# Guideline Summary NGC-10796

## Guideline Title
Combined diet and physical activity promotion programs for prevention of diabetes: Community Preventive Services Task Force recommendation statement.

## Bibliographic Source(s)

## Guideline Status
This is the current release of the guideline.
This guideline meets NGC’s 2013 (revised) inclusion criteria.

## Scope

### Disease/Condition(s)
Type 2 diabetes mellitus

### Guideline Category
Counseling  
Prevention

### Clinical Specialty
Endocrinology  
Family Practice  
Internal Medicine  
Nutrition  
Preventive Medicine

### Intended Users
Advanced Practice Nurses  
Allied Health Personnel  
Dietitians  
Health Care Providers  
Nurses  
Physician Assistants  
Physicians  
Public Health Departments

## Guideline Objective(s)
To provide recommendations on the use of combined diet and physical activity promotion programs to reduce progression to type 2 diabetes in persons at increased risk

## Target Population
Adolescents and adults at increased risk for progression to type 2 diabetes

## Interventions and Practices Considered
Combined diet and physical activity promotion programs

## Major Outcomes Considered
- Incident diabetes  
- Reversion to normoglycemia  
- Body weight  
- Glycemic measures (fasting glucose level, 2-hour glucose level after a 75-g oral glucose tolerance test, or hemoglobin A1c [HbA1c] level)  
- All-cause death  
- Diabetes-related clinical outcomes (such as cardiovascular events, end-stage renal disease, nephropathy, amputation, retinopathy, neuropathy, skin ulcers, or periodontitis)
Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The Task Force commissioned an evidence review that assessed the benefits and harms of programs to promote and support individual improvements in diet, exercise, and weight and supervised a review on the economic efficiency of these programs in clinical trial, primary care, and primary care–referable settings (see the “Availability of Companion Documents” field).

Effectiveness Review

Data Sources
MEDLINE, the Cochrane Central Register of Controlled Trials, CAB Abstracts, Global Health, and Ovid HealthSTAR were searched from 1991 through 27 February 2015 with no language restrictions. Table 1 of the online supplement (see the “Availability of Companion Documents” field) shows the search strategy. The reference lists of related systematic and narrative reviews were also screened and suggestions from the expert panel were considered.

Study Selection
The reviewers included randomized, controlled trials and prospective nonrandomized comparative studies with at least 30 participants per group, as well as prospective single-group intervention studies with at least 100 participants. The population of interest was adults or children at increased risk for type 2 diabetes (that is, with prediabetes) as determined by glycemic measures or diabetes risk assessment tools. They included studies of participants with the metabolic syndrome (who are at increased risk for both diabetes and cardiovascular disease) and studies with participants who were chosen because they were at risk for either type 2 diabetes or cardiovascular disease. However, reviewers excluded studies of participants with established type 2 diabetes or whose only risk factor was obesity or increased risk for cardiovascular disease (without explicit inclusion of participants with prediabetes). The implied or explicit intent of the diet and physical activity promotion programs had to be to prevent diabetes, and the programs had to include at least 2 contact sessions (in-person or virtual) over at least 3 months. Programs had to include both dietary and increased physical activity components and could be conducted in any outpatient setting. The reviewers allowed any type of advice to improve diet and increase physical activity (except for single-food or supplement dietary changes, such as addition of fish oil). Interventions that included antidiabetic medications were excluded. The comparative studies had to include a usual care group (no active diet and physical activity promotion program) or a lower-intensity diet and physical activity promotion program (for example, one with fewer contact sessions or a more liberal diet).

The reviewers required at least 6 months of follow-up for any of the following outcomes: incident diabetes, reversion to normoglycemia, body weight, glycemic measures (fasting glucose level, 2-hour glucose level after a 75-g oral glucose tolerance test, or hemoglobin A1c [HbA1c] level), all-cause death, diabetes-related clinical outcomes (such as cardiovascular events, end-stage renal disease, nephropathy, amputation, retinopathy, neuropathy, skin ulcers, or periodontitis), blood pressure, and lipid levels (total, low-density lipoprotein [LDL], and high-density lipoprotein [HDL] cholesterol and triglycerides).

Titles and abstracts were screened using AbstractCr. Eight researchers double-screened the abstracts after iterative training of all reviewers on the same batches of abstracts. Discordant decisions and queries were resolved at group meetings. Full-text articles were retrieved for all potentially relevant abstracts and rescreened by the same researchers.

Economic Review

Data Sources and Searches
The Cochrane Library, EMBASE, MEDLINE, PsycINFO, Sociological Abstracts, Web of Science, EconLit, and CINAHL were searched for English-language articles published between January 1985 and 7 April 2015. Details of the search strategy are available in the Guide to Community Preventive Services (Community Guide) Web site (www.thecommunityguide.org) and in Appendix Table 1 of the economic review. The reviewers also screened reference lists of relevant studies and reviews and considered studies identified by the parallel review of the effectiveness of diet and physical activity promotion programs.

Study Selection
The reviewers included studies that provided information on program cost; cost-benefit ratio; or incremental cost-effectiveness ratio (ICER), which is measured as dollars per life-year gained (LYG), quality-adjusted life-year (QALY) saved, or disability-adjusted life-year (DALY) averted. Included studies on program cost had to evaluate the actual program implementation cost. Included cost-effectiveness or cost-benefit studies had to meet published criteria for conducting and reporting economic evaluation analysis.

The reviewers used the same inclusion criteria as the aforementioned effectiveness review for study population, intervention, comparison population, and publication language. Criteria included a population at increased risk for type 2 diabetes, based on glycemic measures or risk scores for diabetes, presence of cardiovascular disease, or presence of the metabolic syndrome; intervention with both diet and physical activity components delivered in at least 2 contact sessions over at least 3 months; comparison with a similar population receiving either usual care (standard lifestyle advice) or no intervention for the cost-effectiveness studies; and publication in English. Reviewers further restricted the review to studies in high-income countries to provide economic estimates relevant to U.S. settings and populations.

Number of Source Documents

Effectiveness Review
Appendix Figure 1 of the systematic review (see the “Availability of Companion Documents” field) summarizes the search yield. Of 11,317 citations (plus articles from existing systematic reviews and suggestions from domain experts), 53 studies described 66 diet and physical activity promotion programs in 104 articles. One additional study with 6 major limitations was excluded because of limited quality of execution. The included studies described 26 randomized and 4 nonrandomized comparisons of diet and physical activity promotion programs versus usual care, 12 randomized and 1 nonrandomized comparisons of 2 or more diet and physical activity promotion programs (3 of which also had usual care groups), and 13 single-group evaluations of diet and physical activity promotion programs.

Economic Review
After screening, 28 studies met the inclusion criteria and were included in the final review (see Figure 1 in the economic review (see the “Availability of Companion Documents” field)). Of these, 6 cost-only studies and 6 cost-effectiveness studies provided information on the actual cost of diet and physical activity promotion programs, and 22 contributed cost-effectiveness estimates of the programs. Fourteen studies were U.S.-based. No cost-benefit studies were identified.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence
Not applicable

Methods Used to Analyze the Evidence

- Blood pressure
- Lipid levels (total, low-density lipoprotein [LDL], and high-density lipoprotein [HDL] cholesterol and triglycerides)
- Cost-effectiveness
The Task Force commissioned an evidence review that assessed the benefits and harms of programs to promote and support individual improvements in diet, exercise, and weight and supervised a review on the economic efficiency of these programs in clinical trial, primary care, and primary care–referable settings (see the "Availability of Companion Documents" field).

**Effectiveness Review**

**Data Extraction and Quality Assessment**

Data from each study were extracted by 1 of 7 experienced methodologists and confirmed by a senior methodologist; the same methodologists assessed study quality. Data extraction was conducted in the Systematic Review Data Repository and included elements for study design, including eligibility criteria, population characteristics, detailed descriptions of the diet and physical activity promotion programs and comparison interventions, outcomes, and results.

The reviewers assessed the quality of each study by using 12 Community Guide quality-of-execution questions (see the footnotes of Table 2 of the Supplement; see the "Availability of Companion Documents" field). Per Community Guide protocol, they excluded studies with "limited quality of execution," defined as those with at least 5 major limitations.

**Data Synthesis and Analysis**

All extracted data were placed into summary evidence tables (available in the supporting materials at www.thecommunityguide.org/diabetes/combineddietandpa.html [see also the "Availability of Companion Documents" field]). Two studies that were conducted in children were not included in the meta-analyses and are reported separately. For outcomes with data from at least 3 comparative studies of diet and physical activity promotion versus usual care, reviewers performed meta-analysis of the risk ratio (RR) or net change using a profile likelihood random-effects model. For nonrandomized studies, reviewers preferentially used results of adjusted analyses. Meta-analyses were conducted with the metaan package in Stata 13.1 (StataCorp). For the overall meta-analyses of incident diabetes and reversion to normoglycemia, reviewers used data from the longest reported follow-up. For continuous outcomes, reviewers used data from the longest intervention duration and weight. Differences in effect (for incidence diabetes and weight only) were evaluated using direct comparisons of different diet and physical activity promotion programs within studies, reported within-study subgroup analyses, and across-study metagression (based on predetermined study setting and program features and using a random-effects model) across all programs. Incident diabetes and weight change were chosen for metagression because of their relative importance in determining the effectiveness of diet and physical activity promotion programs. Metagressions were conducted with the metag package in Stata and were considered potentially significant if the P value was less than 0.10. For each outcome with at least 10 studies, reviewers examined the possibility of publication bias with funnel plots and the Harbord test (for diabetes incidence) or the Egger test (for continuous outcomes) using the metabias and metafunnel packages in Stata.

**Economic Review**

**Data Extraction and Quality Assessment**

Two authors extracted data from each article according to the Cochrane systematic review protocol and the Community Guide protocol for economic evaluations.

**Data Synthesis and Analysis**

Intervention costs are reported as program costs per participant, including costs to identify eligible participants (through recruitment in the community, referral from providers, or screening and referral in study settings) and to implement the diet and physical activity promotion program (staff time, training materials, and other costs). The reviewers also generated program costs per participant per session, calculated by dividing program costs per participant by the total number of core and maintenance sessions delivered.

Medians and interquartile intervals (IQIs) of study estimates were reported as summary measures. If there were 4 data points, the range was reported; if there were 3 or fewer data points, all were reported.

Subgroup analyses of intervention costs were done to explore potential factors affecting costs. For delivery setting, each study was grouped into those based on the U.S. DPP (Diabetes Prevention Program) study, in which the intervention was delivered in a clinical trial setting following rigorous procedures as described in study protocols, and those done in real-world settings, in which delivery and physical activity promotion programs were translated to community or primary care settings, with (translational DPP programs) or without (translational non-DPP programs) explicit adaptation of DPP training materials.

For delivery method, each study was categorized into 1 of the following groups: individual-based programs, in which a participant met 1-on-1 with the program provider at each core session; group-based programs, in which the group met as a group with the program provider at each core session; or mixed programs, in which the sessions included both individual and group sessions.

For the type of personnel delivering the program, each study was grouped by whether the program was delivered by health professionals (such as medical staff, physicians, nurses, physical therapists, case managers, or dietitians), trained laypersons (such as certified diabetes educators, lay health educators, trained community health workers, or trained volunteers with type 2 diabetes), or a mix of health professionals and trained laypersons.

Cost-effectiveness estimates were measured as incremental cost-effectiveness ratios (ICERs), with medians and interquartile intervals (IQIs) provided as summary measures. To improve comparability of ICERs across the studies, the reviewers reported them separately by the outcome measures used in different studies: quality-adjusted life-years (QALYs) saved, life-years gained (LYGs), or disability-adjusted life-years (DALYs) averted. For studies found to be cost-saving, reviewers calculated the negative net cost per QALY saved, LYG, or DALY averted whenever possible to calculate the median ICER.

Two economic perspectives were considered: the health system perspective, in which only medical costs and benefits relevant to health systems were considered, and the societal perspective, in which direct nonmedical and indirect costs were also considered. When studies provided sufficient data, ICERs were calculated for perspectives beyond those reported.

As with cost estimates, subgroup analysis of ICERs was done by delivery method. Cost-effectiveness estimates were examined by type of analysis: within-trial analysis, in which ICERs were calculated from data on actual costs and benefits; modeling of a trial over an extension of trials, in which studies used simulation models to estimate program cost and effectiveness during or beyond the trial period; or modeling of the national effect, in which studies estimated ICERs for programs delivered by scaling up programs to the entire country in which the study was conducted.

Because time horizon is important in program planning and budget allocation, ICERs were reported by length of follow-up (short-term [<10 years] or long-term [≥10 years]). In addition, reviewers reported ICERs stratified by country setting (U.S.- or non-U.S.-based) to better inform programs in the United States.

All costs were adjusted to 2013 U.S. dollars by using the Consumer Price Index for medical care services and annual foreign exchange rates from the Federal Reserve Bank for conversion of other currencies. If a study did not mention the year used in cost calculations, costs were assumed to be as of 1 year before the study publication year.

Interventions were considered cost-effective if the ICER was less than $50,000 per QALY saved, less than $50,000 per LYG, or less than the per capita gross domestic product of the relevant country for cost per DALY averted, as recommended by the World Health Organization.

**Methods Used to Formulate the Recommendations**

**Expert Consensus**

**Description of Methods Used to Formulate the Recommendations**

The Community Preventive Services Task Force makes recommendations about community- and system-based interventions, determined by the Task Force to be of public health importance in preventing illness, injury, or premature death. The Task Force bases its recommendations on a systematic review of the evidence on effectiveness and also considers additional benefits, potential harms, and applicability to settings and populations other than those studied. For interventions with evidence of effectiveness, the Task Force also conducts a systematic review of the evidence on economic efficiency, including assessments on program costs, cost-effectiveness, and cost-benefit ratios.

For the recommendations on programs for diabetes prevention, the Task Force commissioned an evidence review that assessed the benefits and harms of programs to promote...
and support individual improvements in diet, exercise, and weight and supervised a review on the economic efficiency of these programs in clinical trial, primary care, and primary care–referable settings (see the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Categories of Task Force Recommendations and Findings

Recommended

The systematic review of available studies provides strong or sufficient evidence that the intervention is effective. The categories of "strong" and "sufficient" evidence reflect the Task Force's degree of confidence that an intervention has beneficial effects. They do not directly relate to the expected magnitude of benefits. The categorization is based on several factors, such as study design, number of studies, and consistency of the effect across studies.

Recommended Against

The systematic review of available studies provides strong or sufficient evidence that the intervention is harmful or not effective.

Insufficient Evidence

The available studies do not provide sufficient evidence to determine if the intervention is, or is not, effective. This does NOT mean that the intervention does not work. It means that additional research is needed to determine whether or not the intervention is effective.

Task Force findings may include a rationale statement that explains why they made a recommendation or arrived at other conclusions.

Cost Analysis

An economic review of 28 studies (search period, January 1985 to April 2015) showed that combined diet and physical activity promotion programs for persons at increased risk for type 2 diabetes are cost-effective. Twelve studies provided information on program costs, including the cost of identifying persons at increased risk for type 2 diabetes (reported in only 4 studies) and the cost of implementing the program. The median cost per participant was $653 (interquartile interval [IQI], $383 to $1160). The wide range in costs was partially explained by variation across programs in the number of sessions, delivery method of the core sessions (individual vs. group), setting (clinical trial vs. community or primary care), and type of personnel used (health professionals vs. trained laypersons).

Twenty-one studies assessed the cost-effectiveness of programs by estimating incremental cost-effectiveness ratios (ICERs) from a health system perspective. The median ICER was $13,761 (IQI, $3067 to $21,899 [16 studies]) per quality-adjusted life-year (QALY). The wide range in ICERs was partially explained by variation in the cost and effectiveness of the programs, program delivery methods, patient follow-up times, and delivery settings. Subgroup analysis of 5 studies that reported ICERs for both individual and group-based programs indicated that the latter were more cost-effective.

Economic evidence indicates that combined diet and physical activity promotion programs to prevent type 2 diabetes among people at increased risk are cost-effective. Twelve studies provided information on program costs, including the cost of identifying persons at increased risk for type 2 diabetes (reported in only 4 studies) and the cost of implementing the program. The median cost per participant was $653 (interquartile interval [IQI], $383 to $1160). The wide range in costs was partially explained by variation across programs in the number of sessions, delivery method of the core sessions (individual vs. group), setting (clinical trial vs. community or primary care), and type of personnel used (health professionals vs. trained laypersons).

See the full report of the economic review for details (see the "Availability of Companion Documents" field).

Method of Guideline Validation

Not stated

Description of Method of Guideline Validation

Not applicable

Recommendations

Major Recommendations

Definitions for the categories of task force recommendations and evidence (recommended, recommended against, or insufficient evidence) are provided at the end of the "Major Recommendations" field.

Summary of Recommendations and Evidence

The Task Force recommends combined diet and physical activity promotion programs for persons at increased risk for type 2 diabetes on the basis of strong evidence of effectiveness in reducing new-onset diabetes. Combined diet and physical activity promotion programs also increase the likelihood of reversion to normoglycemia and improve diabetes and cardiovascular disease risk factors (weight, blood glucose levels, blood pressure, and lipid levels). These programs are effective across a range of counseling intensities, settings, and implementers. Programs commonly include a weight-loss goal, individual or group sessions (or both) about diet and exercise, meetings with a trained diet or exercise counselor (or both), and individually tailored diet or exercise plans (or both). Higher-intensity programs lead to greater weight loss and reduction in new-onset diabetes.

Economic evidence indicates that combined diet and physical activity promotion programs to prevent type 2 diabetes among people at increased risk are cost-effective. A summary of the Task Force findings and rationale can be found at www.thecommunityguide.org/diabetes/combineddietandpa.html.[7]

Definitions

Categories of Task Force Recommendations and Findings

The Task Force uses the terms below to describe its findings.

Recommended

The systematic review of available studies provides strong or sufficient evidence that the intervention is effective.

The categories of "strong" and "sufficient" evidence reflect the Task Force's degree of confidence that an intervention has beneficial effects. They do not directly relate to the expected magnitude of benefits. The categorization is based on several factors, such as study design, number of studies, and consistency of the effect across studies.

Recommended Against

The systematic review of available studies provides strong or sufficient evidence that the intervention is harmful or not effective.

Insufficient Evidence

The available studies do not provide sufficient evidence to determine if the intervention is, or is not, effective. This does NOT mean that the intervention does not work. It means that additional research is needed to determine whether or not the intervention is effective.

Task Force findings may include a rationale statement that explains why they made a recommendation or arrived at other conclusions.

Clinical Algorithm(s)

None provided

Evidence Supporting the Recommendations
Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Findings from a systematic review of 53 studies that described 66 programs demonstrated the effectiveness of combined diet and physical activity promotion programs in reducing the risk for type 2 diabetes, increasing the likelihood of reversion to normoglycemia, and reducing weight among persons at increased risk for type 2 diabetes. Combined programs also were effective at reducing participants' blood glucose levels and blood pressure and improving their lipid levels. The effectiveness of these programs in reducing cardiovascular disease, diabetes-related complications, and death was unclear because few studies reported these outcomes or had results from long-term follow-up. The beneficial effects of combined programs were seen across a wide range of intensity levels.
- In 17 studies that reported blood pressure outcomes and 14 that reported lipid outcomes, programs reduced systolic and diastolic blood pressures and improved lipid levels, including total, low-density lipoprotein, and high-density lipoprotein cholesterol levels and triglyceride levels.
- Although the evaluated programs differed too greatly to draw firm conclusions about the unique contributions of specific components, results from 12 studies that directly compared programs showed that persons who received more intensive programs (based on such features as number of sessions, individual sessions, and additional personnel) lost more weight and were less likely to develop diabetes.

Potential Harms

None of the studies included in this review reported any long-term harms directly related to program participation.

Qualifying Statements

- The Task Force recognizes that a decision to implement an evidence-based intervention involves more consideration than evidence alone. Potential implementers should understand the evidence but customize decision making to the specific populations and settings in which the intervention will be implemented, and take into account relevant constraints (for example, resources).
- Recommendations made by the Task Force are independent of the U.S. government and should not be construed as an official position of the Centers for Disease Control and Prevention or the U.S. Department of Health and Human Services.

Implementation of the Guideline

Description of Implementation Strategy

Considerations for Implementation

In 2010, the U.S. Congress authorized the Centers for Disease Control and Prevention to establish the National Diabetes Prevention Program (DPP). The goal of the program, an alliance of public and private organizations (including insurers), is to achieve widespread implementation and coordination of lifestyle change programs to prevent or delay type 2 diabetes. Several national and state organizations, most of which are part of the DPP, have successfully implemented combined diet and physical activity promotion programs. In 2008, Montana implemented a group session-based adaptation of the program used in the DPP study. The Montana program has had success in line with the DPP study, and more than 4500 adults at high risk for type 2 diabetes have been referred by physicians, recruited, and enrolled into the program since 2008. Of those enrolled, 81% have completed the program and 45% have achieved the program's weight-loss goal of 7%. In 2004, the YMCA began offering an adaptation of the DPP study program that provided participants with low-cost group sessions for 1 year and included 16 weekly core sessions followed by 8 monthly maintenance sessions. In 2010, the YMCA began partnering with health plans to scale up the program, and by 2012 they had reached 46 communities in 23 states and trained 500 lifestyle coaches at a cost of about $400 per program participant. Since 2010, about 16,000 program participants have been enrolled in almost 750 community locations in 39 states. Another example of a successful program working in concert with the principles of the DPP is the Diabetes Prevention demonstration project of the Special Diabetes Program for Indians, which has been implemented in 36 health care programs and serves 80 American Indian and Alaska Native tribes.

Health care providers are usually the primary resource for persons newly diagnosed as being at increased risk for type 2 diabetes. Providers need to be aware of the benefits of combined diet and physical activity promotion programs and of pertinent local programs offered by community centers or run by insurers or nonprofit or other private contractors. The ability to pay for program services can be a barrier for some people. However, many employers provide programs as a covered health benefit, and an increasing number of private insurance companies reimburse for program delivery. Program uptake can increase greatly when health insurers (private or public) cover participation costs. For example, in Montana, the state collaborated with the state Medicaid program to reimburse program sites for services delivered to program participants enrolled in Medicaid. In addition, several organizations provide free online materials for use by programs and participants, including some designed for specific groups (for example, African American faith-based programs). Training materials from successful programs, including the DPP study, are also available online.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need
- Staying Healthy

IOM Domain
- Effectiveness
- Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)


Adaptation

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

Date Released

2015 Sep 15
**Community Preventive Services Task Force**

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**Financial Disclosures/Conflicts of Interest**

Dr. Chin reports a grant from the Merck Foundation outside the submitted work. Authors not named here have disclosed no conflicts of interest. Disclosures can also be viewed at [www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M15-1029](http://www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M15-1029).

**Guideline Status**

This is the current release of the guideline.

This guideline meets NGC’s 2013 (revised) inclusion criteria.

**Guideline Availability**

Available from the [Annals of Internal Medicine Web site](http://www.annals.org/lookup). Additional supporting materials, including the analytic framework, evidence gaps, evidence tables, included studies, and search strategies, are available from the [Community Guide Web site](http://www.thecommunityguide.org/). Additional supporting materials, including the analytic framework, evidence gaps, evidence tables, included studies, and search strategies, are available from the [Community Guide Web site](http://www.thecommunityguide.org/).

**Availability of Companion Documents**

The following are available:


**Patient Resources**

None available

**NGC Status**

This NGC summary was completed by ECRi Institute on December 16, 2015. The information was verified by the guideline developer on January 25, 2016.

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