

# Diabetes Prevention and Control: Combined Diet and Physical Activity Promotion Programs to Prevent Type 2 Diabetes Among People at Increased Risk

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## Task Force Finding and Rationale Statement

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## **Task Force Finding and Rationale Statement**

### **Intervention Definition**

Combined diet and physical activity promotion programs aim to prevent type 2 diabetes among people who are at increased risk of the disease. These programs actively encourage people to improve their diet and increase their physical activity using the following:

- Trained providers in clinical or community settings who work directly with program participants for at least 3 months
- Some combination of counseling, coaching, and extended support
- Multiple sessions related to diet and physical activity, delivered in-person, or by other methods

Programs may also use one or more of the following:

- Providers who are diet counselors of different specialties (for example, nutritionists, dietitians, diabetes educators), exercise counselors of different specialties (for example, physical educators, physiotherapists, trainers), physicians, nurses, trained laypeople, and others
- A range of intensity in the counseling, with numerous or few sessions, longer or shorter duration sessions, and individual or group sessions
- Individually tailored or generic diet or physical activity programs
- Specific weight loss or exercise goals
- A period of maintenance sessions following the primary core period of the program

Program participants may be considered at increased risk of type 2 diabetes if they have blood glucose levels that are abnormally elevated, but not high enough to be classified as type 2 diabetes.<sup>1</sup> Participants may also be identified using diabetes risk assessment tools.

### **Task Force Finding (July 2014)**

The Community Preventive Services Task Force recommends combined diet and physical activity promotion programs for people at increased risk of type 2 diabetes based on strong evidence of effectiveness in reducing new-onset diabetes. Combined diet and physical activity promotion programs also increase the likelihood of reverting to normoglycemia (normal blood sugar) and improve diabetes and cardiovascular disease risk factors, including overweight, high blood glucose, high blood pressure, and abnormal lipid profile.

Based on the evidence, combined diet and physical activity promotion 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.

## Rationale

### Basis of Finding

The Task Force recommendation is based on evidence from a systematic review of 47 studies that described 60 programs (search period 1991 – June 26, 2014). Findings demonstrated the effectiveness of combined diet and physical activity programs in reducing the risk of type 2 diabetes, increasing the likelihood of reverting to normoglycemia, and reducing weight among people at increased risk of type 2 diabetes. These programs also were effective at reducing participants' blood glucose and blood pressure, and improving their lipid levels. The effectiveness of these programs on cardiovascular disease, diabetes-related complications, and death was unclear since few studies reported these outcomes or had long-term follow-up results.

Magnitude of effect estimates, number of studies, and consistency of effects provide the basis for the strong evidence finding (Table). The Table summarizes the data from the 26 studies conducted in adults that compared combined diet and physical activity promotion programs with usual care. One of two studies of adolescents had similar findings that are summarized in the text below. The remaining 19 studies compared more versus less intensive programs or only a single program (all without a usual care group). These are incorporated into the analyses described below.

### Combined Diet and Physical Activity Promotion Programs to Prevent Type 2 Diabetes: Health Outcomes

<b>Outcome (No. of studies)</b>	<b>Summary Effect (95% Confidence Interval) vs. Usual Care</b>	<b>Median Risk Difference</b>
New-onset type 2 diabetes mellitus (14 studies)	Relative risk = 0.58 (0.51, 0.65)*	-11 percentage points (IQI: [-16 to -5])*
Failure to achieve normoglycemia (6 studies)	Relative risk = 0.65 (0.58, 0.73)*	-12 percentage points (IQI: [-6 to -14])*
Weight (21 studies)	Net change = -2.4% (-3.6, -1.2)*	--
Fasting blood glucose (14 studies)	Net change = -2.1 mg/dL (-3.8, -0.5)*	--
2 hour plasma glucose after 75-g glucose load (10 studies)	Net change = -10 mg/dL (-15, -4)*	--
Hemoglobin A1c (8 studies)	Net change = -0.07 percent (-0.12, -0.02)*	--

Outcome (No. of studies)	Summary Effect (95% Confidence Interval) vs. Usual Care	Median Risk Difference
Mortality (3 studies)	Hazard ratio = 0.71 (0.51, 0.99) at 23 years (1 study), but benefit restricted to women; not significant earlier times or in other 2 studies	3 studies: -10 percentage points (23 y) -2 percentage points (11 y) -0.6/1000 person-years (3 y)
CV-mortality (2 studies)	Hazard ratio = 0.59 (0.36, 0.96) at 23 years (1 study), but benefit restricted to women; not significant earlier times or other study	2 studies: -8 percentage points (23 y) -0.2 percentage points (3 y)
Diabetes-related morbidity (3 studies)	Limited evidence‡	
Blood pressure (15 studies)	Systolic blood pressure net change = -2.2 mmHg (-3.3, -1.2)* Diastolic blood pressure net change = -1.7 mmHg (-2.4, -1.1)*	--
Total cholesterol (10 studies)	Net change = -4.4 mg/dL (-7.7, -1.2)*	--
Low density lipoprotein (LDL) cholesterol (8 studies)	Net change = -2.9 mg/dL (-5.5, 0.1)†	--
High density lipoprotein (HDL) cholesterol (8 studies)	Net change = 1.1 mg/dL (0.5, 1.8)*	--
Triglycerides (8 studies)	Net change = -7 mg/dL (-12, -2)*	--

Note: This table summarizes the 26 studies conducted in adults that compared combined diet and physical activity programs with usual care. The two studies conducted in adolescents and the other 19 studies without a usual care group are described in the text.

\* Statistically significant difference favoring program intervention

† Non-significant difference favoring program intervention

‡ Reported outcomes include all-cause mortality (3 studies), cardiovascular death (2 studies), cardiovascular events (2), nephropathy (1), neuropathy (1), and retinopathy (1). A single study reported a statistically significant reduction in severe

retinopathy (hazard ratio = 0.53 [Confidence Interval = 0.29, 0.99]); other outcomes had no significant difference, often due to lack of power (few events).

IQI = Interquartile Interval

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The beneficial effects of combined diet and physical activity promotion programs were seen across programs that used a wide range of intensity levels. The 47 studies evaluated 60 programs that ran from 3 months to 6 years in total. Two programs (in 1 study) ran for 3 months and one program ran for 4 to 6 months; the remainder ran for at least 6 months, with a median of 12 months (interquartile interval [IQI]: 11.5 to 34.5 months). All studied programs included a core period that lasted between 2 months and 5 years, with a median of 6 months (IQI: 5 to 12 months). Among programs with maintenance periods (27 programs), these lasted between 4 and 68 months, with a median of 12 months (IQI: 7 to 26 months). Evaluated programs provided between 3 and 72 sessions, with a median of 13.5 sessions (IQI: 8 to 24 sessions). During the core period, there were between 3 and 72 sessions, with a median of 9 sessions (IQI: 6 to 16 sessions). During the maintenance period, there were between 0 and 42 sessions, with a median of 4 sessions (IQI: 0.5 to 8.5 sessions). In some programs, the maintenance period contacts were by telephone or email only.

With the exception of six programs that were delivered entirely over the internet, by video, or email, programs used a combination of in-person individual and group sessions. Programs offered individual sessions on diet (37 programs) or exercise (38 programs), group sessions on diet (38 programs) or exercise (35 programs), or both individual and group sessions on diet (23 programs) or exercise (22 programs). Sessions were led by different combinations of trained diet counselors including dietitians, nutritionists, or others (35 programs); trained exercise counselors including physical trainers or others (25 programs); nurses (13 programs); physicians or psychologists (9 programs); or trained laypeople (10 programs). Many studies included specific weight loss goals (41 programs), diet goals (30 programs), and physical activity goals (28 programs). Some studies included individually tailored plans for diet (15 programs) and physical activity (22 programs).

Regardless of program features, almost all programs led to weight loss, reduced risk of diabetes, or both.

In 21 studies, the programs used protocols outlined by the U.S. Diabetes Prevention Program (DPP) or Finnish Diabetes Prevention Study (DPS), or modifications of them. Among the studies comparing programs to usual care, participants in DPP- or DPS-like programs had a lower risk of developing diabetes (compared with people who did not participate in the programs) than those in studies of programs not based on DPP or DPS (RR = 0.47 vs. 0.63;  $P < 0.001$ ) and experienced a non-significantly greater weight loss (-2.9% vs. -1.4%;  $P = 0.11$ ). Across all 47 studies, programs that were based on DPP or DPS had similar effects on the risk of developing diabetes as other programs ( $P = 0.21$ ), but they resulted in greater weight loss (-3.3% vs. -1.6%;  $P = 0.056$ ).

While evaluated programs were too different from each other to draw firm conclusions about the unique contributions of specific program components, results from 12 studies that directly compared programs showed that people who received more intensive programs (based on features such as number of sessions, individual sessions, and additional personnel) lost more weight and were less likely to develop diabetes. In contrast, the studies that compared combined diet and physical activity programs with controls had very similar effects on diabetes risk across studies. However, across all studies, programs that provided individual (vs. group) diet sessions resulted in greater reductions in fasting blood glucose (-4.3 vs. -0.3 mg/dL;  $P = 0.022$ ), as did programs that used diet counselors (-4.4 vs. -1.2 mg/dL;  $P = 0.036$ ).

Four studies evaluated programs that were conducted via web-tools, social networking, email, text messaging, video, or a combination of these, with no in-person sessions. One study found smaller, but still significant improvements in weight and blood glucose compared with an in-person program. Two studies found similar effects on weight loss as found in studies with in-person sessions. The fourth study, in adolescents, however, found no effect on weight (although, this was also true for a similar program with group sessions).

Two studies were conducted in adolescents. One found that when compared to a control group, those who participated in twice-a-week group sessions were significantly more likely to revert to normoglycemia, lose weight, and reduce their blood glucose levels and blood pressure (though there were no effects on lipids, except triglycerides). In addition, none of the participating adolescents developed diabetes during the 6 month follow-up period. However, another study in adolescents that evaluated three different programs (web, web and text message, and web and group session programs) found no difference in weight loss compared with control after 6 and 12 months. The study did not report incident diabetes or blood glucose outcomes.

### Applicability and Generalizability Issues

The Task Force finding is considered applicable to a range of settings within or outside the United States; in healthcare or community-based settings; and in urban, suburban, or rural communities.

Included studies were conducted in the U.S. (19 studies), Western Europe (14 studies), other high-income countries (Australia, Japan, and Canada; 9 studies), and middle income countries (India, China, Pakistan, Brazil; 5 studies). Studies were conducted in healthcare settings (23 studies), community settings (18 studies), and other settings (6 studies). None of the studies were conducted in a worksite setting, although one study recruited program participants at a worksite. Individual studies were conducted in multiple geographic regions (17 studies), in urban environments (23 studies), and in suburban, mixed, or unclear settings (7 studies). Two studies were conducted in adolescents at increased risk of type 2 diabetes.

Based on evidence from two of the larger studies (the U.S. DPP and the Finnish DPS), findings are applicable to wide populations across race and ethnicity, socioeconomic status, risk factor status, and other demographic features. Both the DPP and DPS studies found larger effects in older participants; however there were no effect differences based on sex, race, ethnicity, income, or educational attainment.

Based on the two adolescent studies and the pathophysiology of type 2 diabetes, the Task Force finding is considered applicable to adolescents. The disease mechanisms of type 2 diabetes suggest that combined diet and physical activity promotion programs would be effective in reducing risk among young people at increased risk of type 2 diabetes. Although most cases of diabetes in children are due to type 1 diabetes, nearly all cases of diabetes that develop from pre-diabetes (being at increased risk of diabetes) are due to type 2 diabetes. Key aspects of the pathophysiology of type 2 diabetes are similar in individuals of all ages; thus, the programs are likely to be effective regardless of age, assuming the programs are effective at changing children's diet and physical activity.

The effect is applicable across a broad range of diet and physical activity promotion programs that vary by intensity of counseling, deliverers, content of counseling sessions, specific diet and physical activity goals, and different number and duration of sessions. However, programs that include diet or exercise counselors or have longer core phase durations may be more effective.

### **Data Quality Issues**

Of the 47 included studies, 32 were randomized controlled trials, 3 were non-randomized comparative studies, and 12 were single group (non-comparative) studies. The most common limitations affecting this body of evidence were poor descriptions of the study populations, intervention programs, and their components; problems with data measurement or interpretation; and high dropout rates. While half the studies (24) analyzed all enrolled participants, nine had more than 20% drop-out (or loss-to-follow-up) rates. Eleven studies, including the DPP study, had no important limitations.

### **Other Benefits and Harms**

In 13 studies that reported blood pressure outcomes and 9 studies that reported lipid outcomes, the combined diet and physical activity programs lowered systolic and diastolic blood pressure, and improved lipid levels, including LDL cholesterol, HDL cholesterol, triglycerides, and total cholesterol.

Included studies did not report any long-term harms directly related to the combined diet and physical activity promotion programs. In one study (DPP), muscle and joint aches and pains were more commonly reported by those who participated in the program. While it is known that physical activity can lead to minor or major injuries, the risk of major injuries is expected to be low.

### **Economic Evidence**

An economic review of 26 studies (search period January 1985 - July 2014) shows that combined diet and physical activity promotion programs for people at increased risk for type 2 diabetes are cost-effective. All monetary values reported are in 2013 U.S. dollars.

Twelve of the included studies provided information on program costs, defined as the cost of identifying people at increased risk for type 2 diabetes and the cost of implementing combined diet and physical activity promotion programs. They found a median cost per participant of \$652 (IQI: \$383 to \$1,160), and a median program cost per participant per session of \$30 (IQI: \$16 to \$54). The variation in program costs per participant is partly explained by the number of sessions, delivery mode of the core sessions (individual vs. group), setting (clinical trial vs. community or primary care), and type of personnel used (health professionals vs. trained laypeople). Subgroup analyses indicated that program costs per participant were lower for group-based programs (median \$407, IQI: \$335 to \$652; 7 studies) and for programs that translated the intervention tested in the DPP study into community or primary care settings (median \$424, IQI: \$340 to \$793; 8 studies).

Twenty studies assessed the cost-effectiveness of combined diet and physical activity promotion programs by estimating incremental cost-effectiveness ratios (ICER) from the health system perspective. The health system perspective considered only direct medical costs, which included costs associated with program delivery and the medical costs averted from preventing or delaying diabetes and its complications. Included studies reported cost-effectiveness estimates derived from data collected in actual programs or simulation modeling. The median ICER of combined diet and physical activity promotion programs per quality-adjusted life year (QALY) was \$13,367 (IQI: \$2,302 to \$23,327; 15 studies). The variation in ICERs is partially explained by variation in cost and effectiveness of the programs, program delivery modes, patient follow-up times, and delivery settings.

Subgroup analyses of five studies that reported ICER for both individual and group-based programs indicate that group-based programs were more cost-effective. The group-based programs had a median ICER of \$1,819 (IQI: -\$5,028 to \$28,178) per QALY saved. The individual-based programs had a median ICER of \$15,846 (IQI: \$7,979 to \$136,122) per QALY saved.



Two studies reported ICERs of \$21,195 and \$50,707 per disability-adjusted life year averted from the health system perspective. Six other studies reported a median ICER of \$2,684 per life year gained (IQI: -\$2,444 to \$17,410).

### Considerations for Implementation

In 2010, the U.S. Congress authorized CDC to establish the National Diabetes Prevention Program, an alliance of public and private organizations (including insurers) managed by CDC to achieve wide-scale implementation and coordination of lifestyle change programs to prevent or delay type 2 diabetes (Albright & Gregg, 2013). The National Diabetes Prevention Program is not affiliated with the DPP study. As of May 2014, more than 500 organizations in all states and the District of Columbia have applied to CDC for recognition of their diabetes prevention programs. The National Diabetes Prevention Program includes training for program implementers, certifies programs, supports program sustainability, and promotes program resources to people at high risk of type 2 diabetes and health care professionals. More information about the National Diabetes Prevention Program can be found at [www.cdc.gov/diabetes/prevention](http://www.cdc.gov/diabetes/prevention).

Combined diet and physical activity promotion programs have been successfully implemented by several national and state-wide organizations, the majority of which are part of the National Diabetes Prevention Program. The state of Montana and the YMCA both have programs that are being coordinated with, and are in the process of receiving recognition from, the National Diabetes Prevention Program. In 2008, the state of Montana implemented a group session-based adaptation of the program used in the DPP study. The Montana program has experienced success in line with the DPP study, and since 2008, more than 4,500 adults at high-risk of type 2 diabetes have been referred by physicians, recruited, and enrolled into the program. Of those enrolled in the program, 81% have completed the program and 45% achieved the program's 7% weight loss goal (Vanderwood et al., 2010).

In 2004, the YMCA began offering an adaptation of the DPP study program that provided participants low-cost group sessions for 1 year and included 16 weekly core sessions followed by 8 monthly maintenance sessions (Ackermann & Marrero, 2007). 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 (Vojta et al., 2013). 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 National Diabetes Prevention Program is the Special Diabetes Program for Indians diabetes prevention demonstration project, which has been implemented in 36 healthcare programs and serves 80 American Indian and Native Alaskan tribes (Jiang et al., 2013).

Healthcare providers are usually the primary resources for individuals newly diagnosed as being at increased risk of type 2 diabetes. Providers need to be aware of the benefits of combined diet and physical activity promotion programs and of local programs, which may be offered by community centers, insurer-run programs, or non-profit or other private contractors among others.

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. Health insurers (private or public) that cover participation costs may greatly increase program uptake. In Montana, the state collaborated with the State Medicaid Program to reimburse program sites for services delivered to program participants enrolled in Medicaid.



Many of the organizations that have successfully implemented programs have made program materials available online, including some designed for specific groups (e.g., African-American faith-based programs). Training materials from successful programs, including the DPP study, are also available online.

Organizations implementing combined diet and physical activity promotion programs may want to address factors that make it difficult for some people to participate. Examples include limited time to cook or exercise due to work schedules or childcare needs; limited access to inexpensive and healthful food, safe and convenient places to exercise and transportation there; and cognitive or physical disabilities.

### Evidence Gaps

Several areas would benefit from additional research on the effectiveness of combined diet and physical activity promotion programs. Future research should aim to do the following:

- Assess potential differences in the effectiveness of specific programs in different populations (e.g., by race, SES, educational attainment, age, cognitive or physical disabilities)
- Study the effectiveness of programs delivered via the Internet, email, apps, or social networking
- Assess the relative effectiveness of individual and group sessions
- Identify effective structures for the maintenance phase of these programs to help program participants continue their improvements to diet and physical activity following completion of the programs' core phase
- Conduct long-term follow-up of community-based programs to evaluate the durability of the programs' effect on diabetes incidence, weight loss, other diabetes risk factors, morbidity, and mortality
- Determine attrition rates, understand the reasons program participants drop out, and develop methods to retain them in the programs

Regarding economic analyses, more evidence is needed on the costs and benefits of programs implemented in community or primary care settings based on actual data, including findings on cost-effectiveness, cost-utility, and cost-benefits. It would be especially useful to have more information about group-based programs delivered by trained laypeople in community settings.

Studies also should evaluate costs associated with recruiting eligible individuals to participate, which may be expensive in both clinical and community settings. More rigorous research is needed to better understand costs associated with program implementation and ways to further lower them in community or primary care settings, including start-up costs, costs of delivery by program duration and setting, and costs to different stakeholders and society as a whole. To better understand long-term economic benefits of the program, research should assess actual health care expenditures averted in total, and by expenditure category. Ideally this would be done by following an intervention cohort and its comparison group for a longer period of time.

*The data presented here are preliminary and are subject to change as the systematic review goes through the scientific peer review process.*

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### Disclaimer

The findings and conclusions on this page are those of the Community Preventive Services Task Force and do not necessarily represent those of CDC. Task Force evidence-based recommendations are not mandates for compliance or spending. Instead, they provide information and options for decision makers and stakeholders to consider when determining which programs, services, and policies best meet the needs, preferences, available resources, and constraints of their constituents.

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