



Guideline Summary NGC-10414

Guideline Title

Clinical guideline for the treatment of primary insomnia in middle-aged and older adults.

Bibliographic Source(s)


University of Texas at Austin School of Nursing, Family Nurse Practitioner Program. Clinical guideline for the treatment of primary insomnia in middle-aged and older adults. Austin (TX): University of Texas at Austin, School of Nursing; 2014 May. 28 p. [63 references]

Guideline Status

This is the current release of the guideline.

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [May 15, 2014 - Eszopiclone \(Lunesta\)](#) : The U.S. Food and Drug Administration (FDA) has notified health professionals and their medical care organizations of a new warning that the insomnia drug Lunesta (eszopiclone) can cause next-day impairment of driving and other activities that require alertness. FDA recommends a decreased starting dose of Lunesta to 1 mg at bedtime. Women and men are equally susceptible to impairment from Lunesta, so the recommended starting dose of 1 mg is the same for both. FDA approved changes to the Lunesta prescribing information and the patient Medication Guide to include these new recommendations. The drug labels for generic eszopiclone products will also be updated to include these changes.

Scope

Disease/Condition(s)

Primary insomnia

Guideline Category

Management

Treatment

Clinical Specialty

Family Practice

Geriatrics

Internal Medicine

Nursing

Psychiatry

Sleep Medicine

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Guideline Objective(s)

To provide evidence-based recommendations for the treatment of primary insomnia in the middle-aged to older adult population in the primary care setting

Target Population

Middle-aged to older adults (45+ years) with primary insomnia

Interventions and Practices Considered

1. Sleep hygiene education
2. Cognitive behavioral therapy (e.g., stimulus control therapy and sleep restriction therapy)
3. Pharmacological interventions
 - Ramelteon
 - Doxepin
 - Non-benzodiazepine hypnotics
 - Mirtazapine
 - Trazodone
4. Non-pharmacological/herbal interventions
 - Exercise
 - Tai chi

Note: The following interventions were considered but not recommended: antihistamines, benzodiazepines, tricyclic antidepressants (with the exception of low-dose doxepin), melatonin, valerian, acupressure/acupuncture, bright light therapy, massage therapy, yoga, tart cherry juice.

Major Outcomes Considered

- Sleep quality and quantity
- Daily functioning
- Quality of Life
- Side effects of therapy

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Searches of electronic databases: PubMed, Medline, Cumulative Index to Nursing and Allied Health Literature (CINAHL) Plus, Cochrane, PsycINFO, PsycARTICLES from 2000 to 2014

Keywords: insomnia, older adult, management

Inclusion criteria: peer reviewed, human studies, primary insomnia, research on treatment of primary insomnia, ages 45+

Exclusion criteria: secondary causes of insomnia, restless leg syndrome, obstructive sleep apnea, depression, dementia, osteoarthritis, pain, bipolar, chronic obstructive pulmonary disease (COPD), stroke, outcomes not client focused, research based on secondary causes of insomnia, residents of long-term care facilities

Additional source data: The National Guideline Clearinghouse (NGC) summary of the American Academy of Sleep Medicine guideline Clinical guideline for the evaluation and management of chronic insomnia in adults (no longer available), the NGC summary of the Health Technology Assessment Unit, Lain Entralgo Agency guideline [Clinical practice guidelines for the management of patients with insomnia in primary care](#), UpToDate, 2012 AGS Beers Criteria, and position statements from the American Association for Geriatric Psychiatry and American Geriatrics Society.

Number of Source Documents

64

Methods Used to Assess the Quality and Strength of the Evidence

Subjective Review

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence (Based on the U.S. Preventive Services Task Force [USPSTF] Ratings)

High: The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.

Moderate: The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as:

- The number, size, or quality of individual studies.
- Inconsistency of findings across individual studies.
- Limited generalizability of findings to routine primary care practice.
- Lack of coherence in the chain of evidence.

As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.

Low: The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:

- The limited number or size of studies.
- Important flaws in study design or methods.
- Inconsistency of findings across individual studies.
- Gaps in the chain of evidence.
- Findings not generalizable to routine primary care practice.
- Lack of information on important health outcomes.

More information may allow estimation of effects on health outcomes.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Journal articles were analyzed for quality based on type of study design, method, number of subjects, representative sample, generalizability of results, and applicability for target population of older adults.

Methods Used to Formulate the Recommendations

Expert Consensus

Informal Consensus

Description of Methods Used to Formulate the Recommendations

Family nurse practitioner (FNP) students developed the guideline via a literature review and analysis.

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations (Based on the U.S. Preventive Services Task Force [USPSTF] Ratings)

A: The USPSTF recommends the service. There is high certainty that the net benefit is substantial.

B: The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.

C: The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.

D: The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.

I: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Family nurse practitioner (FNP) students developed the guideline and submitted it to the University of Texas at Austin FNP faculty for review. Revisions were made and submitted to an external expert source. Final revisions were made based on reviewer recommendations before submission to the guideline review committee.

Recommendations

Major Recommendations

Strength of recommendations (**A, B, C, D, I**) and quality of evidence (**High, Moderate, Low**) are defined at the end of the "Major Recommendations" field.

Behavioral Interventions

Sleep Hygiene Education

Sleep hygiene is broadly defined as universal sleep-promoting behaviors or practices. Patients are educated on behaviors to avoid (i.e., alcohol, caffeine, daytime napping, bright light before bedtime) and the creation of a sleep-conducive environment (i.e. consistent bedtime routine, bed for sleep/sex only). Sleep hygiene is recommended as an initial intervention for all adults with insomnia. However, research does not support its success as a sole line of treatment. Greatest benefit is obtained when sleep hygiene is used as an adjunct therapy (Lichstein & Morin, 2000; Nau et al., 2005; Petit et al., 2003; Roszkowska & Geraci, 2010; Woodward, 2012). (**Grade B, High Evidence**)

Cognitive Behavioral Therapy

Cognitive Behavioral Therapy (CBT) is recommended for first-line treatment of primary insomnia in older adults. Research supports that CBT is moderately effective in the treatment of primary insomnia. Studies have shown that older adults already taking hypnotic medications for chronic insomnia experience improvements in sleep quality when CBT is added to the treatment plan. Common components of CBT are Stimulus Control Therapy (SCT) and Sleep Restriction Therapy (SRT). Evidence suggests that the combination of the two therapies is more effective than SCT or SRT alone. (Belanger, LeBlanc, & Marin, 2012; Bloom et al., 2009; Creti et al., 2005; Epstein et al., 2012; Fetveit, 2009; Irwin, Cole, & Nicassio, 2006; Morin & Benca, 2012; Nau et al., 2005; Soeffing et al., 2008) (**Grade B, High Evidence**)

Pharmacological Interventions

Ramelteon

Ramelteon is recommended for both short- and long-term treatment of primary insomnia in older adults, especially when there is concern of abuse or dependence. Research has shown it to be effective in reducing time to sleep onset. Additionally, evidence shows decreased risk of adverse events that are often associated with hypnotic drugs. (Fetveit, 2009; Mini, Wang-Weigand, & Zhang, 2007; Richardson et al., 2009; Roehrs & Roth, 2012; Roth et al., 2006; Shimazaki & Martin, 2007; Zammit et al., 2009) (**Grade B, High Evidence**)

Doxepin

Low-dose doxepin (1-6 mg) may be used for the treatment of primary insomnia in adults ages 45 to 64 years. Low-dose doxepin (1 mg or 3 mg) may be used for the treatment of primary insomnia in older adults. This recommendation is supported by the *2012 AGS Beers Criteria for Potentially Inappropriate Medications Use in Older Adults*. Low-dose doxepin has few of the anticholinergic side effects of other tricyclic antidepressants and has been shown to be effective and well tolerated. (Krystal et al., 2010; Roth et al., 2007) (**Grade C, Moderate Evidence**)

Non-benzodiazepine Hypnotics

Use of non-benzodiazepine hypnotics, specifically eszopiclone, zolpidem and zaleplon, should be limited to short-term use and used only on a case-by-case basis in the adult and older adult population. This recommendation is supported by the *2012 AGS Beers Criteria for Potentially Inappropriate Medications Use in Older Adults*. Past medical history, social history and benefits versus risks should be evaluated prior to prescribing. (Ancoli-Israel et al., 2010; Boyle et al., 2009; Brandt & Piechocki, 2013; McCrae et al., 2007) (**Grade C, Moderate Evidence**)

Mirtazapine

There is limited evidence-based data on the use of mirtazapine as treatment for primary insomnia. However, for patients with co-morbid depression and certain select populations, such as patients with cancer, it has been shown to be an effective treatment. Given the frequent side effects of increased appetite and body weight gain, it could be especially useful for elderly patients with insomnia who are also experiencing unintentional weight loss. (Bain, 2006; Roth, McCall, & Liguori, 2011; Tariq & Pulisetty, 2008; Wiegand, 2008) (**Grade C, Low Evidence**)

Trazodone

Despite a lack of evidence-based research, trazodone is one of the most widely prescribed medications for management of insomnia. This is likely owing to its sedating qualities, limited anticholinergic properties, and limited potential for addiction and tolerance. However, there have been no long-term studies of trazodone for the treatment of primary insomnia. Short-term studies (six weeks or less) have shown that when prescribed in low doses, it improves both sleep onset and duration without risk of addiction. Potential adverse side effects that should be considered for older adults include excessive daytime sleepiness, dizziness, headaches, and psychomotor impairment. The more rare side effect of priapism has been seen in select populations and should be evaluated when prescribing for men. (Bain, 2006; Bossini et al., 2012; Kamel & Gammack, 2006; Ringdahl, Pereira, & Delzell, 2004; Roth, McCall, & Liguori, 2011; Tariq & Pulisetty, 2008; Wiegand, 2008) (**Grade C, Low Evidence**)

Antihistamines

Antihistamines are not recommended due to a lack of proven efficacy as well as a potential for significant adverse side effects including confusion, urinary retention, and other anticholinergic effects. (Bain, 2006; Tariq & Pulisetty, 2008) (**Grade D, Moderate Evidence**)

Benzodiazepines

Short-, intermediate-, and long-acting benzodiazepines are not recommended for treatment of primary insomnia in adults. The risks of an adverse event such as cognitive impairment, falls, delirium, or fractures generally do not outweigh the benefits. (Buscemi et al., 2007; Glass et al., 2005) (**Grade D, Moderate Evidence**)

Tricyclic Antidepressants

With the exception of low-dose doxepin, tricyclic antidepressants are not recommended for primary insomnia due to a lack of evidence and well-designed studies. Tricyclic agents can have significant side effects including orthostasis, cardiac arrhythmias, and anticholinergic side effects. (Bain, 2006; Roehrs & Roth, 2012; Schneider, 2002) (**Grade D, Moderate Evidence**)

Melatonin

The use of melatonin is not supported due to lack of well-designed studies and evidence. Nonetheless, anecdotal evidence in clinical use has shown it to be effective particularly for those with a history of addiction and delayed sleep

onset. For patients seeking a "natural" remedy over pharmaceuticals, providers should exercise professional judgment and experience in recommending melatonin. (Gooneratne, 2008; MacMahon, Broomfield, & Espie, 2005; Shimazaki & Martin, 2007) (**Grade I, Low Evidence**)

Valerian

Although limited studies on older adults have demonstrated subjective improvement in sleep with the use of Valerian, objective testing demonstrated less consistent results. Valerian is not recommended due to a lack of available standardized form, and the need for additional research. (Gooneratne, 2008; Shimazaki & Martin, 2007) (**Grade I, Low Evidence**)

Non-pharmacological Interventions

Exercise

Exercise can be recommended as a complementary approach to existing therapy as it is low cost, generally safe, and may enhance sleep and quality of life. Timing of exercise is considered important and should be avoided within 2 hours of bedtime. Advise using professional judgment to determine appropriate select patients. (Lichstein & Morin, 2000; Montgomery & Dennis, 2009; Passos et al., 2012; Yang et al., 2012) (**Grade C, Low Evidence**)

Tai Chi

Tai chi can be recommended as a non-pharmacological approach to sleep enhancement for sleep-disturbed elderly individuals. Advise choosing appropriate individuals with professional judgment. (Li et al., 2004) (**Grade C, Low Evidence**)

Acupressure/Acupuncture

Acupuncture and acupressure, especially auricular therapy, demonstrated some improvement in sleep quality in older adults. Additional research is needed. (Gooneratne, 2008; Kim & Sok, 2007) (**Grade I, Low Evidence**)

Bright Light Therapy

There is insufficient evidence to recommend bright light therapy (daily, timed exposure to a bright light to restore normal circadian rhythm) due to limited study and inconsistent findings. (Friedman et al., 2009; Montgomery & Dennis, 2002) (**Grade I, Low Evidence**)

Massage Therapy

Massage therapy has demonstrated an improvement in sleep parameters for older hospitalized patients, but additional research for the general older population is needed. (Gooneratne, 2008) (**Grade I, Low Evidence**)

Yoga

The practice of yoga has demonstrated an improvement in sleep parameters in older adults; however, research on yoga as a treatment intervention for insomnia is limited. (Gooneratne, 2008) (**Grade I, Low Evidence**)

Tart Cherry Juice

A particular tart cherry juice in a small pilot study showed modest beneficial effects on sleep in older adults with insomnia; however, this research was funded by the owner of the studied proprietary cherry juice blend, and further studies are needed. (Pigeon et al., 2010) (**Grade I, Low Evidence**)

Definitions:

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








More information may allow estimation of effects on health outcomes.























Clinical Algorithm(s)

None provided

Evidence Supporting the Recommendations

References Supporting the Recommendations

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Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate treatment of primary insomnia in the middle-aged to older adult population in the primary care setting

Potential Harms

- Mirtazapine has the frequent side effects of increased appetite and body weight gain.
- Trazodone improves both sleep onset and duration without risk of addiction. Potential adverse side effects that should be considered for older adults include excessive daytime sleepiness, dizziness, headaches, and psychomotor impairment. The more rare side effect of priapism has been seen in select populations and should be evaluated when prescribing for men.

Qualifying Statements

Qualifying Statements

- This guideline represents the view of the University of Texas School of Nursing Family Nurse Practitioner students and faculty, which was arrived at after careful consideration of the evidence available.
- This guideline is intended as an aid to decision making in health care. Health care professionals must use their judgment in applying the recommendations to individual patients.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

University of Texas at Austin School of Nursing, Family Nurse Practitioner Program. Clinical guideline for the treatment of primary insomnia in middle-aged and older adults. Austin (TX): University of Texas at Austin, School of Nursing; 2014 May. 28 p. [63 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 May

Guideline Developer(s)

University of Texas at Austin School of Nursing, Family Nurse Practitioner Program - Academic Institution

Source(s) of Funding

University of Texas at Austin, School of Nursing, Family Nurse Practitioner Program

Guideline Committee

Practice Guideline Committee

Composition of Group That Authored the Guideline

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External reviewer: Ashwin Gowda, MD

Financial Disclosures/Conflicts of Interest

None

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: None available.

Print copies: Available from the University of Texas at Austin, School of Nursing. 1700 Red River, Austin, Texas, 78701-1499, Attn: Nurse Practitioner Program.

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on August 6, 2014.

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