Community Preventive Services Task Force

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

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.[1] Participants may also be identified using diabetes risk assessment tools.

[1]People are classified as being at increased risk of type 2 diabetes if their blood glucose levels are abnormally elevated but still below the threshold for the disease. People at increased risk of diabetes have hemoglobin levels between 5.7% and 6.4%, fasting plasma glucose between 100 and 125 mg/dL, or plasma glucose between 140 and 199 mg/dL after a 75 gram oral glucose tolerance test (American Diabetes Association, 2010). When measures of blood glucose are not available, validated predictive diabetes risk scores may be used to identify people at increased risk.

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 53 studies that described 66 programs (search period 1991 – February 2015). 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 28 studies conducted in adults that compared combined diet and physical activity promotion programs with usual care. Two additional studies comparing programs to usual care in adolescents had similar findings and are summarized in the text below. The remaining 23 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

Outcome (No. of studies)	Summary Effect (95% Confidence Interval) vs. Usual Care	Median Risk Difference
New-onset type 2 diabetes mellitus (16 studies)	Relative risk = 0.59 (0.51, 0.66)*	-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 (24 studies)	Net change = -2.2% (-2.9, -1.4)*	- -
Fasting blood glucose (17 studies)	Net change = -2.2 mg/dL (-3.6, -0.9)*	- -
2 hour plasma glucose after 75-g glucose load (11 studies)	Net change = -8.6 mg/dL (-15.5, -3.1)*	- -

Outcome (No. of studies)	Summary Effect (95% Confidence Interval) vs. Usual Care	Median Risk Difference
Hemoglobin A1c (8 studies)	Net change = -0.08 percent (-0.12, -0.04)*	- -
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 (6 and 20 years) or in other 2 studies (3 and 10 years)	3 studies: -10 percentage points (23 years) -2 percentage points (10 years) -0.6/1000 person-years (3 years)
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 (6 and 20 years) or other study (3 years)	2 studies: -8 percentage points (23 years) -0.2 percentage points (3 years)
Diabetes-related morbidity (3 studies)	Limited evidence†	
Blood pressure (17 studies)	Systolic blood pressure net change = -1.6 mmHg (-2.7, -0.5)* Diastolic blood pressure net change = -1.6 mmHg (-2.5, -0.8)*	- -
Total cholesterol (12 studies)	Net change = -1.8 mg/dL (-4.6, -0.1)*	- -
Low density lipoprotein (LDL) cholesterol (8 studies)	Net change = -3.3 mg/dL (-6.4, 0.3)*	- -

Outcome (No. of studies)	Summary Effect (95% Confidence Interval) vs. Usual Care	Median Risk Difference
High density lipoprotein (HDL) cholesterol (12 studies)	Net change = 1.2 mg/dL (0.7, 1.7)*	- -
Triglycerides (8 studies)	Net change = -6.5 mg/dL (-12.7, -1.8)*	- -

Note: This table summarizes the 28 studies conducted in adults that compared combined diet and physical activity programs with usual care. The two studies conducted in adolescents and the other 23 studies without a usual care group are described in the text.

* Statistically significant difference favoring program intervention

† Reported outcomes include all-cause mortality (3 studies), cardiovascular events (3), cardiovascular death (2 studies), 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 differences, often due to lack of power (few events).

IQI = Interquartile Interval

The beneficial effects of combined diet and physical activity promotion programs were seen across programs that used a wide range of intensity levels. The 53 studies evaluated 66 programs that ran from 3 months to 6 years in total. Five programs (in 4 studies) ran for periods of less than 6 months; the remainder ran for 6 months or longer and overall median program length was 12 months (interquartile interval [IQI]: 10 to 27 months). Programs included a core period that lasted between 1 month and 5 years, with a median of 6 months (IQI: 5 to 12 months). Among programs with maintenance periods (28 programs), these lasted between 4 and 68 months, with a median of 12 months (IQI: 7 to 18 months). Evaluated programs provided between 0 (virtual sessions only) and 72 sessions, with a median of 15 sessions (IQI: 6.5 to 24.5 sessions). During the core period, there were between 0 (virtual sessions only) and 72 sessions, with a median of 10 sessions (IQI: 6 to 16 sessions). During the maintenance period, there were between 0 (virtual sessions only) and 24 sessions, with a median of 6 sessions (IQI: 1.5 to 12 sessions). In some programs, the maintenance period contacts were by telephone or email only.

With the exception of seven programs that were delivered entirely over the internet, by video, email or telephone, programs used a combination of in-person individual and group sessions. Programs offered individual sessions on diet (40 programs) or physical activity (41 programs), group sessions on diet (41 programs) or physical activity (39 programs), or both individual and group sessions on diet (24 programs) or physical activity (24 programs).Sessions were led by different combinations of trained diet counselors including dietitians, nutritionists, or others (37 programs); trained exercise counselors including physical trainers or others (26 programs); nurses (15 programs); physicians or psychologists (8 programs); or trained laypeople (13 programs). Many studies included specific weight loss goals (42 programs), diet goals (19 programs), and physical activity goals (32 programs). Some studies included individually tailored plans for diet (16 programs) and physical activity (23 programs).

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

In 27 studies, the programs explicitly 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, incident diabetes risk reduction was similar in studies that did or did not explicitly use DPP- or DPS-like programs, but participants in DPP- or DPS-like programs had near-significantly greater weight loss than those in other programs (-3.0% vs. -1.6%; P=0.051).

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 studies, programs that included individually tailored exercise plans had a possibly greater reduction in diabetes risk (compared to usual care) than programs that did not (relative risk incident diabetes 0.53 vs. 0.67, P = 0.070). Across all studies, programs that provided individual (vs. group) diet sessions resulted in greater reductions in fasting blood glucose (-4.3 vs. -0.4 mg/dL; P=0.020), as did programs that used diet counselors (-4.5 vs. -1.3 mg/dL; P=0.034).

Five 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. One study in India found that an intervention relying on text messages was effective compared to usual care in reducing incident diabetes, but found no effect on weight loss. Two studies found similar effects on weight loss as found in studies with in-person sessions. The fifth 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 or between the more and less intensive interventions 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. (21 studies), Europe (17 studies), other high-income countries (Australia, Japan, and Canada; 9 studies), and middle income countries (India, China, Pakistan, Brazil; 6 studies). As reported, studies were conducted in healthcare settings (25 studies), community settings (12 studies), and other settings (4 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 (21 studies), in urban environments (25 studies), and in suburban, rural, or mixed 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 53 included studies, 35 were randomized controlled trials, 5 were non-randomized comparative studies, and 13 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 (27) analyzed all enrolled participants, nine had more than 20% drop-out (or loss-to-follow-up) rates. Six studies, including the DPP study, had no important limitations.

Other Benefits and Harms

In 17 studies that reported blood pressure outcomes and 14 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 28 studies (search period January 1985 - April 2015) showed 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, primarily costs attributable to program implementation and delivery, though 4 of these studies also reported the cost of identifying people at increased risk for type 2 diabetes. They found a median cost per participant of $653 (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 $417, IQI: $341 to $600; 8 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-one 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 $13,761 (IQI: $3,067 to $21,899; 16 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: -$5,027 to $16,443) per QALY saved. The individual-based programs had a median ICER of $15,846 (IQI: $7,980 to $72,723) 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.

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 heath 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..

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