Age 62 66% Female 87% White 99% High school diploma or more 63% Child 13% Spouse	None	NA	NA	6 months 12 months	Hospitalizations	Documented directives Goal of care discussions Comfort Care Preference Prevalence

*High risk of bias studies included in evidence map

Abbreviations: char=characteristics; FC=formal caregiver; IC=informal caregiver; N=number; PMID=PubMed Identification Number; PWD=Persons with Dementia; RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status

Appendix Table F.21. PWD outcomes summary low and medium risk of bias studies: advance care planning

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Mitchell 2018[39] (29868778) Decision Support Tool vs. Usual Care Medium Explanatory	Hospitalizations N (%) 12 months	NR	20 (9.5%)	21 (11.1%)	NR
Hanson 2011[44] (22091750) Decision Support Tool vs. Usual Care Medium Explanatory	Assisted Feeding Intervention-Specialized Dysphagia Diet (%) 3 months	NR	89%	76%	0.04

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number

Appendix Table F.22. Caregiver outcomes summary low and medium risk of bias studies: advance care planning

Study (PMID) Comparison Caregiver Type RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Mitchell 2018[39] (29868778) Decision Support Tool vs. Usual Care Medium Explanatory	Documented Do Not Hospitalize Directive N (%) 6 months, 12 months	Adjusted Odds Ratio (95% CI) 6 months: 1.08 (0.69, 1.69) 12: months: 1.07 (0.66, 1.72)	6 months: 133 (63.0%) 12 months: 144 (68.2%)	6 months: 119 (63.0%) 12 months: 126 (66.7%)	NR

Mitchell 2018[39] (29868778) Decision Support Tool vs. Usual Care Medium Explanatory	Goal of care discussions N (%) 6 months, 12 months	Adjusted Odds Ratio (95% CI) 6 months: 1.70 (0.94, 3.07) 12 months: 1.46 (0.86, 2.70)	6 months: 49 (23.2%) 12 months: 72 (34.1%)	6 months: 29 (15.3%) 12 months: 48 (25.4%)	NR
Mitchell 2018[39] (29868778) Decision Support Tool vs. Usual Care Medium Explanatory	Proxies Preferring Comfort Care N (%) 6 months, 12 months	Adjusted Odds Ratio (95% CI) 6 months: 1.28 (0.85, 1.94) 12 months: 0.72 (0.38, 1.38)	6 months: 153 (73.2%) 12 months: 159 (76.1%)	6 months: 140 (76.9%) 12 months: 151 (82.1%)	NR

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number

Appendix Table F.23. Summary of strength of evidence for PWD outcomes: advance care planning

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Decision Support Tool vs. Usual Care Hospitalizations	12 months	1 cluster RCT (n=402)	Similar rates of hospitalizations between intervention and control groups.	Moderate	Unclear	Direct	Imprecise	Insufficient

Abbreviations: n=Number; RCT=Randomized Controlled Trial

Appendix Table F.24. Summary of strength of evidence for caregiver outcomes: advance care planning

Comparison Caregiver Type Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Decision Support Tool vs. Usual Care Documented Do Not Hospitalize Directive	6 months 12 months	1 cluster RCT (n=402)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Decision Support Tool vs. Usual Care Goal of care discussions	6 months 12 months	1 cluster RCT (n=402)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Decision Support Tool vs. Usual Care Proxies Preferring Comfort Care	6 months 12 months	1 cluster RCT (n=402)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient

Abbreviations: n=Number; RCT=Randomized Controlled Trial

Evidence Map: Advance Care Planning

Appendix Table F.25. Characteristics of evidence map studies: advance care planning

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Goossens 2019[45] (31818522) Goossens 2019[46] Belgium High RoB	Knowledge-sharing on shared decision making and internal policies role-play exercises on advance care planning	Waitlist control	Nursing Home Cluster RCT 65 Nursing homes N=311 formal caregivers	None	None	NA	NA	NA	N=311 Age: yes Sex: yes Race: no Education: yes	Training: yes Education: yes Position: yes Length of Service: yes	NR	None	Training
Song, 2019[47] (31373868) US Small sample	Adapt SPIRIT (Sharing Patient's Illness Representation to Increase Trust) for PWD and surrogates; 60 psycho-education	In-person vs videoconference	Community Mixed-methods Dyad	Early stage dementia	N=23 Age: yes Sex: yes Race: yes Education: yes	None	N=23 Age: yes Sex: yes Race: yes Education: yes Relation to PWD: yes	Duration	NA	NA	3 days	Dyad congruence Patient decisional conflict scale	Surrogate decision-making confidence scale
Brazil 2018[38] (28786323) Northern Ireland High RoB	Advance care planning intervention (education, meetings documentation); 2 family meetings	Usual care	Nursing homes Cluster RCT 24 nursing homes 197 Informal caregivers	Dementia without capacity to complete ACP	N=197 Age: no Sex: no Race: no Education: no	None	N=197 Age: yes Sex: yes Race: no Education: no Relation to PWD: yes	None	NA	NA	6 weeks	None	Decisional Conflict Scale FPCS GHQ QOD-LTC

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Hanson 2017[41] (27893884) US High RoB Hanson 2016[42] (27271683)	Goals of care video decision aid and structured discussion with health care providers	Informational video	Nursing homes Cluster RCT 22 Nursing homes 302 PWD and informal caregivers	Severe to advanced dementia; GDS 5 to 7	N=302 Age: yes Sex: yes Race: yes Education no	None	N=302 Age: yes Sex: yes Race: yes Education: yes Relation to PWD: yes	None	NA	NA	3 months 9 months	None	Quality of Communication on Concordance of GOC ACP problem score SWC-EOLD SM-EOLD
Bonner, 2014[48] (24381040) US Pilot Study	Advance Care Treatment Plan (ACT-Plan); a group-based education intervention, with AA dementia caregivers.	Attention-control health promotion conditions.	Adult Daycare centers Non-RCT 68 caregivers	NA	NA	NA	N=32 Age: Yes Sex: Yes Race: No Education: No	Income: Yes Living with PWD: Yes	NA	NA	4 weeks	Feasibility:	Knowledge of dementia, CPR, MV & TF: Knowledge of dementia scale; Self-efficacy: the Confidence in Treatment Decisions Made questionnaire
Einterz, 2014[49] (24508326) US Pilot study	GOC decision aid video viewed by the SDM and structured care plan meeting between the SDM and interdisciplinary NH team.	Usual care	Nursing home RCT 18 Dyads	All types of dementia with moderate to severe (GDS)	N=18 Age: yes Sex: yes Race: yes Education: no	None	N=18 Age: yes Sex: yes Race: yes Education: yes Relationship with PWD: yes	None	NA	NA	3 months	None	Quality of communication and decision-making
Reinhardt 2014[43] (24835382) US High RoB	Structured conversations about end of life care with palliative care team	Social contact via telephone	Skilled nursing facility 110 informal caregivers	Advance dementia, CPS score of 4 to 6	N=110 Age: yes Sex: yes Race: yes Education: no	None	N=101 Age: yes Sex: yes Race: yes Education: yes Relationship with PWD: yes	Employment status: yes	NA	NA	3 months 6 months	None	Satisfaction of care at end-of-life in dementia scale PHQ-9 Satisfaction with Life Scale
Sampson, 2011[50] (21228087) UK Pilot	A palliative care and advance care plan (ACP) intervention	Usual care	Hospital RCT 32 dyads	Severe dementia	N=32 Age: yes Sex: yes Race: yes Education: no	None	N=32 Age: yes Sex: yes Race: yes Education: no Relationship: yes	None	NA	NA	6 weeks 6 months	Number of caregivers making an ACP: Feasibility: Pain: Visual analogue scale distress: KD10 DSI: DCS; STAXI; LSQ	distress: KD10 DSI: DCS; STAXI; LSQ

Abbreviations: char=characteristics; EM=Evidence Map; FC=formal caregiver; IC=informal caregiver; N=number; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; PWD=Persons with Dementia; RS=Reporting Status; SES=socioeconomic status

Palliative Care

Appendix Table F.26. Risk of bias assessment: palliative

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Verrault , 2018[51] (28731379)	1 year	Medium (response rates for caregivers) 57% control, 73% intervention	Medium	Medium	High	Low	X	Government	High
Boogaard, 2018[52] (29343173)	10 months	Medium 11% nursing homes dropped	Medium	X	X	X	High	Gov't	High
Agar, 2017[53] (28786995)		Cluster RCT	Medium 64% decline rate	X	X	X	High (could not measure as planned)		High
Ahronheim, 2000[54] (15859668)	Over 3 years	Low 0%	Medium	Low	Medium	Low	High		High

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: PMID=PubMed Identification Number

Evidence Map: Palliative Care

Appendix Table F.27. Characteristics of evidence map studies: palliative care

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Hanson, 2019[55] (30342242) USA Pilot	Triggered Palliative Care: Received denetia-specific specialty palliative care consultation plus postacute transitional care.	Control: Received usual care and educational information	Hospital RCT 62 dyads	Late-stage (5-7) dementia	N=62 Age: Yes Sex: Yes Race: Yes Education: No	None	N=62 Age: yes Sex: Yes Race: No Education: no Relation: yes	None	NA	NA	60 days	60-day hospital or emergency department visits Patients comfort, family distress etc.	NR
Boogaard, 2018[52] (29343173) Netherlands High ROB	Generic or personal feedback to staff from PWD about end of life care	No feedback	Nursing homes Cluster RCT 18 nursing homes	Late stage dementia	N=668 Age: Yes Sex: Yes Race: no Education: No	None (length of stay)	N=193 Age: yes Sex: Yes Race: No Education: yes Relation: yes	None	NA	NA	10 months	NR	End-of Life in Dementia scales
Verrault, 2018[51] (28731379) Canada High ROB	End of Life care: training for physicians and staff; pain monitoring; regular mouth care; family communication; nurse facilitator	Usual care activities	Long-term care facilities Quasi-experimental 193 dyads	Late stage dementia	N=193 Age: Yes Sex: Yes Race: no Education: No	None (length of stay) (duration of terminal phase)	N=193 Age: no Sex: Yes Race: No Education: no Relation: yes	None	NA	NA	1 year	NR	Family perception of care scale; Symptom management for EoL in dementia Comfort assessment in dying scale
Agar, 2017[53] (28786995) Australia High ROB	Facilitated family case conference for end of life care, registered nurse	Usual care activities	Nursing homes Cluster RCT 20 nursing homes	Late stage dementia	N=131 Age: Yes Sex: Yes Race: no Education: No	None (length of stay) (time to death) (visitor frequency)	None	None	NA	NA	4-6 weeks post-death	Nurse-rated QUALID	Family-rated End of Life Care scales
Ahronheim, 2000[54] (15859668) US High ROB	Palliative care team recommendations	Usual care activities	Hospital	Late stage dementia	N=99 Age: Yes Sex: Yes Race: yes Education: no	None (length of stay)	None	None	NA	NA	Time until death	Number of medical interventions, procedures, and readmissions	NR

Abbreviations: char=characteristics; EM=Evidence Map; FC=formal caregiver; IC=informal caregiver; N=number; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; PWD=Persons with Dementia; QUALID=Quality of Life in Late-stage Dementia; RS=Reporting Status; SES=socioeconomic status

Other Service Provision Interventions

Appendix Table F.28. Risk of bias assessment: other service provision interventions

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Horvath 2013[56] (24195007)		Medium 15%	Low	Medium	High	Low	High		High
Hanson 2011[44] (22091750) Hanson 2010[57] (20729251) Snyder 2013[58] (23273855)	3 months 9 months	Low 3 months: 1% High 9 months:	Low	Medium	Low	Low	Medium	Government	Medium

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: PMID=PubMed Identification Number

Appendix Table F.29. Characteristics of included studies: other service provision interventions

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Hanson 2011[44] (22091750) US Medium Explanatory Hanson 2010[57] (20729251) Snyder 2013 [58](23273855)	Decision aid about dementia, feeding options (feeding tubes, assisted oral feeding); print format reviewed for ~20 minutes	Usual care	Nursing homes Cluster RCT 24 Nursing homes 256 PWD-surrogate dyads	Advanced dementia with feeding problems; score of 5 to 6 on Cognitive Performance Scale in the MDS and severity stage 6 to 7 on GDS	N=256 85 years 78% Female 70% White Education NR	Detailed Race Information: yes	N=256 59 years 63% Female 70% White Education NR 45% Daughter	None	NA	NA	3 months	Assisted Feeding Intervention, Specialized dysphagia diet	Decisional Conflict Scale Frequency of Discussion about Feeding Satisfaction with Decision Scale Decisional Regret Index

*High risk of bias studies included in evidence map

Abbreviations: char=characteristics; FC=formal caregiver; IC=informal caregiver; N=number; PMID=PubMed Identification Number; PWD=Persons with Dementia; RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status

Appendix Table F.30. PWD outcomes summary low and medium risk of bias studies: Other service provision interventions

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Hanson 2011[44] (22091750) Decision Support Tool vs. Usual Care Medium Explanatory	Assisted Feeding Intervention-Specialized Dysphagia Diet (%) 3 months	NR	89%	76%	0.04

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: NR=Not Reported; PMID=PubMed Identification Number; RoB=Risk of Bias

Appendix Table F.31. Caregiver outcomes summary low and medium risk of bias studies: other service provision interventions

Study (PMID) Comparison Caregiver Type RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Hanson 2011[44] (22091750) Decision Support Tool vs. Usual Care Medium Explanatory	Decisional Conflict Scale, Overall Mean Mean Change from Baseline 3 months	NR	1.65 -0.60	1.97 -0.13	<0.001
Hanson 2011[44] (22091750) Decision Support Tool vs. Usual Care Medium Explanatory	Satisfaction with Decision Scale Mean 3 months	NR	1.61	1.66	0.5
Hanson 2011[44] (22091750) Decision Support Tool vs. Usual Care Medium Explanatory	Decisional Regret Index Mean 3 months	NR	11.9	14.3	0.14

Hanson 2011[44] (22091750) Decision Support Tool vs. Usual Care Medium Explanatory	Feeding Discussions, With Physician, NP, or PA Feeding Discussions, Other Nursing Home Staff % 3 months	NR	45% Other staff: 64%	33% Other staff: 71%	0.04 Other staff: 0.42

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number

Appendix Table F.32. Summary of strength of evidence for PWD outcomes: other service provision interventions

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Decision Support Tool vs. Usual Care Assisted Feeding Intervention-Specialized Dysphagia Diet	3 months	1 cluster RCT (n=256)	At 3 months, more PWD in intervention group had a specialized dysphagia diet.	Moderate	Unclear	Direct	Imprecise	Insufficient

Abbreviations: N=Number, RCT=Randomized Controlled Trial

Appendix Table F.33. Summary of strength of evidence for caregiver outcomes: other service provision interventions

Comparison Caregiver Type Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Decision Support Tool vs. Usual Care Decisional conflict	3 months	1 cluster RCT (n=256)	At 3 months, intervention group had less decisional conflict than control group.	Moderate	Unclear	Direct	Imprecise	Insufficient
Decision Support Tool vs. Usual Care Satisfaction with Decisions	3 months	1 cluster RCT (n=256)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Decision Support Tool vs. Usual Care Decisional Regret	3 months	1 cluster RCT (n=256)	No difference between groups.	Moderate	Unclear	Direct	Imprecise	Insufficient
Decision Support Tool vs. Usual Care Feeding Discussions	3 months	1 cluster RCT (n=256)	At 3 months, more feeding discussions with doctor, PA, or NP in intervention group versus control. No difference between groups in feeding discussions with other nursing home staff.	Moderate	Unclear	Direct	Imprecise	Insufficient

Abbreviations: n=number; RCT=Randomized Controlled Trial

Evidence Map: Other Service Provision Interventions

Appendix Table F.34. Characteristics of evidence map studies: other service provision interventions

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Laver 2020[59] 32234275 Australia Pilot	Telehealth	Usual care	N=63	Diagnosed dementia or probable dementia or MMSE< 24/30	N-63 Age: yes Ses: yes	Age: yes Sex: yes' Household characteristics: yes	NA	Age: yes Sex: yes' Household characteristics: yes	NA	NA	16 weeks		CMI PCS CAPU
Villar 2019[60] (29149789) Spain Pilot	Including PLWD with dementia in care planning meetings	Usual care	Nursing homes Cluster RCT Clusters=4 N=52	PLWD living in a residential facility for at least six months, diagnosed with moderate-to-severe dementia	N=52 Age: yes Sex: yes	NR	NA	NA	NR	NR	20-30 minutes	the GDS and GENCAT	NR

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Williams 2019[61] (31660443) US Pilot	FamTechCare video recording support	Telephone support/ attention control	Community-based RCT	Patients diagnosed with dementia Living at home Exclusion criteria	N=39 Intervention group with 42 caregivers 32 Control group with 41 caregivers Age: Y Sex: Y Education: Y Race % majority: Y	N caregivers: Y Ethnicity: Y	Age: Y Sex: Y Race % majority: Y Education: Y Relation to PWD: Y	Ethnicity: Y Marital status: Y Care provided: Y	NR	NR	3 months	NR	Burden Depression Sleep disturbance Competence Desire to institutionalize PWD Reaction to behavioral symptoms
Horvath 2013[56] (24195007) US High ROB	Self-directed educational program for caregiver competence and patient safety; home-based safety tool kit	Customary care	Community-based Recruited from 2 care centers Block randomization RCT	Patients diagnosed with progressive AD PWD reads and speaks English MMSE <=24 Primary informal caregiver at least 4 hours per day Exclusion criteria	N=60 Experimental group with 60 caregivers 48 control group with 48 caregivers Age: Y Sex: Y Education: N Race % majority: Y	NR	Age: Y Sex: Y Race % majority Education: N Relation to PWD: Y	NR	NR	Training: Y	12 weeks	Home safety evaluation Risky behaviors and accidents	Self-efficacy Strain

Abbreviations: AD=Alzheimer's disease; char=characteristics; MMSE=Mini Mental State Examination; N=Number; NR=Not Reported; PMID=PubMed Identification Number; PWD=Person with dementia; RCT=Randomized Controlled Trials; RoB=Risk of Bias; RS=Reporting Status

Collaborative/Coordinated Care Models

Appendix Table F.35. Risk of bias assessment: multidisciplinary integrated team collaborative care

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Halek 2020[62] (32062052)	15 days/unclear	Medium 24%	Low	Low	High	Low	Low	Foundation	High
Possin, 2019[63] 31566651	12 month	Not high	Not high	X	X	X	Not high	Gov't	Move to PRECIS-2
Laporte Uribe 2017[64] (28249632)	12 months	X	High	X	X	X	X	X	High
Thyrian, 2017[65] 28746708	12 months	Medium 21%	Medium (selection concern at GP level)	X	X	X	Medium	Gov't	Move to PRECIS-2
Chodosh, 2015[66] 25656074	6, 12 month	Medium 36% 6 month	Low	Low	Medium	Low	Low	Gov't	Medium (12 month High)
Leontjevas, 2014[67] 23643110	4 months	Low (stepped wedge)	Low	High	Medium	Low	High (43% adherence to treatment)	Gov't	High (for pragmatic) High (for traditional)
Bass, 2013[68] 23869899	6 months	Medium 18% (12 month almost 40%)	Medium	X	X	X	Low	Gov't	Move to PRECIS-2
Chapman, 2007[69] 8537594	8 weeks	Low 2%	Medium	High	Medium	Low	Medium	Gov't	High
Callahan, 2006[70] 16684985	12 month	Medium 18%	Low	Low	Medium	Low	Medium	Gov't	Medium (18 month High ROB)
Vickrey, 2006[71] 17116916	22 months (mean)	Not high	Not high	X	X	X	Not high	Gov't	Move to PRECIS-2
Surr, 2019[72] 31056923	16 months	OK	OK	X	X	X	High (26%)		High ROB for Pragmatic
Ballard, 2018[73] 29408901	9 months	Medium	Low	Medium	Medium	Low	Medium	Gov't	Medium
Lichtwarck, 2018[74]	12 weeks	Medium 12%	Low	Low	Med	Low	Low	Gov't	Medium
Dichter, 2015[75] 26138674		Rolling enrollment	Medium	X	X	X	Medium	Gov't	High
Chenoweth, 2014[76] 24666667	8 months	High 31%	X	X	X	X	X	Gov't	High
van de Ven, 2013[77]	8 months	Rolling stable	Low	X	X	X	Medium	Gov't	Move to PRECIS-2
Rokstad, 2013[78] 24022375		Medium 25%	Low	X	X	X	High	Gov't	High
Chenoweth, 2009[79] 19282246	8 months	Low 18%	Low	Low	High	Low	High	Gov't	Medium

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Eloniemi-Sulkava, 2009[80] (20121986)	1.6 years	Low 0% (use of census data)	Low	Low	Medium	Low	Medium	Gov't	Low
Fossey, 2006[81] 16543297	12 months	Unclear/High	Low	Medium	Medium	Low	High	Gov't	High
Rovner, 1996[82] 8537594	6 months	Low 9%	Low	Medium	High	Low	High	Gov't	Medium

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: NR=Not Reported; PMID=PubMed Identification Number

Appendix Table F.36. Characteristics of included studies: collaborative/coordinated care models

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years) IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Possin, 2019[63] 31566651 [add others} US Medium Pragmatic	Collaborative Care Care team navigator; multidisciplinary team Dyad Telephone/ Internet See Appendix Table F.37	Usual care plus contact information for resources, quarterly newsletters	California, Nebraska, and Iowa participating health systems RCT 780 community-based dyads	Diagnosis by treating physician, over age 45 50% Mild, 28% moderate, 22% advanced	N=780; 512 intervention, 268 control Age: 78 (mean) % Female: 56% Race: 80% white Education: 60% post-secondary	SES Dementia Severity Comorbidity	IC N=780; 512 intervention, 268 control IC Age: 65 (mean) IC: 62% Female IC Race: 80% white IC Education:60% post-secondary IC Relation to PWD: 55% Spouse	Language Living with PWD Health status	NA	NA	6, 12 months	QoL-AD Utilization rates	IC: ZBI PHQ-9 Self-efficacy
Thyrian, 2017[65] 28746708 24152974[83] 24811145[84] 24225205[85] 27534949[86] 22575023[87 2012 2012] 29156941[88] 31409541[89] Germany Pragmatic	Collaborative care/care coordination model; Nurse care coordinators Dyad In-home See Appendix Table F.37	Usual care activities	Community-based Cluster RCT 136 General practitioners PWD	Dementia aged 70+; DemTect instrument for dementia screening in Germany	N=516; 348 intervention, 168 control Age: 80 (mean) % Female: 61% Race: NR Education: NR	Household characteristics	N= IC Age: NR IC: NR IC Race: NR IC Education: NR IC Relation to PWD: 55% Spouse	NR	NA	NA	6 months	QoL-AD NPI ADL Health care resource utilization	Berlin Inventory Caregiver Burden
Chodosh, 2015[66] 25656074 (related to ACCESS[71]) US Medium Balanced	Coordinated care program; guideline-based Social work care managers Dyad In-person plus telephone See Appendix Table F.37	Coordinated care program by telephone contact	Urban underserved community RCT 151 community-based dyads	Dementia Diagnosis by system records, physician, or caregiver-confirmed Dementia severity 11 (0-17 Blessed Roth scale)	N=151; 73 intervention, 71 control Age: 73 (mean) % Female: 63% Race: 74% Hispanic/Latino Education: 69% less than high school	None	IC N=151; 73 intervention, 71 control IC Age: 49 (mean) IC Sex: 65% Female IC Race: 78% Hispanic/Latino IC Education: 36% less than high school IC Relation to PWD: 54% child	Acculturation scale Living with PWD	NA	NA	6, 12 months	HUI Utilization rates	IC: ZBI RMBPC
Bass, 2013[68] 23869899 25666216[90] 29854922{ US Medium Pragmatic	Care coordination with Partners in Care coaching model Care coordinators Caregivers Telephone, email, mail See Appendix Table F.37	Usual care activities	Veterans health system Matched system-level pairs randomized	At least one dementia diagnosis in VA medical records receiving primary care, aged 50+	N=508	NA	IC N=486; 299 intervention, 187 control IC Age: 69 (mean) IC Sex: NR IC Race: NR IC Education: NR IC Relation to PWD: 73% spouse	Duration Employment	NA	NA	6, 12 months	None	IC: Unmet needs Role captivity Physical health strain CESD Caregiver support service use Number informal helpers

Study (PMID) **Country** **RoB*** **Type**	**Intervention** **Intervention Focus** **Theoretical Model** **Delivery Person** **Intervention Target** **Recipient** **Mode** **Components** **Frequency** **Duration**	**Comparison** **Target** **Mode** **Components** **Frequency** **Duration**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PWD Dementia Characteristics** **Dementia Types** **Dementia Severity** **Diagnostic Criteria** **Age of Diagnosis**	**PWD Non-Disease Char** **PWD N** **PWD Age (mean)** **PWD Sex (% female)** **PWD Race (% majority)** **PWD Education (mean years)**	**PWD Non-Disease Char Reporting Status (RS)** **PWD SES** **PWD Prior Disability** **PWD Household Characteristics** **PWD Health Insurance** **PWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years)** **IC Relation to PWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Vickrey, 2006[71] 17116916 ACCESS 19670955[91] 22435836[92] 23320655[93] US Medium Pragmatic	Coordinated care program; guideline-based Social work care managers Dyad Telephone See Appendix Table F.37	Usual care	Urban California Cluster RCT 18 primary care clinics 408 community-based dyads	Dementia over age 65 receiving Medicare; 76% AD Administrative database codes Dementia severity 5.7 intervention, 6.3 control (0-17 Blessed Roth scale)	N=408; 238 intervention, 170 control Age: 80 (mean) % Female: 55% Race: 86% White Education: 81% at least high school	Health Insurance Comorbidity	IC N=408; 238 intervention, 170 control IC Age: 65 (mean) IC Sex: 69% Female IC Race: 87% White IC Education: 94% at least high school IC Relation to PWD: 55% spouse	Duration Living with PWD Comorbidity	NA	NA	22 months (mean follow-up)	Adherence to 23 dementia guidelines recommendations HUI	Caregiver knowledge, mastery, confidence EuroQoL-5D
Callahan, 2006[70] 16684985 US Medium Explanatory	Collaborative care program; integrated in primary care Geriatric nurse practitioner care manager Dyad In-person See Appendix Table F.37	Augmented usual care; physician could pursue any evaluation or treatment deemed appropriate	Urban University-affiliated care systems Cluster RCT 74 primary care physicians 153 community-based dyads	Possible or probably Alzheimer disease; Diagnostic and Statistical Manual of Mental Disorders, 3rd edition	N=153; 84 intervention, 69 control Age: 77 (mean) % Female: 43% Race: 49% Black Education: 8-9 years (mean)	Medicaid SES Chronic disease score	IC N=153; 84 intervention, 69 control IC Age: 61 (mean) IC Sex: 89% Female IC Race: NR IC Education: NR IC Relation to PWD: 44% spouse/36% child	Live with patient	NA	NA	6, 12, 18 months	NPI ADL CSDD (proxy) Health care resource use MMSE	IC: PHQ-9
Lichtwarck, 2018[74] 23992241[94] Process eval[95] Norway Medium Explanatory	TIME Person centered care and CBT Team Staff training PWD assessment and tailored plan	Brief education only, usual care activities	Nursing homes Cluster RCT 33 nursing homes PWD	Probably dementia, 27% moderate, 69% severe CDR 1 or higher; moderate degree of agitation	N=229; 125 intervention, 104 control Age: 83 (mean) % Female: 70% Race: NR Education: NR	None	NA	NA	NA	NA	8, 12 weeks	NPI CMAI CSDD QoL in late stage dementia scale	NR
Ballard, 2018[73] 29408901 Sustainability[96] Cost effectiveness[97] UK Medium Balanced	WHELD programme person-centered care and social interaction Team PWD Training and delivery of WHELD	Usual care activities	Nursing homes Cluster RCT 69 nursing homes PWD	Probably dementia, 9% moderate, 60% moderately severe, 21% severe CDR 1 or higher; moderate degree of agitation	N=847; 404 intervention, 443 control Age: 88 (mean) % Female: 69% Race: NR Education: NR	None	NA	NA	NR	NR	9 months	DEMQOL (proxy CMAI NPI Serious adverse events Cost differences	NR
van de Ven, 2013[77] 23844003 Netherlands Medium Pragmatic	Dementia care mapping, training staff to be certified dementia-care mappers, care action planning	Usual care activities	Nursing homes Cluster RCT 14 care homes PWD	Dementia, Diagnostic and Statistical Manual of mental disorders – IV criteria	N=268; 102 dementia care mapping, 166 control Age: 84 (mean) % Female: 74% Race: 97% born in Netherlands Education: NR	None	NA	NA	NA	NA	8 months	CMAI NPI QUALID EuroQoL 5D	GHQ-12
Chenoweth, 2009[79] 19282246 (104505176)[98] (22078076)[99] Australia Medium Balanced	I1: person-centered care individualized care program; I2: dementia care mapping	Usual care activities	Nursing homes Cluster RCT 15 care sites PWD	Medical diagnosis of dementia, unspecified	N=289; 109 dementia care mapping, 98 person-centered care, 82 control Age: 84 (mean) % Female: 77% Race: 69% English speakers Education: NR	Resident classification	NA	NA	NA	NA	8 months	CMAI QUALID NPI	NR

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years) IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Eloniemi-Sulkava, 2009[80] (20121986) Finland Medium Explanatory	Care coordination; coordinator embedded in multidisciplinary team, includes speer support groups, psychoeducation In-person	Usual care	Community-based RCT Dyads	Community-dwelling PWD; 87% AD, predominately mild to moderate severity	N=125; 63 intervention, 62 control Age: 78 (mean) % Female: 77% Race: NR Education: NR	None	N=125; 63 intervention, 62 control Age: 75 (mean) % Female: 72% Race: NR Education: 28% less than 8 years	None	NA	NA	20 to 24 months (phased recruitment)	Time to institutionalization Use of services Service expense	NA
Rovner, 1996[82] 8537594 US Medium Explanatory	Collaborative dementia care program Unclear delivery person PWD In-person See Appendix Table F.37	Usual care	Urban Nursing Home RCT 89 PWD	Degenerative or multi-infarct dementia with behavior disorder Diagnostic and Statistical Manual of Mental Disorders, 3rd edition	N=81; 42 intervention, 39 control Age: 81 (mean) % Female: 77% Race: 83% White Education: NR	None	NA	NA	NA	NA	6 months	No useable outcomes	NA

*High risk of bias studies included in evidence map

Abbreviations: AD=Alzheimer's disease; ADL=Activities of Daily Living; CBT=Cognitive Behavior Therapy; CDR=Clinical Dementia Rating; CESD=Center for Epidemiologic Studies Depression Scale; char=characteristics; CMAI=Cohen-Mansfield Agitation Inventory; CSDD=Cornell Scale of Depression in Dementia; char=Characteristics; DEMQOL=Dementia Quality of Life; CG= Caregiver Quality of Life; char=characteristics; CMAI= Cohen Mansfield Agitation Inventory; EUROQOL-5D=European Quality of Life-5 Dimensions; FC=formal caregiver; HUI=Health utilities index; IC=informal caregiver; N=number; NA=Not Applicable; NPI=Neuropsychiatric Inventory; NR=Not Reported; PHQ-9=Patient health questionnaire-9 items; PMID=PubMed Identification Number; PWD=Persons with Dementia; QoL=Quality of life; QUALID=Quality of life in late-stage dementia; RCT=Randomized Controlled Trials; RMBPC=Revised memory and behavior problem checklist; RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status; TIME=Targeted interdisciplinary model for evaluation; WHELD=Well-being and Health for People with Dementia; ZBI=Zarit burden inventory

Appendix Table F.37. Intervention details for multidisciplinary integrated team collaborative care

Study (PMID	Team	Contact Frequency	Delivery	Caregiver Elements	PWD elements	Co-location	Other supports
Possin, 2019[63] 31566651 HCB Care Ecosystem	Care team navigator (unlicensed; some bilingual Spanish, Cantonese) APN, SW, pharmacist; nurse-supervisor	Monthly by phone; email mail also; CG-initiated for problems	Telephone/ internet, some in-person	Screen for problems, Standardized education; personalized support, manualized; ACP	Medication review, monitor health status	Yes	None
Thyrian, 2017[65] 28746708	Nursing care coordinator embedded in German health systems; general physician and social service professionals; initial weekly meeting with nursing scientist, neurologist/ psychiatrist, psychologist, pharmacist for initial assessment	Monthly 1 hour home visits	In-home	Included in PWD contacts, if the PWD had an informal caregiver	Initial assessment, intervention task list	Unclear	Intervention management software system
Chodosh, 2015[66] 25656074 HCB ACCESS	Bilingual social work care managers from health system; in-person included care manager from local Association; In-person included care manager from local Association; Both used local resources from participating organizations	Minimum 7 contacts, average 31 contacts in telephone arm, 22 in in-person arm	In-person vs telephone/ internet	Protocolized problem assessment, self-management counseling, education, referrals and follow-up	Unclear	Unclear. Care manger within County health services with primary care clinics	Help cover cost of phone minutes for informal caregivers; Steering committee for cross-organization collaboration
Bass, 2013[68] 23869899 VA Based on Partners in Dementia Care	Care coordinators, embedded in VA system	Minimum 1 contact per month	Telephone/ internet, mail	Protocolized initial assessment, action plan, ongoing monitoring and reassessment	None noted	Yes	Software system
Vickrey, 2006[71] 17116916 HCB ACCESS	Social work care managers from 3 health care organizations, 3 local community agencies could also have care managers; supervisor unclear	Frequency based on as-needed; 6 month reassessments	Telephone	Protocolized problem assessment, self-management counseling, education, referrals and follow-up	Primary care provider training	Unclear	Software systems linked; Steering committee for cross-organization collaboration
Callahan, 2006[70] 16684985 HCB	Geriatric nurse practitioner care manager, Primary care physician; geriatrician, geriatric psychiatrist, psychologist	Bi-weekly initially, then monthly, up to 12 months	In-person	Manualized psychoeducation, coping skills, group sessions, legal/financial advice, exercise guidelines, printed caregiver guide,	Medication, problem assessments, non-drug behavioral interventions; PWD group exercise sessions	Unclear	Software tracking system
Rovner, 1996[82] 8537594 NH	Unclear; day program created within nursing home; Psychiatrist, Creative arts therapist, nursing aides	Daily	In-person	None	Activity program, medication management, team consulting	Unclear	None

Abbreviations: ACP= advance care practice; APN=Advanced practice nurse; CG= caregiver; HCB= Home and community-based; NH= Nursing Home; PMID=PubMed Identification Number; PWD= Person With Dementia; SW= Social Worker; VA= Veterans Affairs

Appendix Table F.38. Modified PRECIS-2: multidisciplinary integrated team collaborative care

Study (PMID)	Eligibility Criteria	Recruit-ment Path	Setting	Intervention Organization	Flexibility of Delivery of Intervention	Flexibility of Adherence to Intervention	Followup	Primary Outcome	Analysis	Overall Category Applicability and/or Qualifiers
Possin, 2019[63] 31566651	Mostly Explanatory	Mostly Explanatory	Pragmatic	Pragmatic	Mostly Pragmatic	Mostly Pragmatic	Pragmatic to disease management	Mostly Pragmatic	Mostly Pragmatic	Pragmatic
Thyrian, 2017[65] 28746708	Mostly Pragmatic	Balanced	Pragmatic	Mostly Pragmatic	Mostly Pragmatic	Mostly Pragmatic	Mostly Pragmatic	Mostly Pragmatic	Some reporting issues	Pragmatic
Chodosh, 2015[66] 25656074	Balanced	Mostly Explanatory	Pragmatic	Balanced	Mostly Pragmatic	Mostly Pragmatic	Pragmatic to disease management	Mostly Pragmatic	Balanced	Balanced
Bass, 2013[68] 23869899	Pragmatic	Unclear	Pragmatic	Balanced	Unclear	Unclear	Pragmatic	Mostly Pragmatic	Some reporting issues	Pragmatic
Vickrey, 2006[71] 17116916	Pragmatic	Mostly Pragmatic	Pragmatic	Pragmatic	Mostly Pragmatic	Mostly Pragmatic	Pragmatic to disease management	Mostly Pragmatic	Mostly Pragmatic	Pragmatic
New PCC Section										
van de Ven, 2013[77]	Pragmatic	Mostly Pragmatic	Pragmatic	Pragmatic	Mostly Pragmatic	Mostly Pragmatic	Pragmatic	Mostly Pragmatic	Some reporting issues	Pragmatic
Chenoweth, 2009[79] 19282246	X	X	Pragmatic	Mostly Explanatory	X	X	X	Mostly Explanatory	X	Explanatory

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: NA=Not Assessed; PMID=PubMed Identification Number

Appendix Table F.39. PWD outcomes summary low and medium risk of bias studies: multidisciplinary integrated team collaborative care

Study (PMID) Comparison RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Possin, 2019[63] 31566651 Medium Pragmatic	Unstandardized Beta (CI) QoL-AD (proxy) (13-52; higher is better) 12 months	Favors intervention; 0.53 (0.25 to 1.30)	NA	NA	0.04
Possin, 2019[63] 31566651 Medium Pragmatic	Unstandardized Beta (CI) ED visits (lower is better) 12 months	Favors intervention; -0.14 (-0.29 to -0.01) NNT for single ED visit = 5 Prevented 120 visits (predicted based on based on usual care data)	NA	NA	0.04
Possin, 2019[63] 31566651 Medium Pragmatic	Unstandardized Beta (CI) Hospitalization (lower is better) 12 months	No statistical difference; -0.03 (-0.18 to 0.12) Prevented 13 visits (predicted based on based on usual care data)	NA	NA	0.71
Possin, 2019[63] 31566651 Medium Pragmatic	Unstandardized Beta (CI) Ambulance use (lower is better) 12 months	No statistical difference; -0.10 (-0.23 to 0.03) Prevented 16 uses (predicted based on based on usual care data)	NA	NA	0.12
Possin, 2019[63] 31566651 Medium Pragmatic	Mean cost estimates Based on national estimates 12 months	$600 per PWD across ED, ambulance, and hospitalization, over latter 6 months.	NA	NA	NA
Thyrian, 2017[65] 28746708	Adjusted mean difference (CI) QoL-AD (13-52; higher is better) 12 months	No statistical difference 0.02 (-0.09 o 0.05) Effect size 0.07	NA	NA	0.26
Thyrian, 2017[65] 28746708	Adjusted mean difference (CI) NPI 12 months	High risk of bias for missing data 36% of completers	NA	NA	NA
Thyrian, 2017[65] 28746708	Daily living activities	No statistical difference, no data reported	NA	NA	NA
Thyrian, 2017[65] 28746708	Institutionalization	No statistical difference, no data reported	NA	NA	NA
Chodosh, 2015[66] 25656074 Medium Balanced	Adjusted mean difference (CI) HUI (proxy) (lower is better) 6 month Grouped with QoL	No statistical difference; -0.064 (0.14 to 0.03)	NA	NA	0.19
Chodosh, 2015[66] 25656074 Medium Balanced	19 quality indicators	All 19 indicators improved in both arms; Comparable proportional increases in quality indicators for program, ACCESS (original protocol study) vs this study (Table 6, original publication)	NA	NA	NA
Eloniemi-Sulkava, 2009[80] (20121986) Medium Balanced	Time to nursing home placement	Favors intervention at 1.6 years, but no longer statistically significant at 2 years; Hazard ration 0.53 CI (0.23 to 1.19)	1.6 years 25.8%	1.6 years 11.1%	0.03
Vickrey, 2006[71] 17116916 Medium Pragmatic	23 quality indicators	All but 2 showed significant improvement.	NA	NA	≤0.013
Vickrey, 2006[71] 17116916	Adjusted mean difference (CI) HUI	Favors intervention; 0.06 (0.005 to 0.11) (MID 0.03	NA	NA	0.034

Medium Pragmatic	18 month Grouped with QoL				
Callahan, 2006[70] 16684985 Medium Explanatory	Adjusted mean difference (CI) NPI (lower is better) 12 months	Favors intervention -5.6 (-9.9 to -1.3)	8.0 (12.0)	16.1 (19.4)	0.01
Callahan, 2006[70] 16684985 Medium Explanatory	Adjusted mean difference (CI) CSDD (lower is better) 12 months	No statistical significance -1.0 (-2.6 to 1.5)	3.5 (3.9)	5.8 (5.9)	0.65
Callahan, 2006[70] 16684985 Medium Explanatory	Adjusted mean difference (CI) ADL (Higher is better) 12 months	No statistical significance 1.4 (-2.3 to 5.1)	48.6 (17.7)	44.6 (17.0)	0.44
Callahan, 2006[70] 16684985 Medium Explanatory	Nursing home placement 12 months	No statistical significance	6%	1.5%	0.22
Lichtwarck, 2018[74]	Standardized mean difference NPI-NH-10 12 weeks	Favors intervention 0.25	31.1 (26.7 to 35.6)	41.4 (37.3 to 45.5)	0.053
Lichtwarck, 2018[74]	Standardized mean difference CMAI 12 weeks	Favors intervention 0.29	59.4 (55.2 to 63.6)	67.1 (63.3 to 70.9)	0.006
Lichtwarck, 2018[74]	Standardized mean difference CSDD 12 weeks	Favors intervention 0.26	10.2 (8.7 to 11.7)	12.4 (10.9 to 13.8)	0.010
Lichtwarck, 2018[74]	Standardized mean difference QUALID 12 weeks	Favors intervention 0.17	27.2 (25.3 to 29.1)	29.6 (27.8 to 31.5)	0.044
Ballard, 2018[73] 29408901	Mean difference (CI) DEMQOL (proxy) 9 months	Favors Intervention, 2.54 (0.81 to 4.28) Cohen's D 0.24; NNT 9			0.004
Ballard, 2018[73] 29408901	Mean difference (CI) CMAI 9 months	Favors Intervention, 4.27 (-7.39 to -1.15) Cohen's D 0.23; NNT 6			0.008
Ballard, 2018[73] 29408901	Mean difference (CI) NPI - NH 9 months	Favors Intervention, 4.55 (-7.07 to -2.02) Cohen's D 0.30; NNT 9			<0.001
Ballard, 2018[73] 29408901	Serious adverse events 9 months	Balanced between groups reported	291	258	

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: ADL=Activities of Daily Living; CI=Confidence Interval; CMAI=Cohen-Mansfield Agitation Inventory; CSDD=Cornell Scale for Depression in Dementia**;** DEMQOL=Dementia Quality of Life**;** ED=Emergency Department; HUI=Health utilities index; N=Number; NPI=Neuropsychiatric Inventory; NPI-NH= Neuropsychiatric Inventory-Nursing Home; QoL-AD=Quality of Life-Alzheimer's disease; QUALID=Quality of Life in Late-stage Dementia; PMID=PubMed Identification Number; ROB=Risk of Bias

Appendix Table F.40. Caregiver outcomes summary low and medium risk of bias studies: multidisciplinary integrated team collaborative care

Study (PMID) Comparison Caregiver Type RoB Category*	Outcome Timing	Summary Finding	Intervention	Comparator	p-value
Possin, 2019[63] 31566651 Medium Pragmatic	Unstandardized Beta (CI) PHQ-9 (0-27; lower is better) 12 months	Favors intervention; -1.14 (-2.15 to -0.13) NNT=12	NA	NA	0.03
Possin, 2019[63] 31566651 Medium Pragmatic	Unstandardized Beta (CI) Self-efficacy (higher is better) 12 months	No statistical difference; 0.64 (0.14 to 1.41)	NA	NA	0.11
Possin, 2019[63] 31566651 Medium Pragmatic	Unstandardized Beta (CI) 12-item ZBI (0-48; lower is better) 12 months	Favors intervention; -1.90 (-3.89 to -0.08)	NA	NA	0.046
Thyrian, 2017[65] 28746708	Adjusted mean difference (CI) Berlin Inventory for Caregiver burden 12 months	Favors intervention; -0.50 (-1.09 to 0.08), one-sided analysis Effect size -0.18	NA	NA	0.045
Bass, 2013[68] 23869899 Medium Pragmatic	Unstandardized B, no CI provided Unmet needs (lower is better, 0-39 items) 6 months	Favors intervention; -2.24	NA	NA	0.01
Bass, 2013[68] 23869899 Medium Pragmatic	Unstandardized B, no CI provided Role captivity (lower is better, 0-12) 6 months	No statistical difference; 0.12	NA	NA	NR
Bass, 2013[68] 23869899 Medium Pragmatic	Unstandardized B, no CI provided Physical health strain (lower is better, 0-12) 6 months	No statistical difference; -0.14	NA	NA	NR

Bass, 2013[68] 23869899 Medium Pragmatic	Unstandardized B, no CI provided Relationship strain (lower is better, 0-24) 6 months	No statistical difference; 0.38	NA	NA	NR
Bass, 2013[68] 23869899 Medium Pragmatic	Unstandardized B, no CI provided 11- item CESD (lower is better, 11-33) 6 months	No statistical difference; -0.69 (above from table, text reported beta -0.08, p=0.047)	NA	NA	NR
Bass, 2013[68] 23869899 Medium Pragmatic	Unstandardized B, no CI provided Number of informal helpers (higher is better) 6 months	No statistical difference; -0.32	NA	NA	NR
Bass, 2013[68] 23869899 Medium Pragmatic	Unstandardized B, no CI provided Caregiver support service use (higher is better) 6 months	Favors intervention; 0.20 (above from table, text reported beta 0.14, p=0.008)	NA	NA	NR
Chodosh, 2015[66] 25656074 Medium Balanced	Adjusted mean difference (CI) ZBI (lower is better) 6 month	No statistical difference; 1.8 (-3.46 to 7.05)	NA	NA	0.5
Chodosh, 2015[66] 25656074 Medium Balanced	Adjusted mean difference (CI) PHQ-9 (lower is better) 6 month	No statistical difference; 0.36 (-2.00 to 2.73)	NA	NA	0.76
Vickrey, 2006[71] 17116916 Medium Pragmatic	Adjusted mean difference (CI) EuroQol-5D 18 month	No statistical difference; 0.02 (-0.01 to 0.06)	NA	NA	0.127
Vickrey, 2006[71] 17116916 Medium Pragmatic	Adjusted mean difference (CI) Caregiving-attributable health strain 18 month	No statistical difference; 4.3 (-0.3 to 8.8)	NA	NA	0.063
Callahan, 2006[70] 16684985 Medium Explanatory	Adjusted mean difference (CI) PHQ-9 (lower is better) 12 month	No statistical difference; -0.9 (-2.2 to 0.5)	3.1 (3.9)	4.6 (5.6)	0.50
Callahan, 2006[70] 16684985 Medium Explanatory	Adjusted mean difference (CI) Caregiver NPI (lower is better) 12 month	Favors intervention; -2.2 (-4.2 to -0.2)	3.5 (5.8)	7.7 (8.7)	0.03

*Explanatory studies are listed first, followed by pragmatic studies.

Abbreviations: CI=Confidence Interval; CESD=Center for Epidemiologic Studies Depression Scale; EuroQol-5D=European Quality of Life-5 Dimensions; NA=Not Applicable; NNT=Number Needed to Treat; NPI=Neuropsychiatric Inventory; PMID=PubMed Identification Number; RoB=Risk of Bias; ZBI=Zarit Burden Interview

Appendix Table F.41. Summary of strength of evidence for PWD outcomes: multidisciplinary integrated team collaborative care

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Collaborative care vs usual care QoL	6-12 months	4 Pragmatic trials (n=1,746)	QoL-AD benefit, no benefit HUI benefit, no benefit	Medium	Consistent	Direct	Imprecise	Low (Weighted to larger, quality pragmatic trials)
Collaborative care vs usual care NPI	6-12 months	1 Explanatory Cluster Trial (N=152)	One benefit	Medium	Unknown	Direct	Imprecise	Insufficient
Collaborative care vs usual care Utilization	6-12 months	1 Pragmatic Trial (n=780)	ED visits benefit, hospitalization no difference, ambulance use no difference	Medium	Unknown	Direct	precise	Low
Collaborative care vs usual care ADL	6-12 months	1 Pragmatic 1 Explanatory Cluster Trial (n=560)	2 no difference	Medium	Consistent	Direct	Imprecise	Insufficient
Collaborative care vs usual care Quality indicators	6-12 months	2 Pragmatic (n=559)	Quality indicators, 2 benefit	Medium	Consistent	Direct	Imprecise	Low (Weighted to larger, quality pragmatic trials)
Collaborative care vs usual care Depression	6-12 months	1 Explanatory Cluster Trial (N=152)	CSDD, no difference	Medium	Unknown	Direct	Imprecise	Insufficient
Collaborative care vs usual care Nursing home placement	6-12 months	1 Pragmatic 1 Explanatory Cluster Trial (n=560)	2 no difference (not long enough for balance toward mild/moderate)	Medium	Consistent	Direct	Imprecise	Insufficient

Abbreviations: ADL=Activities of Daily Living; CSDD=Cornell Scale for Depression in Dementia**;** ED=Emergency Department; HUI=Health utilities index; N=Number; NPI=Neuropsychiatric Inventory; QoL=Quality of Life; QoL-AD=Quality of Life-Alzheimer's disease

Appendix Table F.42. Summary of strength of evidence for caregiver outcomes: multidisciplinary integrated team collaborative care

Comparison Caregiver Type Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Collaborative care vs usual care	6-12 months	1 Pragmatic Trial (n=408)	EuroQol-5D no difference	Medium	Unknown	Direct	Imprecise	Insufficient

Informal QoL								
Collaborative care vs usual care Informal Self-efficacy	6-12 months	1 Pragmatic Trial (n=780)	No benefit	Medium	Unknown	Direct	Imprecise	Insufficient
Collaborative care vs usual care Informal Burden	6-12 months	4 Pragmatic (n=1,719)	ZBI 2 Benefit, 1 Berlin no benefit; Role captivity, 2 physical health strain, relationship strain, all no benefit; Caregiver NPI no difference	Medium	Inconsistent	Direct	Imprecise	Insufficient (Weighted to larger, quality pragmatic trials)
Collaborative care vs usual care Informal Quality	6-12 months	1 Pragmatic Trial (n=486)	Unmet needs, informal helpers, support service use 2 of 3 no difference	Medium	Consistent	Direct	Imprecise	Insufficient (Weighted to larger, quality pragmatic trials)
Collaborative care vs usual care Informal Depression	6-12 months	3 Pragmatic, 1 Explanatory (n=1,570)	1 benefit, 3 No difference	Medium	Consistent	Direct	Imprecise	Insufficient (Weighted to larger, quality pragmatic trials)

Abbreviations: EuroQoL-5D=N=Number; NPI=Neuropsychiatric Inventory; QoL=Quality of Life; ZBI=Zarit Burden Index

Evidence Map: multidisciplinary integrated team collaborative care

Appendix Table F.43. Characteristics of evidence map studies: multidisciplinary integrated team collaborative care

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PWD Dementia Characteristics**	**PWD Non-Disease Char** **PWD N** **PWD Age (mean)** **PWD Sex (% female)** **PWD Race (% majority)** **PWD Education (mean years)**	**PWD Non-Disease Char Reporting Status (RS)** **PWD SES** **PWD Prior Disability** **PWD Household Characteristics** **PWD Health Insurance** **PWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Froggat 2020[100] UK Pilot	Namaste: structured personalized care	Usual care activities	Nursing home	Advanced dementia	N=32 Age: Yes Sex: Yes Race: no Education: No	None	NA	NA	NA	NA	24 weeks	QUALID Comfort in dying	NA
Halek 2020[62] (32062052) Germany High ROB	Two dementia-specific Case Conference models	Usual care	Nursing homes Cluster not specified N=413	Documented diagnosed dementia from nursing charts, FAST score > 1, living at least 15 days in the unit	N=224 Age: yes Sex: yes	Low	NA	NA	N=189	Position: yes	15 days/unclear		Burnout risk (CBI)
Chen, 2019[101] China Pilot	Interdisciplinary care team	Usual care activities	Community based, China	Not specified	N=148 Age: Yes Sex: Yes Race: no Education: No	None	None	None	NA	NA	6 month	CDR QoL ADL NPI	ZBI
Saxena, 2018[102] 29193721 Singapore Unable to evaluate	Primary care Dementia Clinic (PCDC): Each visit consists of a 15-min consultation with FP & 15 min consultation with a nurse	(1) Standard primary care at other National healthcare Group polyclinic (2) Specialist care at the MC	Clinic Quasi 263 PWD	Not specified	N=263 Age: Yes Sex: Yes Race: Yes Education: No	Marital status	None	None	NA	NA	12 months		Quality of life: Qol-AD CG satisfaction: Cost effectiveness:
Mavandadi, 2017[103] 28134558 US Pilot	Dementia care management: Telephone-based patient- and caregiver (CG)-centered, collaborative care management program that involves CG education and psychosocial support	Usual care	Community RCT 75 Caregivers	All types dementia and stages of severity	N=75 Age: Yes Sex: no Race: no Education: no	None	N=75 Age: Yes Sex: yes Race: yes Education: no Relationship: yes	Informal caregivers of veterans	NA	NA	6 months	Activities of daily living: ADL; IADL	Bother: RMBPC Distress: NPI-Q, Burden: ZBI Cognitive coping: Perceived mastery over caregiving:

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Laporte Uribe 2017[64] (28249632) Germany High RoB	PWD and informal CG using DCN	None	Community-dwelling Quazi-experimental 560 PWD and IC	Dementia diagnosis by medical professionals and living with IC using DCN	N=389 Age: Yes Sex: Yes Race: no Education: no Living with CG: Yes	None	N=385 Age: Yes Sex: Yes Race: no Education: no Relationship Yes				12 months	CMAI IADL EQ-5D L	BIZA-D
Samus, 2014[104] US Pilot	Home-based care coordination: to systematically identify & address dementia related care needs- Received the written results of the JHDCNA & 18 months of care coordination	Augmented usual care: Received the written results of the JHDCNA following the BL vist including recommendations for each identified unmet need.	Community RCT 303 PWD	Type of dementia: not specified Severity: Mild – severe	N=303 Age: Yes Sex: Yes Race: yes Education: Yes Living with CG: Yes	NA	NA	NA	NA	NA	18 months	Time to transfer from home: Study partner report Unmet care needs:JHDC NA	None
Leontjevas, 2013[105] 23643110 Netherland High ROB	Act in Case of Depression (AiD) at dementia unit: A multidisciplinary care program that involved 2-step screening & diagnostic procedure; multidiscipline treatment; & monitoring of treatment effects.	AiD at somatic unit:	Nursing home RCT (cluster) 793 PWD		N=793 Age: Yes Sex: Yes Race: no Education: no	NA	NA	NA	NA	NA	?	Depression: CSDD	None
Chapman, 2007[69] 18232242 US High ROB	Advanced illness care teams (AICTs): holistic approach that focused on four domains: (1) medical, (2) meaningful activities, (3) psychological, and (4) behavioral	Usual care; received all the services typically provided by the facility	Nursing homes RCT 118 NH residents	Advance dementia	N=118 Age: Yes Sex: Yes Race Yes Education: no Marital status: Yes	SES: Yes	NA	NA	NA	NA	8 weeks	Agitated behavior:CMAI Pain:FLACC Depression: CSDD	None
Bass, 2003[106] 12604748 14690867[107] US Pilot/ demonstration	Care coordination integrated within health system; average 12 contacts per year	Usual care activities	Community-based RCT 157 Dyads	Dementia diagnosis in health records	N=157 Age: no Sex: no Race: no Education: no Marital status: no	Lives alone	NA	NA	NA	NA	12 month	Utilization	IC: CES-D Caregiver strain
Person-Centered Care	And Dementia Care Mapping												
Surr, 2019[72] 31056923 UK High ROB	Dementia care mapping to reduce agitation in nursing homes	Usual care activities	Dementia care homes Cluster RCT 50 Care homes	Care home residents	N=726 Age: yes Sex: Yes Race: no Education: no Marital status: no	None	NA	NA	Information at care home level	NA	16 months	CMAI Resident behaviors QoL	System-level outcomes: Quality of interactions schedule

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Li, 2017[108] US Pilot	Person-centered dementia care: included in-class staff training plus supervision and support in practice of individualized care	Control : no intervention	Assisted Living facility RCT 28 PWDs	All types of dementia except those with Parkinson & in severe stage	N=22 Age: yes Sex: Yes Race: Yes Education: no Marital status: Yes	None	NA	NA	NA	NA	3 months 1 month post intervention follow up	Sleep-wake pattern: Actigraphy social engagement: DCM	None
Ballard, 2016[109] 26585409 UK Pilot	Person centered care combined with medication review, social interaction, and exercise		Nursing homes Cluster randomized factorial analysis 16 homes	Dementia residents	N=187 Age: yes Sex: Yes Race Yes Education: no Marital status: no	None	NA	NA	NA	NA	9 months	DEMQOL-proxy antipsychotic use	None
Moyle, 2016[110] Australia Pilot	Capabilities model based on a person-centered approach	Usual care activities	Nursing home Quasi-experimental	Confirmed dementia diagnosis	N=48 Age: no Sex: no Race: no Education: no Marital status: no	None	N=75 Age: Yes Sex: yes Race: no Education: yes Relationship: yes	Employment	N=81 Age: Yes Sex: Yes Race: no Education: Yes	Position	6, 12 months	QoL-AD	Staff experience of working with demented residents questionnaire
Dichter, 2015[75] 26138674 Germany High ROB	Dementia Care Mapping: (A) DCM applied since 2009: received two DCM cycles per year until 2009. (B) DCM newly introduced during the intervention (C) received an intervention based on a regular and standardized QoL rating that was integrated into the usual care.		Nursing home Quasi 315 PWD	Types of dementia: Not specified	N=154 Age: yes Sex: Yes Race: No Education: no	None	NA	NA	NA	NA	18 months	Quality of life: QoL-AD Challenging behavior: NPI-NH Functional ability: PSMS	None
Rokstad, 2013[78] 24022375 Norway High ROB	(1) Dementia Care Mapping (DCM): a process to develop the care staff's skills in delivering PCC to the patients (2) VPM: a weekly consensus meeting in the nursing home ward of 45–60 min using the indicators in the VIPS framework to analyze a challenging patient-nurse interaction.	Control: Education on dementia: received five DVDs with lectures (30 min each) about dementia.	Nursing home RCT 624 PWD	All types and stages of dementia	N=624 Age: yes Sex: Yes Race: No Education: no	General physical health: yes	NA	NA	NA	NA	10 months	Agitation: BARS NPIQ: Quality of life: QUALID	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Fossey, 2006[81] 16543297 UK High ROB	A training & support intervention: intervention delivered to nursing home staff over 10 months, focusing on alternatives to drugs for the management of agitated behavior in dementia	Treatment as usual	Nursing homes RCT (cluster) 349 PWD	Type of dementia unspecified Mild to severe	N=349 Age: yes Sex: Yes Race: No Education: no	None	NA	NA	NA	NA	12 months	Agitated behavior:	NA
Chenoweth, 2014[76] 24666667 Australia High ROB	(1) A person-centered care (PCC) (2) Person centered environment (PCE) (3) PCE +PCC	Usual care + usual environment	Aged care homes RCT (Cluster) 601 PWD	Only AD & severe/very severe were specified in %	N=601 Age: yes Sex: Yes Race: No Education: no	None	NA	NA	NA	NA	4 months 8 months follow up (4 months post intervention)	Quality of life: DEMQOL Agitation: CMAI Cost of program:	NA

Abbreviations: ADL=Activities of Daily Living; AICT=Advanced illness care teams; AiD=Act in Case of Depression; BARS=Brief Agitation Rating Scale; BIZA-D= Berlin Inventory of Caregivers' Burden with of Dementia Patients; CDR=Clinical Dementia Rating; CESD= Center for Epidemiologic Studies Depression Scale CG=Caregiver; char=Characteristics; CMAI=Cohen-Mansfield Agitation Inventory; CSDD=Cornell Scale of Depression in Dementia; DCM=Dementia Care Mapping; DEMQOL=Dementia Quality of Life; DVD=Digital Video Disc; EQ-5D L=Quality of Life Instrument; FLACC=Face Legs Activity Cry Consolability; FP=Family Physicians; IADL=Instrumental Activities of Daily Living; JHDCNA=Johns Hopkins Dementia Care Needs Assessment; NH=Nursing home; NPI=Neuropsychiatric Inventory; NPI-NH= Neuropsychiatric Inventory-Nursing Home; NPI-Q= Neuropsychiatric Inventory Questionnaire; MC=Memory Clinic; min=Minutes; PCDC=Primary care Dementia Clinic; PCC=Person Centered Center; PCE=Person Centered Environment; PSMS= Physical Self-Maintenance Scale; PWD=Person with Dementia; QoL-AD=Quality of Life-Alzheimer's Disease; QoL=Quality of Life; QUALID=Quality of Life in Late-Stage Dementia; RCT=Randomized Controlled Trial; RMBPC=Revised memory and behavior problem checklist; RoB=Risk of Bias; SES=Socioeconomic Status; VPM=VIPS practice model; ZBI=Zarit Burden Index

Formal Caregiver Training

Appendix Table F.44. Risk of bias assessment: Informal caregiver training

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Gozalo, 2014[111] (24697702)	2 years	Medium	Low	Medium	High	Low	High	Gov't Developer	High
Schindel Martin, 2016[112](27659392)	6 month	X	High	X	X	X	X	Gov't Developer	High
Galik, 2013[113] (24092822)	6 months	X	Medium	X	X	X	X	X	High

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: PMID=PubMed Identification Number

Evidence Map: Formal Caregiver Training

Appendix Table F.45. Characteristics of included studies: Formal caregiver training

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Williams, 2017[114] (27048705) US Small sample	CHAT: communication training designed to alert nursing staff to elder speak communication and its negative effects	Usual care activities	Nursing Home Cluster RCT 13 Nursing homes	Patients with diagnosis of AD	PWD N=83 Age: yes Sex: yes Race yes Education: no	None	NA	NA	N=130 Age: yes Sex:: yes Race: yes Education: yes	Training Position	3 months	Resistance to care	FC: Communication
Conway, 2016[115] (26821868) Australia Small sample	MESSAGE communication intervention to facilitate patient support and staff and patient experience	Usual care activities	Nursing home Cluster RCT 12 Nursing homes	Patients with diagnosis of AD with ability to respond to direct assessment	NR	NR	NA	NA	N=38 Age: yes Sex: yes Race: no Education: yes	Training Position	3 months	Self-efficacy M-NCAS ADQ	FC: Communication
Schindel Martin, 2016[112] (27659392) Canada High ROB	Standardized dementia education training on gentle persuasion approaches	Usual education supports	Hospitals Quasi-experimental 12 clinical areas at 2 hospitals	AD diagnosis	NR	NR	NA	NA	N= 745 Age: yes Sex: yes Race: no Education: yes	Training Length of service	8 weeks	None	FC: Self-Perceived Behavioral Management Self-Efficacy Profile
Hattink, 2015[116] (26519106) Netherlands & UK Pilot	Access to a Web-based portal consisting of 8 modules & to online peer and expert communities for support and information exchange	Wait-list	Community setting RCT Caregivers	AD diagnosis	NR	NR	N59 Age: yes Sex: yes Race: no Education: no IC Relation to PWD: yes	IC Duration IC Employment status	N=24 Age: yes Sex: yes Race: no Education: no	Length of service	4 months	ADKS ADQ IRI QoL Burden: assessed with 1 question SSCQ	Usefulness of training
Gozalo, 2014[111] (24697702) US High ROB	Education program on bathing patients with dementia to improve bating experience of patients	Usual care activities until crossover	Nursing homes Crossover cluster RCT 6 Nursing homes	Dementia unspecified	N=240 Age: yes Sex: yes Race: yes Education: no	Health insurance Race Information	NA	NA	NR	NR	2 years	Bath duration Aggressive activity	Usefulness of BWAB in reducing aggressive patient behavior during bathing
O'Shea 2014[117] (24633858) Ireland Pilot	Dementia Education Program Incorporating Reminiscence for staff facilitated by experienced nurse educators, delivered over 3 days (2 at the beginning and 1 six weeks later) and augmented by telephone support and one site visit	usual care provided by care staff who did not receive the structured education program	Long term care Cluster RCT 18 Residential units 304 PWD	Dementia diagnosis	N=304 Age: yes Sex: yes Race: no Education: no	None	NR	NR	NR	NR	18-22 weeks	QoL-AD CSDD	QoL-AD ZBI

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PWD Dementia Characteristics**	**PWD Non-Disease Char** **PWD N** **PWD Age (mean)** **PWD Sex (% female)** **PWD Race (% majority)** **PWD Education (mean years)**	**PWD Non-Disease Char Reporting Status (RS)** **PWD SES** **PWD Prior Disability** **PWD Household Characteristics** **PWD Health Insurance** **PWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Galik, 2013[113] (24092822) US High ROB	Function-focused care training	Usual care activities	Nursing home Cluster RCT 4 Nursing homes	Patients with MMSE <16	N=103 Age: yes Sex: yes Race: yes Education: N	Comorbidity Marriage status	NA	NA	N=77 Age: yes Sex: yes Ethnicity: yes Education: yes	NR	6 months	Barthel ADL CMAI CSDD Apathy Inventory Falls ED transfers Death	Restorative Care Behavior Checklist Knowledge Restorative Care Activities: self-efficacy and outcome expectations
Clare, 2013[118] (22840185) UK Pilot	Training in observation of awareness in patients with severe AD	No training	Nursing homes Cluster RCT 8 Nursing homes	Participants with AD moderate to severe	N=32 residents Age: yes Sex: yes Race: yes Education: no		NA	N	N=63 Age: no Sex: yes Ethnicity: yes Qualifications: yes	Training	8 weeks	Measures of resident, family and staff quality of life Resident and staff care measures at baseline and follow-up	Resident quality of life Secondary outcome: resident well-being, behavior and cognition; staff attitudes and well-being
Ghandehari, 2013[119] (23457681) Canada Pilot	Education program in pain management	Randomized control trial	N=131 staff Focus group of 28 participants (16 nurses, 12 aides) 29 control subjects (13 nurses, 16 aides From 2 health care regions	Not reported	Not Reported	Not reported	NA	NA	Not reported	Training: yes	2 weeks	Evaluation of training session and workshop knowledge	Assessment of an expert-based education program on pain management
Wenborn, 2013[120] (23637069) UK Pilot	Assessment of an occupational therapy program to increase provision of activity in residential care home patients	Randomized control trial with blinded assessment	Intervention group of 8 homes, 104 residents Control group of 8 homes, 106 residents	Patients with AD with DSM_IV score less than 25 Age 60 or older, residing at residential home for at least2 months with no other serious physical or mental health problems	N=104 intervention group 106 control group Age 84.2 intervention group 84.2 control group Sex 66% female intervention group 75% control group Race 95% white intervention group 88% white control group Education: no	SES: no Prior disability: no Household characteristics: no Health insurance: no Race information: yes	NA	NA	Not reported	Not reported	12 weeks	Measures of resident, family and staff quality of life Resident and staff care measures at baseline and follow-up	Effectiveness of training in promoting activity engagement for patients with AD
Leone, 2012[121] (22700526) France Pilot	Evaluation of staff education in managing apathy in older nursing home patients with AD	Randomization of intervention group and control group by nursing home site; 16 total sites	N=119 patients, 284 caregivers in intervention group 111patients , 279 caregivers in reference group	Patients with diagnosis of AD, per medical records information, MMSE<24 and presence of apathy per diagnostic criteria	N=119 intervention group 111 control group Age 87.83 intervention group 88,82 reference group Sex: 72.3% intervention group 87.4 reference group Race: no Education: no	Not reported	NA	NA	Not reported	Not reported	17 weeks	Measures of resident emotional blunting, interest, level of initiative	Effectiveness of staff training measures in reducing patient apathy in AD patients

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PWD Dementia Characteristics**	**PWD Non-Disease Char** **PWD N** **PWD Age (mean)** **PWD Sex (% female)** **PWD Race (% majority)** **PWD Education (mean years)**	**PWD Non-Disease Char Reporting Status (RS)** **PWD SES** **PWD Prior Disability** **PWD Household Characteristics** **PWD Health Insurance** **PWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
McCurry 2012 (22367233) US Small sample	4 training sessions to develop and implement individualized PWD behavioral sleep plans	Usual care	Adult family homes residents RCT 47 PWD	Dementia diagnosis by primary care physicians with mean±SD MMSE score being 8.1±7.6 and has one or more sleep problems on the Sleep Disorders Inventory	N=31 Age yes Sex yes Race: yes Education yes	None	NA	NA	N=37 Mean Age: yes Sex: yes Race: yes Education: yes	None	1 month 6 months	Actigraphy CSDD RMBPC ESS	NA
Zimmerman, 2010[122] (No Id #) US Training pilot	Evaluation of staff education program on dementia care focused on leadership, knowledge about AD and pain reduction	Randomization of care centers receiving training vs control group; 16 residential care and nursing home sites in 4 states	N=213 staff, 78 supervisors in 8 centers for intervention group 278 staff, 93 supervisors for control group	Not reported Intervention center patients with AD= 62% Control center patients with AD=48%	Not reported	Not reported	NA	NA	N=490 Age: yes Sex: yes Race: yes Education: yes	Health Status :no Training: yes Education: yes Position: yes Length of Service: yes	3 months	Measures of supervisor leadership and measures of work stress, work satisfaction and knowledge	Benefit of training for staff and supervisory personnel
Deudon,2009[123] (19370714) France Training pilot	8 week, 12 session staff training on dementia and BPSD; feedback sessions		Nursing homes Cluster RCT 16 sites 306 PWD		N=306 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	12 week post intervention	NPI CMAI Observation Scale (OS)	NA
Kuske, 2009[124] (19193252) Germany Training pilot	Evaluation of a staff education program on caregiver knowledge and competence; evaluation relaxation training for staff	3 arm cluster randomized control trial clustered in 6 nursing homes	N=68 patients, 89 caregivers in intervention group 68 patients, 90 caregivers in relaxation group 74 patients, 94 caregivers in control group	Patients with AD, per MMST and Barthel Index scores	N=68 intervention group 68 patients relaxation group 74 patients control group Age: yes Sex: yes Race: no Education: no	Not reported	NA	NA	Age: yes Sex: yes Race: no Education: yes	Health Status: yes Training: yes Education: yes Position: yes Length of Service: yes	6 months	Measures of knowledge, competence and emotional/health status	Benefit of training on quality of care for AD patients and in reducing caregivers' burden in caring for patients
Chang, 2005[125] (16238764) Taiwan Pilot	Effects of a training program on feeding skills for nursing assistants (NA) feeding patients with AD Pilot study	2 AD-specialized long term-care treatment centers randomly assigned as training or control group	One patient per NA pre and post training, not matched	Patients diagnosed with AD and evaluated by NA as having eating problems and requiring assistance	N=31 NA in training group 36 NA in control group Patient information not reported; 12 patients matched pre and post training to NA in training group; 8 patients matched in control group	Not reported	NA	NA	Age: yes Sex: yes Race: no Education: no	Health Status: no Training: no Education: no Position: yes Length of Service: yes	One post training assessment	Assessment of NA knowledge, using checklist Food intake Feeding time EdFED score	Caregiver skills and attitude developed through training Effects of caregiver training on patient eating behavior
Sloane, 2004[126] (15507054) US Small sample	Techniques to reduce agitation, aggression and discomfort in AD patients 1) Training for person-centered showering or 2) towel bath	Usual care activities	Nursing homes, Crossover Cluster RCT 15 Cluster N 69 PWD 37 FC	Patients 65 and older with diagnosis of AD or related dementia who required assistance with bathing	N=69 PWD, Age: yes Sex: yes Race: yes Education: yes	SES: no Prior disability: no Household characteristics: no Health insurance: no Race information: yes	NA	NA	N: 37 Age: yes Sex: yes Race: no Education: no	Health Status: no Training: no Education: no Position: yes Length of Service: yes	6 weeks	Bathing-associated aggression, agitation, and discomfort	Comparison of bathing behavior difficulty of non-trained staff and person-centered vs towel bath intervention

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PWD Dementia Characteristics**	**PWD Non-Disease Char** **PWD N** **PWD Age (mean)** **PWD Sex (% female)** **PWD Race (% majority)** **PWD Education (mean years)**	**PWD Non-Disease Char Reporting Status (RS)** **PWD SES** **PWD Prior Disability** **PWD Household Characteristics** **PWD Health Insurance** **PWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Magai, 2002[127] (11395344) US Pilot	Training in sensitivity to nonverbal communication, 10 – 1 hr sessions	C1: Waitlist C2: dementia education training	Nursing homes Cluster RCT 3 Cluster N	Dementia unspecified	N=91 Age: yes Sex: yes Race: yes Education: no	None	NA	NA	N=21 Age: yes Sex: yes R: yes Education: no	None	12 weeks	CDS CMAI BEHAVE-AD	BSI
Bourgeois, 2001[128] (No ID) US Pilot	Use of memory aids as augmentation or alternative in communicating with nursing home residents with AD	Sub-set of a larger study of the effectiveness of memory aids for communication with patients with AD Intervention and control groups	7 nursing homes; subset of 66 out of 125 residents	Patients diagnosis of AD, MMSE below 25, remaining in care facility for at least 3months	N=33PWD, 33FC treatment group 33PWD, 33FC control group Age: yes Sex: yes Race: yes Education: yes	SES: N Prior disability: no Household characteristics: no Health insurance: no Race information: yes	NA	NA	N: yes Age: yes Sex: yes Race: no Education: no	Health Status: no Training: no Education: no Position: yes Length of Service: no	3 months	Content of patient conversation evaluated for specific content items and qualities	Comparison of conversation between patients and staff; untrained staff vs trained staff using communication aids
Wells, 2000[129] (10798473 Canada Small sample	Evaluation of training program for morning care of nursing home patients with AD	Randomized control study with one experimental care unit and 3 control units	Four cognitive support units in a large geriatric care center	Patients with a diagnosis of dementia or AD residing in the memory assistance care units for at least 4 weeks; MMSE <19; Control group selected for age and MMSE equivalency with experimental group	N=20 PWD, 16 FC experimental group 20PD, 28FC control group Age: yes Sex: yes Race: no Education: no Primary diagnosis: yes	SES: no Prior disability: no Household characteristics: no Health insurance: no Race information: no	NA	NA	N: yes Age: yes Sex: yes Race: no Education: yes	Health Status: no Training: yes Education: yes Position: yes Length of Service: yes	6 months	Measurements of resident interaction behavior, level of agitation, perceived ease of caregiving, level of stress	Level of resident interaction with caregivers with or without training
McCallion, 1999[130] (10568079) US	Evaluation pf an education program to improve effectiveness of nursing home assistants with residents with dementia	Randomized partial crossover control study; control group given training after 6 month assessment	Two nursing homes, including 2 care units housing patients with dementia in each	Patients with diagnosis of dementia and MMSE score assessed against educational level; GDS of stage 3 or above	N=49PWD, 39 FC treatment group 56 PWD, 49 FC control group Age: yes Sex: yes Race: no Religion: yes Education: yes Primary diagnosis: no	SES: no Prior disability: no Household characteristics: no Health insurance: no Race information: yes	NA	NA	N: yes Age: yes Sex: yes Race: yes Education: yes	Health Status: no Training: yes Education: yes Position: yes Length of Service: yes	9 months	FC interviews, KAT, MHQ; staff turnover rate; Resident assessments of signs of and symptoms of depression and aggressive behaviors	Changes in level of behavioral disturbances in PWD; Changes in FC knowledge and patient management
Proctor, 1999[131] (10406361) UK Pilot	Evaluation of training and education intervention in nursing and residential care facilities	Randomized control trial	Twelve matched care facilities, selected randomly as intervention or control groups; 10 patients with difficult behavioral problems selected by staff at each facility	Patients selected by staff; Centers paired by size and accreditation status and randomly selected to intervention or control arm	N=54 PWD, 51 PWD control group Age: yes Race: no Education: no Primary diagnosis: no Counts for intervention vs control group not reported	SES: no Prior disability: no Household characteristics: no Health insurance: no Race information: no	NA	NA	Not reported	Not reported	6 months	Measurements of patient cognitive impairment, depression, behavioral disturbance and functional ability	Changes in patient depression scores, level of cognitive impairment and behavior

Abbreviations: AD=Alzheimer's Disease; ADKS=Alzheimer's Disease Knowledge Scale; ADL=Activities of Daily Living; ADQ=Approaches to Dementia Questionnaire; BEHAVE-AD=behavioral pathology in Alzheimer's disease rating scale; BSI=Brief symptom inventory; BWAB=Bathing without a Battle; CDS=Cornell depression scale; char=characteristics; CMAI=Cohen-Mansfield Agitation Inventory; CPS= Cognitive Performance Scale; CSDD=Cornell Scale for Depression in Dementia DSM-IV=Diagnostic and Statistical Manual of Mental Disorders; EdFED= Watson feeding difficulty scale for AD patients; EM=Evidence Map; ESS=Epworth Sleepiness Scale; FAST=Functional Assessment Staging; FC=formal caregiver; GDS= Global Deterioration Scale; GPA=Gentle Persuasive Approaches; IC=informal caregiver; ICD=International Classification of Diseases; IRI=Individual Reactivity Index; KAT=Knowledge Alzheimer's Test; MHQ= Penn State Mental Health Questionnaire; MMSE= Mini-mental State Examination; MMST=German version of MMSE, Mini-mental State Assessment; M-NCAS=Modified Nursing Care Assessment; MZBI=Modified Zarit Burden Interview; N=number; NA=Not Applicable; NR=Not Reported; PMID=PubMed Identification Number; PWD=Persons with Dementia; QOL-AD=Quality of Life – Alzheimer's Disease; RMBPC=Revised Memory and Behavior Problems Checklist; RS=Reporting Status; RTC=Restiveness to Care; SBMSEP=Self-perceived Behavioral Management Self-Efficacy Profile; SES=socioeconomic status; SSCQ=Short Sense of Competence Questionnaire; ZBI=Zarit Burden Interview

Informal Caregiver Training

Appendix Table F.46. Risk of bias assessment: Informal caregiver training

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Hepburn, 2001[132] (113477900)	5 months	Medium 20%	Low	Medium	High	Low	High	Gov't Developer	High
Hepburn, 2006[133] (43539927)	6 month	Medium 21%	Low	Medium	High	Low	High	Gov't Developer	High
Hepburn, 2007[134] (17378189)	6 months	High 49%	Medium	X	X	X	X	X	High

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: PMID=PubMed Identification Number

Appendix Table F.47. Characteristics of evidence map studies: informal caregiver training

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Hattink, 2015[116] (26519106) Netherlands & UK Pilot	Access to a Web-based portal consisting of 8 modules & to online peer and expert communities for support and information exchange	Wait-list	Community setting RCT Caregivers 142	Dementia unspecified	N= Age: no Sex: no % majority race: no Education: no	None	IC N=59 IC Age: yes IC Sex: yes IC % majority race: no IC Education: no IC Relation to PWD: yes	IC Duration IC Employment status	FC N=24 FC Age: yes FC Sex: yes FC Race: no FC Education: no	Length of service	4 months	ADKS ADQ IRI QoL SSCQ	FC: Usefulness of training IC: Burden: assessed with 1 question
Liddle, 2012[135] (23092595) Australia Small sample	DVD-based training for memory and communication support skills	No training	Community RCT Caregivers	Dementia (Alzheimers, vascular, frontotemporal, not otherwise specified)	N=29 Age: yes Sex: yes % majority race: no Education: yes	None	N=29 Age: yes Sex: yes % majority race: no Education: yes Relationship: yes	None	NA	NA	3 months	None	ZBI PAC RMBPC CSDD
Klodnicka Kouri,2011[136] ?? Canada Pilot	Individual communication training, 5 weekly 90-120 minute session	Printed information	Community RCT Caregivers	Mild probable Alzheimer's disease	N= Age: no Sex: no % majority race: no Education: no	None	N=50 Age: no Sex: yes % majority race: yes Education: no Relationship: yes	Duration; Living with PWD; Employment	NA	NA	6 weeks post intervention	None	IC: Caregiver self-efficacy scale; RMBPC communication knowledge and skills
Neely, 2009[137] (19294562) Sweden Small sample	Trained in and practiced strategies to support everyday mnemonic and occupational performance, home-based, 8 – 1 hour sessions	No training	Community RCT Dyad	Mild to moderate Alzheimer's disease or with vascular dementia	N=30 Age: yes Sex: yes % majority race: no Education: no	None	N=30 Age: yes Sex: yes % majority race: no Education: no Relationship: no	None	NA	NA	8 weeks	None	ZBI Beck depression
Hepburn, 2007[134] (17378189) USA High ROB	Group caregiving role-training and mastery-focused coaching 6 - 2 hour sessions	Wait-list control	Community RCT Caregivers	Dementia unspecified	N= Age: no Sex: no % majority race: no Education: no	None	N=102 Age: yes Sex: yes % majority race: yes Education: yes Relationship: yes	SES Duration	NA	NA	5 months	None	Relational deprivation Role captivity Competence Mastery Loss of self- Distress
Hepburn, 2005[133] ?? USA High ROB	Group caregiving role-training and mastery-focused coaching 6 weekly 2 hour sessions	Wait-list control	Community RCT NA NA	Dementia unspecified	N=215 Age: NR Sex: NR % majority race: NR Education: NR	NA	IC N=215 IC Age: yes IC Sex: yes IC % majority race: no IC Education: yes IC Relation to PWD: no	None	NA	NA	6 and 12 months	None	BACS remainder were development of distress measure

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Martin-Cook, 2005 Martin-Cook, 2005 #15808} (16136843) US Small sample	Individual communication training through modeling and feedback, 4 sessions	Not specified	Community RCT Caregivers	Mild to moderate dementia, primarily Alzheimer's disease	N= Age: yes Sex: yes % majority race: yes Education: yes	None	N=47 Age: no Sex: yes % majority race: no Education: yes Relationship: yes	Duration	NA	NA	17 weeks	ILS/I-ILS ADCS MMSE; NPI; GDS	FMTCS; GSE
Done, 2001[138] (11536349) UK Small sample	Group communication training 1 hour/week, 2 weeks	Information booklet	Community Cluster RCT Local groups (day center or local home) 45 Caregivers	Dementia unspecified	N= Age: no Sex: no % majority race: no Education: no	None	N=45 Age: no Sex: no % majority race: no Education: no Relationship: no	None	NA	NA	6 weeks	None	IC: The relatives stress scale TACI
Gormley, 2001[139] (11395344) UK High ROB	Brief behavior management training program, 4 home sessions	Attention control: sessions about general care questions	Community RCT Caregivers	Dementia unspecified	N= Age: yes Sex: yes % majority race: no Education: no	None	N=62 Age: yes Sex: yes % majority race: no Education: no Relationship: no	None	NA	NA	8 weeks	BEHAVE-AD; MMSE; Blessed Dementia Rating Scale; Zarit Burden Interview	None
Hepburn, 2001[132] (11347790) USA High ROB	Group caregiving role-training and mastery-focused coaching 7 weekly 2 hour sessions	Wait-list control	Community RCT Caregivers	Dementia unspecified	N=117 Age: NR Sex: NR % majority race: NR Education: NR	None	IC N=117 IC Age: yes IC Sex: yes IC % majority race: yes IC Education: yes IC Relation to PWD: yes	IC: SES	NA	NA	5 months	None	BACS Revised Zarit burden scale CESD
Burgener, 1998[140] (9708136) US Pilot	Individual education I1: dementia education only I2: behavioral education only I3: Both I1 and I2 training	No training	Community RCT Caregivers	Moderate to severe Alzheimer's or multi-infarct dementia	N= Age: yes Sex: yes % majority race: no Education: yes	None	N=54 Age: yes Sex: yes % majority race: no Education: yes	Duration	NA	NA	6 month post-intervention	Dementia Behavior Disturbance; ADL	Alzheimer's Disease Knowledge Test; Relative Stress Scale
Robinson, 1994[141] (7993133) US Small sample	I1: Behavior management skill training I2: Social skills training to mobilizing a social network. Both 6 90-min sessions over 2 weeks; individual	No training	Community RCT Caregivers	Dementia unspecified	None	None	N=33 Age: yes Sex: no % majority race: no Education: yes Spouse/partner	None	NA	NA	1 month post-intervention		IC: Montgomery objective and subjective burden Attitude toward adult day care, asking for help

Abbreviations: ADCS=Alzheimer's Disease Cooperative Study; ADKS=Alzheimer's Disease Knowledge Scale; ADL=Activities of Daily Living; ADQ=Approaches to Dementia Questionnaire; BEHAVE-AD=behavioral pathology in Alzheimer's disease rating scale; BACS=Beliefs about Caregiving Scale; CESD=Center for Epidemiologic Studies Depression Scale; CSDD=Cornell scale for depression in dementia; char=characteristics; DBD=dementia behavior disturbance scale; EM=Evidence Map; FC=formal caregiver; FMTCS=Finding Meaning through Caregiving Scale; GDS=Geriatric Depression Scale; GSE=General Self-Efficacy; IC=informal caregiver; ILS=Independent Living Scale; ILS/I=Independent Living Scale Informant version; IRI=Individual Reactivity Index; MMSE=Mini Mental State Examination; N=number; NA=Not Applicable; NPI=Neuropsychiatric Inventory; NR=Not Reported; PAC=Positive aspects of caregiving; PMID=PubMed Identification Number; PWD=Persons with Dementia; QoL=Quality of Life; RCT=randomized controlled trial; RMBPC=Revised memory and behavior problems checklist; RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status; SSCQ=Short Sense of Competence Questionnaire; TACI= Thomas Assessment of Communication Inadequacy; ZBI=Zarit caregiver burden interview.

Family Involvement

Appendix Table F.48. Risk of bias assessment: Family involvement in training

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Funder	Overall Rating
Jablonski, 2005[142] (16138529)	9 months	High 39%	Medium	X	X	X	X		High
Maas, 2004[143] 15084992	9 month	High 41% by 5 months	High	X (no blinded assessors)	X	X	X		High

X indicates that domain was not assessed due to high risk of bias.

Abbreviations: PMID=PubMed Identification Number

Evidence Map: Family Involvement

Appendix Table F.49. Characteristics of evidence map studies: family involvement in training

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Bramble, 2011[144] (21702706) Australia Pilot	FIC: An education programme delivered to staff by the research team.	Not reported	Long term care facility Quasi 58 Caregiver dyads	NA	NA	NA	N=57 Age: Yes Sex: Yes Race: No Education: Yes Relationship: Yes	Employment: Yes Marital status: Yes	N=58 Age: Yes Sex: Yes % majority race: No Education: Yes	Occupation: Yes Employment: Yes	9 months	NA	Staff knowledge; Stress; Staff attitude towards family CGs; Caregiving roles;
Robison, 2007[145] (17766671) USA Pilot	The partners in caregiving in a special care environment program: Staff and family received training sessions on communication and conflict-resolution techniques	Not reported	Nursing homes Cluster RCT 20 nursing homes	NR	N=388 Age: Yes Sex: Yes Race: Yes Education: Yes	None	NA	NA	N=384 Age: Yes Sex: Yes Race: Yes Education: Yes	None	2 & 6 months follow up	NA	IC: Frequency of conflicts; Staff empathy; Negative staff behavior; Engagement in NH activities; Burden; Depression FC: Frequency of conflicts; Depression; Job burnout; Job satisfaction
Jablonski, 2005[142] (16138529) USA High RoB	Family involvement in care protocol to help family negotiate a partnership with formal staff	Not reported	Nursing home RCT 164 PWD	Not reported	N=164 Age: Yes Sex: Yes Race: Yes Education: Yes	Marital status: Yes Occupation: Yes	NA	NA	NA	NA	2months; 4 months, 6 months	Functional abilities: FAC	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Maas, 2004[143] 15084992 US High ROB	Family involvement in care protocol to help family negotiate a partnership with formal staff	Usual Care	Nursing home Quasi-experimental Paired nursing homes assigned	PWD in special care units for dementia	N=185 Age: no Sex: no Race: no Education: no	Time in NH	N=185 Age: Yes Sex: Yes % majority race: yes Education: Yes Relationship: Yes	None	NA	NA	9 months	None	Family Perceptions of Caregiving Role Family Perceptions of Care Tool Staff Perceptions of Caregiving Role Caregiver Stress Inventory Attitudes Toward Families Checklist
McCallion, 1999[146] US Pilot	Family training in nonverbal communication and structuring family visits	Usual care activities	Nursing home RCT 66 dyads	Moderate dementia with behavioral problems	N=66 Age: Yes Sex: Yes Race: Yes Education: no	None	N=66 Age: Yes Sex: Yes Race: yes Education: Yes Relationship: Yes	None	NA	NA	3 and 6 months	MOSES CSDD CMAI GIPB medication use	IC: DMSS CHS-M Visit satisfaction

Abbreviations: char=characteristics; CHS-M= Caregiver Hassel Scale modified; CG=Caregiver; CHS-M=Caregiving hassles scale; CMAI=Cohen-Mansfield Agitation Inventory; CSDD=Cornell Scale for Depression in Dementia; DMSS= Dementia Management Strategy Scale; EM=Evidence Map; FAC=Functional Abilities Checklist; FC=formal caregiver; FIC=Family involvement in care; GIPB=geriatric indices of positive behavior; IC=informal caregiver; MOSES=Multidimensional Observation Scale for Elderly Subjects; N=number; NA=Not Applicable; NH=Nursing homes; NR=Not Reported; PMID=PubMed Identification Number; PWD=Persons with Dementia; RCT=Randomized Controlled Trial; RoB=Risk of Bias; RS=Reporting Status; SES=socioeconomic status

Multi-tier training interventions

Appendix Table F.50. Risk of bias assessment: multi-tier training intervention

Study (PMID)	Outcome Timing	Attrition Bias Attrition %	Selection Bias	Detection Bias	Performance Bias	Reporting Bias	Fidelity Bias	Overall Rating
Kunik, 2017[147] (27743840)	3, 6, 12 month	Medium	Low	Low	Medium	Low	Low	Medium
Teri 2005[148] (16326662)	2 months 6 months	Low 2 months: 12.6%	Medium	Medium	Medium	Low	Low	Medium

Abbreviations: PMID=PubMed Identification Number

Appendix Table F.51. Characteristics of included studies: Caregiver focused training intervention

Study (PMID) Country RoB* Type	Intervention Intervention Focus Theoretical Model Delivery Person Intervention Target Recipient Mode Components Frequency Duration	Comparison Target Mode Components Frequency Duration	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics Dementia Types Dementia Severity Diagnostic Criteria Age of Diagnosis	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
Teri 2005[148] (16326662) US Medium Exploratory Teri 2005[149] (16199404) Teri 2012[150] (22247431)	STAR-C: 8 weekly sessions between community consultants and caregivers, followed by four monthly phone calls; to train the caregivers to give consultants the freedom to use clinical judgment and modify the order of session topics in response to a caregiver's needs	Routine medical car (RMC)e	resided in a home setting outside of a nursing home or assisted living facility RCT 95 PWD and caregivers	Primary physician diagnosis of probable or possible AD with mean MMSE score of 14	N=95 66% Female 80 years Race yes Education yes	None	NA	N=95 70% Female 65 years Race yes Education yes	NA	NA	2 months 6 months	NPI RMBPC QoL-AD;	CES-D HDRS Caregiver Sleep Questionnaire PSS SSCQ

*High risk of bias studies included in evidence map

Abbreviations: AD=Alzheimer's disease; char=characteristics; CES-D=Center for Epidemiological Studies Depression Inventory; FC=formal caregiver; CSC=Cognitive Status Scale; IC=informal caregiver; ICD=International Classification of Diseases; HSC=Hopkins Symptoms Checklist; PBS= Problematic Behavior Scale; PMID=PubMed Identification Number; PWD=Persons with Dementia; RCT=Randomized Controlled Trial; RoB=Risk of Bias; RS=Reporting Status

Appendix Table F.52. PWD outcomes summary low and medium risk of bias studies: Caregiver focused training intervention

Study (PMID) Comparison RoB Category	Outcome Timing	Intervention	Comparator	p-value
Teri 2005[148] (16326662) STAR vs RMC Medium Exploratory	Mean difference (SD) Caregiver depression CES-D 6 months	12.5 (7.7)	15.8 (10.5)	0.046
Teri 2005[148] (16326662) STAR vs RMC Medium Exploratory	Mean difference (SD) Caregiver depression HDRS 6 months	6.7 (3.9)	8.5 (5.7)	0.284
Teri 2005[148] (16326662) STAR vs RMC Medium Exploratory	Mean difference (SD) Caregiver burden 6 months	21.4 (12.5)	25.8 (13.7)	0.011
Teri 2005[148] (16326662) STAR vs RMC	Mean difference (SD) Caregiver reaction 6 months	21.9 (15.6)	23.4 (14.5)	0.024

Medium Exploratory				
Teri 2005[148] (16326662) STAR vs RMC Medium Exploratory	Mean difference (SD) Caregiver sleep questionnaire 6 months	9.1 (4.6)	9.1 (5.2)	0.124
Teri 2005[148] (16326662) STAR vs RMC Medium Exploratory	Mean difference (SD) PWD_QoL 6 months	28.4 (5.4)	28.2 (4.6)	0.049
Teri 2005[148] (16326662) STAR vs RMC Medium Exploratory	Mean difference (SD) PWD RMBPC-memory subscale 6 months	2.8 (0.8)	3.1 (1.0)	0.070

Abbreviations: CES-D=Center for Epidemiological Studies Depression Inventory; CI=Confidence Interval; NR=Not Reported; PMID=PubMed Identification Number; RoB=Risk of Bias

Appendix Table F.53. Summary of strength of evidence for PWD outcomes: Caregiver focused training intervention

Comparison Outcome	Timing	# Studies/ Design (n analyzed)	Finding or Summary Statistic	Study Limitations	Consistency	Directness	Precision	Overall Grade/ Conclusion
Consultation vs Control Nursing home admission	12 months	1 RCT (n=84)	Nursing home admissions showed no difference between the comparison groups.	Moderate	Unknown	Direct	Imprecise	Insufficient
Consultation vs Control Symptom management self-efficacy score	12 months	1 RCT (n=84)	Symptom management self-efficacy scores were not different between the comparison groups	Moderate	Unknown	Direct	Imprecise	Insufficient
Consultation vs Control Support service self-efficacy	12 months	1 RCT (n=84)	Support service self-efficacy was not different between the comparison groups	Moderate	Unknown	Direct	Imprecise	Insufficient
Consultation vs Control CES-D score	12 months	1 RCT (n=84)	CES-D scores were not different between the comparison groups	Moderate	Unknown	Direct	Imprecise	Insufficient
Consultation vs Control Zarit burden score	12 months	1 RCT (n=84)	Zarit burden scores were not different between the comparison groups	Moderate	Unknown	Direct	Imprecise	Insufficient
Consultation vs Control Hopkins symptom checklist score	12 months	1 RCT (n=84)	Hopkins symptom checklist scores were not different between the comparison groups	Moderate	Unknown	Direct	Imprecise	Insufficient

Abbreviations: CES-D=Center for Epidemiological Studies Depression Inventory; n=Number; RCT=Randomized Controlled Trial

Evidence Map: Multi-tier training interventions

Appendix Table X.9. Characteristics of evidence map studies: multi-tier training interventions

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PWD Dementia Characteristics**	**PWD Non-Disease Char** **PWD N** **PWD Age (mean)** **PWD Sex (% female)** **PWD Race (% majority)** **PWD Education (mean years)**	**PWD Non-Disease Char Reporting Status (RS)** **PWD SES** **PWD Prior Disability** **PWD Household Characteristics** **PWD Health Insurance** **PWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Livingston 2019[151] (30221615) UK Pilot	DREAM-START Intervention: cognitive-behavioral components, including psychoeducation, light therapy, establishing a new sleep–wake schedule (based on actiwatch data), behavioral activation, relaxation, and coping skills for families	Treatment as usual	Community-dwelling RCT 62 PWD	Clinical diagnosis of dementia and a SDI item score ≥4	N=62 Age: yes Sex: yes Race: yes Education: yes	None	N=62 Age: yes Sex: yes Race: yes Education: yes	None	NA	NA	3 months	referral rates; follow-up rates at three months; all psychotropic medication prescription (to define rescue medication's role); reported side effects: co-morbid physical illnesses and patient falls sleep via actigraphy ESS, NPI,DEMQOL	PSQI SCI HADS ZBI HSQ-12
Kinnunen 2018[152] (30538021) UK Pilot Livingston 2018[153] (30221615)	DREAMS START: 6 sessions of manual-based intervention for caregiver's understanding sleep and dementia, comprising a cognitive–behavioral component and light therapy	Treatment as usual	Memory service Cluster RCT 62 PWD	Dementia diagnosis (any type and severity) and sleep disturbances (who scored ≥4 on at least one question on SDI) Sleep Disorders Inventory)	N=62 Age: yes Sex: yes Race: yes Education: yes	Annual Income=yes	N=62 Age: yes Sex: yes Race: yes Education: yes	None	NA	NA	3 months	Feasibility Acceptability Referral rate Follow-up rate Use of psychotropic medications Adverse effects and comorbid physical illnesses	Caregiver burden depression

Study (PMID) **Country** **EM Reason**	**Intervention**	**Comparison**	**Setting and Design** **Setting** **Design** **Cluster N** **Participants Randomized N**	**PWD Dementia Characteristics**	**PWD Non-Disease Char** **PWD N** **PWD Age (mean)** **PWD Sex (% female)** **PWD Race (% majority)** **PWD Education (mean years)**	**PWD Non-Disease Char Reporting Status (RS)** **PWD SES** **PWD Prior Disability** **PWD Household Characteristics** **PWD Health Insurance** **PWD Detailed Race Information**	**Informal Caregiver (IC) Characteristics** **IC N** **IC Age (mean)** **IC Sex (% female)** **IC Race (% majority)** **IC Education (mean years** **IC Relation to PWD (% majority)**	**Informal Caregiver (IC) Char. RS** **IC Duration** **IC Living with PWD** **IC Payment** **IC Health Status** **IC Dementia Family History** **IC Employment Status** **IC Training**	**Formal Caregiver (FC) Characteristics** **FC N** **FC Age (mean)** **FC Sex (% female)** **FC Race (% majority)** **FC Education (mean years)tics**	**Formal Caregiver (FC) Char. RS** **FC Health Status** **FC Training** **FC Education** **FC Position** **FC Length of Service**	**Outcome Timing(s)**	**PWD Outcomes**	**Caregiver Outcomes** **IC:** **FC:**
Kunik 2017[147] (27743840) US High RoB	PAVeD: 6 to 8 weekly sessions of 45-minute home visits. To give instruction to caregivers on recognizing pain, enhancing communication, and making daily activities pleasant and enjoyable, and at least two elective sessions	EU-PC: 8 weekly 15-minute phone calls to query symptom severity, ascertain needs for immediate psychiatric care, and provide minimal support.	Veterans' Health Administration (VHA) outpatient database for persons with a diagnosis of dementia RCT 213 PWD	Mild-to-moderate dementia (defined using FAST 2-6 Functional Assessment Staging validated clinician-rated measure of functional decline in dementia)	N=203 Age: yes Sex: yes Race: yes Education: yes	None	N=203 Age: yes Sex: yes Race: yes Education: yes	NA	NA of ≥	NA	3 months 6 months 12 months	CMAI PGPIS GDS PES-AD	Caregiver burden Caregiver-patient relationship Caregiver satisfaction and perceptions of usefulness of PAVeD
Suominen 2015[154] (26482691) Finland Small sample	Tailored nutritional guidance on the basis of the food diaries, the results of the weight measurement, the home visits and discussions with the PWD and caregiver	Got a written guide about nutrition in older adults and all community-provided normal care	Community dwelling RCT 99 PWD	Diagnosis criteria for a probable AD diagnosis based on the NINCDS-ADRDA Alzheimer's criteria	N=99 Age: yes Sex: yes Race: no Education: no	None	NA	NA	NA	NA	6 months 12 months	weight change; changes in protein and other nutrients intake, QoL and rate of falls.	NA

Study (PMID) Country EM Reason	Intervention	Comparison	Setting and Design Setting Design Cluster N Participants Randomized N	PWD Dementia Characteristics	PWD Non-Disease Char PWD N PWD Age (mean) PWD Sex (% female) PWD Race (% majority) PWD Education (mean years)	PWD Non-Disease Char Reporting Status (RS) PWD SES PWD Prior Disability PWD Household Characteristics PWD Health Insurance PWD Detailed Race Information	Informal Caregiver (IC) Characteristics IC N IC Age (mean) IC Sex (% female) IC Race (% majority) IC Education (mean years IC Relation to PWD (% majority)	Informal Caregiver (IC) Char. RS IC Duration IC Living with PWD IC Payment IC Health Status IC Dementia Family History IC Employment Status IC Training	Formal Caregiver (FC) Characteristics FC N FC Age (mean) FC Sex (% female) FC Race (% majority) FC Education (mean years)tics	Formal Caregiver (FC) Char. RS FC Health Status FC Training FC Education FC Position FC Length of Service	Outcome Timing(s)	PWD Outcomes	Caregiver Outcomes IC: FC:
McCurry 2005[155] (15877554) US Small Sample	Written materials describing age- and dementia-related changes in sleep and standard principles of good sleep hygiene. CG also received specific recommendations for sleep hygiene program for the dementia patient. PWDs to walk daily and increase daytime light exposure with the use of a light box	Control PWD got general dementia education and caregiver support	Community-dwelling RCT 36 PWD	PWDs diagnosed for probable or possible AD with mean MMSE score±SD of 11.8±8.4 and at least one sleep problem on the Neuropsychiatric Inventory Nighttime Behavior scale	N=22 Age: yes Sex: yes Race: yes Education: yes	None	N=22 Age: yes Sex: yes Race: yes Education: yes Relationship: yes	NA	NA	NA	2 months 6 months	total night sleep, percentage of time asleep, number of awakenings, and duration of time awake Light exposure outcomes CESD Daily sleep logs RMBPC	sleep-wake activity PSQI ESS SDQ
McCurry 2003[156] (14511168) US Pilot	Written materials describing age- and dementia-related changes in sleep and standard principles of good sleep hygiene. CG also received specific recommendations for sleep hygiene program for the dementia patient.	Control PWD got general dementia education and caregiver support	Community-dwelling RCT 22 PWD	Dementia diagnosis according to NINCDS–ADRDA criteria for probable or possible AD confirmed in writing by their primary care physicians. With mean MMSE score±SD of 10.7±7.8 and at least one sleep problem on the Neuropsychiatric Inventory Nighttime Behavior scale	N=22 Age: yes Sex: yes Race: no Education: no	None	N=22 Age: yes Sex: yes Race: no Education: no	NA	NA	NA	2 months	sleep-wake activity CESD Daily sleep logs	sleep-wake activity PSQI ESS

Abbreviations: BAGS=Behavior Assessment Graphical System; BEHAVE-AD=Behavioral Pathology in Alzheimer's Disease; BI=Barthel Index; CANE=Camberwell Assessment of Need for the Elderly; CAPE-BRS=Clifton Assessment Procedures for the Elderly-Behavior Rating Scale; CBS=Challenging Behavior Scale; CDR=Clinical Dementia Rating; CESD=Center for Epidemiologic Studies Depression Scale; CMAI= Cohen-Mansfield Agitation Inventory; CSDD=Cornell Scale for Depression in Dementia; DEMQOL=Dementia Quality of Life; DSM=Diagnostic and Statistical Manual; EM=Evidence Map; ESS=Epworth Sleepiness Scale; HADS=Hospital Anxiety and Depression Scale; HSQ-12=Health Status Questionnaire-12; MMSE=Mini-mental State Examination; N=number; NA=Not Applicable; NPI=neuropsychiatric inventory; NR=Not Reported; PAS=Psychogeriatric Assessment Scale; PMID=PubMed Identification Number; PSQI=Pittsburgh Sleep Quality Index; QoL-AD=Quality of Life in Alzheimer's Disease; RAID=Rating for Anxiety in Dementia; RMBPC=Revised Memory and Behavior Problem Checklist; SCI=Sleep Condition Indicator; SDQ=Sleep Disorders Questionnaire; ZBI=Zarit Burden Interview

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