Lifestyle Intervention for the Prevention of Type 2 Diabetes: Translation and Future Recommendations

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The effectiveness of lifestyle intervention for the prevention of type 2 diabetes has recently been demonstrated. Four clinical trials using lifestyle interventions comprised of weight loss, physical activity, and diet have successfully prevented or delayed the onset of diabetes development in high-risk individuals. As we attempt to translate these results from the clinical trial to the community, it is important to understand the various components of the lifestyle intervention efforts used. After a description of the key lifestyle components of these clinical trials is provided, a discussion of possible suggestions for implementing these findings in the broader community setting is presented.

Introduction

The role of lifestyle intervention in the prevention of type 2 diabetes has recently been demonstrated in several clinical trials involving individuals at high risk for the disease [1,2,3•,4••]. Never before have we been able to document a decrease in the development of diabetes through diet, physical activity, and weight loss intervention. A brief description of each of these four clinical trials is provided, followed by a discussion of the implications for the translation of these lifestyle interventions.

Malmo, Sweden

This 6-year feasibility study originated from screening programs in men carried out between 1974 and 1985, from which 260 men were identified with impaired glucose tolerance (IGT). A diet and physical activity program was offered to these men, of which 181 chose to participate and 79 did not, the latter serving as the reference group. One limitation of this study was that the men were not randomly assigned to the treatment conditions. Another limitation was that the two arms of the trial differed at baseline by medical condition [1].

Compared to the reference group, men who participated in the intervention had higher mean maximal oxygen uptake values, decreased body weights, and lower 2-hour insulin and glucose concentrations taken over the entire study period. The incidence of diabetes development at the 5-year follow-up for men participating in the lifestyle intervention was less than half of what was found in the reference group (10.6% vs 28.6%) [1].

Lifestyle intervention

Participants who were overweight were asked to reduce their weight, although no specific weight loss goal was provided [1]. The diet goals were to reduce calories if overweight, reduce saturated fat, substitute polyunsaturated fat for saturated fat when possible, and to reduce simple sugars and increase complex carbohydrates [5]. The physical activity goal was two 45- to 60-minute sessions per week of moderate intensity activities, which included walking, jogging, calisthenics, soccer, and badminton. The more intense physical activities were not a major part of the intervention until late in the training period.

At baseline, a physician and a dietitian met with the men and their wives to provide diet and activity information. After initial instruction, participants could opt to follow the diet and exercise program on their own or in organized groups of 10 to 15 once per month. Sixty-eight participants (38%) followed the protocol as organized groups, consisting of a 6-month period of supervised physical training followed by a 6-month period of dietary treatment, or vice versa. After 12 months, the participants could either follow the protocol on their own or together with previous group partners.

Specific changes in diet outcomes were not reported. The estimated maximal oxygen uptake averaged over the entire study period was significantly higher for the intervention group than for the reference group, suggesting that the activity intervention was successful. At 1 year, the mean weight loss was greater than 6 kg (a 7% weight loss), and at 6-year follow-up the mean weight loss was 3.3 kg. This study found a 63% reduction in the incidence of diabetes in the intervention group compared to the reference group [1].

Da Qing, China

A total of 110,660 men and women, aged 25 and older, from 33 area health clinics in Da Qing were screened, of which 577 were identified as having IGT. Eligible participants with IGT were then randomized by clinic into one of four groups: physical activity, diet, diet and physical activity, or to the control group [2].

The cumulative incidence of diabetes at the end of 6 years among the 530 individuals who completed the study was significantly lower in each of the three intervention groups compared with the control group. Adjusted for baseline body mass index (BMI) and fasting glucose, the risk reduction associated with the diet and physical activity intervention was 31% for diet alone, 46% for physical activity alone, and 42% for diet and physical activity combined [2].

Lifestyle intervention

Both the weight loss and diet goals were based on each individual's initial BMI [2]. There was no weight loss goal for lean participants (BMI < 25), whereas for participants with a BMI greater than 25, the goal was to lose 0.5 to 1 kg/mo until a BMI of 23 was achieved. The diet goals for lean participants were 25 to 30 kcal/kg, 55% to 65% carbohydrate, 10% to 15% protein, and 25% to 30% fat, with a focus on more vegetables, less simple sugars, and controlling alcohol intake. Alternatively, participants with a BMI greater than 25 received individualized calorie targets based on initial weight and an exchange-type diet itemizing the number of servings to consume each day from cereals, vegetables, meat, milk, and oils.

The physical activity goal was to increase leisure physical activity by a minimum of 1 U/d. One unit of leisure physical activity was defined as either 5 minutes of very strenuous activity, 10 minutes of strenuous activity, 20 minutes of moderate activity (brisk walking), or 30 minutes of mild activity. Progression and type of physical activity that was recommended depended on age, past exercise patterns, and the existence of health problems other than IGT; however, walking was emphasized [2].

Participants in the diet and diet plus exercise intervention groups received individual nutrition counseling sessions with a physician at baseline and every 3 months thereafter. In addition, they received counseling sessions in small groups weekly for 1 month, monthly for 3 months, and once every 3 months thereafter.

At baseline, the diet intervention group was consuming an average of 2485 kcal/d, 60% carbohydrate, 11% protein, 26% fat, and 3 g of alcohol per day. The baseline diet of the diet plus exercise group was similar. At follow-up assessment, there was no significant difference in calories, in percent of calories from carbohydrate, protein, and fat, or in alcohol intake in the diet or diet plus exercise intervention groups. This may be due to the imprecision of the diet assessment instrument or because the lean participants in either of the diet groups may not have changed their intake or composition of their diet because they were already adhering to the recommended diet prescription at baseline. Similarly, there was no significant change in BMI in the lean participants. The lean participants in the diet only intervention group did not experience a lower incidence of diabetes compared to the control group. In contrast, the overweight participants in the diet and diet plus exercise groups were prescribed weight loss targets, had reductions in BMI, and did experience significantly lower diabetes incidence rates than the overweight control group [2].

Both the physical activity and the diet and activity groups appeared to increase their units of leisure activity reported per day at follow-up, compared to baseline values, whereas the two nonexercising groups did not. There was a significantly lower incidence rate of diabetes in both activity arms for lean and for overweight individuals alike [2].

Finnish Diabetes Prevention Study

Eligible subjects were recruited from five study centers through the screening of high-risk groups and randomized to either the diet and activity intervention or the control arm [3•]. A total of 523 overweight (BMI of 25 kg/m^2 or higher) men and women with IGT, aged 40 to 65 years, participated.

Over the 4-year study, 86 individuals (27 in the intervention and 59 in the control group) developed diabetes. The cumulative incidence of diabetes was 11% in the intervention group and 23% in the control group. These findings resulted in a 58% reduction in diabetes for those individuals who participated in the lifestyle intervention arm of the trial ($P < 0.001$) [3•].

Lifestyle intervention

Participants had the same weight loss and diet goals regardless of initial BMI. The weight loss goal was to lose greater than 5% of initial body weight. The nutrition goals were to reduce calories to achieve the weight goal, decrease total fat to less than 30% of calories, decrease saturated fat to less than 10% of calories, and increase dietary fiber to at least 15 g per 1000 cal/d [3•]. Participants who received the lifestyle intervention had seven sessions with a nutritionist in the first year and one session every 3 months thereafter.

The physical activity goal was to perform a minimum of 30 minutes of moderate physical activity per day. Each participant was also given individual guidance for increasing physical activity levels and endurance exercise was recommended. To improve functional capacity and the strength of large muscle groups, supervised circuit-type resistance training sessions were offered to participants in the intervention group [3•].

The participants in the intervention group lost 4.2 kg (4.7%) at year 1 and 3.5 kg at year 2. After the first year, 43% of intervention participants had achieved the weight loss goal, 47% achieved the fat intake goal, 26% achieved the saturated fat intake goal, and 25% had achieved the fiber intake goals. The changes in calorie, fat, saturated fat, and fiber intake from baseline were not reported [3•].

Information about adherence to the physical activity portion of the intervention has to be assumed from questions

regarding the self-reported change in physical activity habits at 1 year. A total of 36% of the intervention arm compared to 16% of the control arm reported increasing their physical activity levels ($P < 0.001$), as determined by a reported shift to a higher physical activity category. Likewise, the percent of subjects who reported nonsedentary activity levels was greater in the intervention group than in the control group (86% vs 71%) [3•]. There was a 58% reduction in diabetes observed in those individuals who participated in the lifestyle intervention arm of this study ($P < 0.001$) [3•].

Diabetes Prevention Program

The Diabetes Prevention Program (DPP) was a randomized clinical trial of diabetes prevention in 3234 overweight men and women with IGT ranging in age from 25 to 85 years across 27 US sites. Of the participants who were enrolled in the DPP, 68% were women and 45% represented minority groups. Eligible participants were randomly assigned into one of three groups: standard lifestyle recommendations plus metformin, standard lifestyle recommendations plus placebo, or lifestyle modification [4••].

Study participants were followed for an average of nearly 3 years, at which point the incidence of diabetes was found to be 11.0, 7.8, and 4.8 cases per 100 person-years in the placebo, metformin, and lifestyle groups, respectively. Participants randomly assigned to receive the lifestyle intervention reduced their risk of developing type 2 diabetes by 58%, faring much better than those randomized to either the metformin or placebo groups. This decrease in the development of diabetes for individuals randomized to the lifestyle intervention arm was similar in both men and women and held across all age and ethnic groups [4••].

Lifestyle intervention

In the DPP, the weight loss goal for lifestyle intervention participants was to lose greater than 7% of initial body weight [4••,6••]. Calorie and fat gram goals were selected based on initial body weight and were designed to achieve a weight loss of 1 to 2 lb/wk and a diet with 25% of calories from fat. The goal of the physical activity portion of the intervention was 150 min/wk of moderate activity similar to that of a brisk walk.

Lifestyle coaches met individually with participants to review a 16-session "core curriculum" that focused on diet, physical activity, and behavioral modification strategies that was to be presented over the course of 6 months. The minimum frequency of follow-up for lifestyle participants was at least once every 2 months in person with an alternate monthly contact via phone or e-mail; however, participants could also be followed as often as weekly if needed. If participants were not meeting study goals, then lifestyle coaches used a variety of toolbox strategies to address specific barriers to adherence. In addition to individual follow-up sessions, participants were offered "after core" group classes and motivational campaigns three times per year to provide peer support and help sustain progress with lifestyle changes [4••,6••,7].

The proportion of the lifestyle intervention participants who reported meeting the weekly activity goal based on the activity logs was 74% at the completion of the 24-week curriculum and 58% at the end of the clinical trial. In addition, the change from baseline in reported leisure physical activity was significantly higher over the 4 years of intervention for the lifestyle intervention group compared to the other two treatment arms [4••,8].

Likewise, after completion of the 16-session core curriculum, 50% of lifestyle participants had achieved the weight loss goal. At 1 year, they had reduced calorie intake by an average of 450 kcal and reduced fat intake by 6.6%. At study end, lifestyle participants had a mean weight loss of 5.6 kg (5%), with 38% of participants maintaining at least a 7% weight loss. The DPP lifestyle intervention group had a 58% reduced incidence of type 2 diabetes [4••].

Lifestyle Goals of These Clinical Trials

Diet

All of the lifestyle interventions focused on a diet low in fat (< 30% of calories from fat), high in vegetables and fiber, and moderate in alcohol (Table 1). Most of these lifestyle interventions focused on calorie targets to promote weight loss except for the Da Qing study, in which lean participants were given calorie targets for weight maintenance. Interestingly, only the DPP reported any change in diet due to the intervention.

Weight loss

Both weight loss goals and initial BMI eligibility criteria varied across these studies (Table 1). In the Malmo and the Da Qing studies, BMI was not a criterion for entry eligibility. In the Malmo study, weight loss was recommended but no specific goal was set. In the Da Qing study, if a participant's BMI was less than 25, a weight loss goal was not prescribed. The lean Da Qing participants in the diet alone intervention did not appear to make any significant changes in the macronutrient composition of their diets, did not lose weight, and did not experience a reduction in diabetes incidence compared to the control group. In contrast, the Finnish Diabetes Prevention Study (DPS) and DPP had both BMI eligibility criteria and weight loss goals set. In the DPS, individuals had to have an initial BMI of 25 or greater in order to be eligible for entry into the study and were given a 5% weight loss goal. The DPS documented a significant weight loss in the intervention arm of the study. Alternatively, in the DPP eligible participants had to have a BMI of at least 24 kg/m^2, except for Asian-Americans who were eligible with a BMI greater than 22 [4••]. The DPP lifestyle intervention, which aimed for a 7% weight loss regardless of initial BMI, was equally effective in all ethnic groups and at all levels of baseline BMI.

Physical activity

The activity goals of these four clinical trials (Table 1) were similar to the national public health recommendations [8,9], which calls for moderate levels of physical activity, such as walking for approximately 30 minutes on most days of the week. The type of activity recommended was aerobic (although the Finnish study also incorporated strength training in the regimen) and consisted primarily of brisk walking. In regard to the weekly activity goal, all but the Finnish trial recommended a goal of between 120 to 150 min/wk. (The most prevalent activity in the Da Qing trial was walking and a brisk walk was to be carried out 20 min/d or 140 min/wk). In contrast, the Finnish DPS recommended 30 min/d (210 min/wk), although the actual weekly minutes performed by the participants in this trial have not yet been determined.

Conclusions and Future Directions

There is evidence-based support for a lifestyle intervention that focuses on weight loss, physical activity, and diet intervention to prevent type 2 diabetes. In general, in the four clinical trials that have been summarized here the weight loss goal was around 5% to 7% of initial body weight, with a physical activity goal of at least 150 to 200 min/wk of moderate aerobic activity, and a diet goal that was low in fat (< 30% of calories from fat, < 10% saturated fat) and high in vegetables and fiber.

The obvious next question then becomes the following: Are these goals appropriate or should they be modified based on what we have learned? Although there has not been any diabetes prevention efforts examining the effects of variations of these weight loss, diet, and activity goals on diabetes prevention, it is likely that the most effective combination of these three goals that should be recommended for a specific individual will vary by the individual in question. In other words, someone relatively active will likely benefit most from the nutrition part of a lifestyle intervention and visa versa. Someone overweight should obviously work toward a weight loss goal, whereas their normal weight counterpart may benefit the most from an activity program to beneficially alter fat distribution. Results from the Da Qing study suggested this very thing. Lean individuals in the diet only arm were not given a weight loss goal and did not decrease their incidence of diabetes. In contrast, lean individuals in the activity only arm were given an activity goal and did have a significantly lower incidence of diabetes over time.

Weight losses of as little as 2.3% at 5 years seem to have benefits in diabetes risk reduction [1]. In the DPP, every 1 kg of weight lost was associated with a 13% risk reduction in type 2 diabetes [4••,10]. A low-fat, low-calorie diet with calorie targets based on initial weight and a limit of 25% to 30% of total calories from fat is conducive to a weight loss of 1 to 2 lb/wk. In the DPP, this resulted in calorie targets between 1200 and 2000 calories and fat gram intake goals from 33 to 55 g/d. Most research also supports increased fiber intake, especially with increased vegetable consumption, because this can help people feel satiated on lower calorie levels. Unfortunately, these clinical trials do not provide evidence-based results regarding the macronutrient composition of the diet for those who are lean. However, the DPP results suggested that a lifestyle intervention that included weight loss may still be beneficial for Asian Americans and possibly others who have relatively lower BMIs (*ie,* the BMI inclusionary criteria of 22 used for Asian Americans in the DPP).

Because physical activity produces beneficial changes in body mass and body composition and improves insulin sensitivity, adequate activity levels are important in the individual at high risk for diabetes regardless of whether weight loss is recommended or not [11]. The physical activity component of the intervention should be gradual in progression, flexible to suit the needs of the individual, and rooted in safety. In lifestyle efforts in which both weight loss and increases in activity are needed, it makes sense that the diet component be introduced first followed by the activity component because diet appears to be most important to weight loss and activity most important to weight maintenance.

In conclusion, we know how to help individuals make beneficial lifestyle changes. The process of lifestyle intervention in these studies involved goal setting with simple, clear, individually tailored goals; self-monitoring of these goals; the use of coaches and other participants to provide support; and frequent contact during the maintenance phase. In addition, lifestyle coaches in the DPP taught participants to use a problem-solving approach to manage high-risk situations and to deal with barriers to lifestyle change. What becomes difficult is helping our participants sustain these lifestyle changes over the long term, after the frequent contact from our staff ends. Future research needs to focus on translating the intervention efforts that have been shown to be effective in these clinical trials to that which would work in the community setting with less manpower and a smaller budget. A key translation issue is the role of the health care setting within a community in providing affordable lifestyle intervention and follow-up contact needed to sustain these efforts for its community members.

Diabetes Prevention Program lifestyle materials are available online at http://www.bsc.gwu.edu/dpp/manuals.htmlvdoc and the features of the lifestyle process have been described [6••,12]. In addition, the National Diabetes Education Program has launched a translation initiative "Small Steps. Big Rewards. Prevent Type 2 Diabetes" to help translate the DPP lifestyle change program into clinical practice (http://www.ndep.nih.gov).

Table 1. Description of the weight loss, nutrition, and physical activity interventions used in type 2 diabetes clinical trials

Clinical trial	WL goal	Diet goals	Activity goal (type)	Activity goal (F/I/T)	Change in WL	Change in diet/activity	RR
Malmo study [1]: 181 M, 0 F	WL suggested but no specific goal set	Reduce calories, saturated fat, and simple sugars; increase complex carbohydrates	Aerobic (walk), jog, soccer, calisthenics, and badminton	Moderate (more intensive activity performed late in training); two weekly, 60-min sessions	WL: confirmed WL > 6 kg at 1 y and 3.3 kg at 5 y	Diet: not reported Activity: significant increase in mean oxygen uptake values based on submaximal bicycle ergometer test	63%
Da Qing study [2]: 210 M, 187 F	If BMI < 25: no WL goal If BMI ≥ 25: lose 0.5 to 1.0 kg/mo to BMI of 23	If BMI < 25: 25–30 kcal/kg, 55% to 65% carbohydrates, 10% to 14% protein, 25% to 30% fat, more vegetables, less simple sugars, control alcohol If BMI ≥ 25: individualized calorie targets, exchange-type diet	Aerobic (ranging from slow walking to running), swimming, and basketball	Mild to strenuous intensity; 1 unit/day, time dependent on intensity. Most individuals did brisk walking for 20 min/d	WL: inconclusive WL, varies by intervention group and DM status Diet only: +0.93 kg (no DM); -2.43 kg (DM) Exercise only: +0.71 kg (no DM); -1.93 kg (DM) Diet and exercise: -1.77 kg (no DM); -3.33 kg (DM)	Diet: no significant change in calories/macronutrient profile Activity: significant increase in reported average units per day of exercise	Diet: 31% Activity: 46% Diet and activity: 42%
Finnish Diabetes Prevention study [3•]: 91 M, 174 F	≥ 5% of initial weight	Decrease total calories to achieve weight goal, < 30% fat, < 10% saturated fat, ≥ 15 g of fiber per 1000 kcal	Aerobic (also some resistance training)	Moderate to somewhat vigorous intensity; 30 min/d	WL: confirmed WL. 4.2 kg at 1 y and 3.5 kg at 2 y	Diet: not reported Activity: significant increase in reported physical activity levels	58%
Diabetes Prevention Program [4••]: 345 M, 734 F	≥ 7% of initial weight	Individualized calorie targets to achieve a 1–2 lb/wk WL, < 25% fat	Aerobic (brisk walking)	Moderate intensity; 150 min, minimum of 10 min per time, spread over 3 d or more per wk	WL: confirmed WL. 7% WL at 6 mo and 5.6 kg (5% WL) at study end	Diet: calories decreased by 450 ± 26 kcal/d and fat decreased by 6.6% at y 1 Activity: 74% met goal of 150 min at 6 mo and 58% at 2.8 y. Significant increase in reported activity levels	58%

BMI—body mass index; DM—diabetes mellitus; F—female; F/I/T—frequency/intensity/time; M—male; RR—risk reduction; WL—weight loss.

References and Recommended Reading

Papers of particular interest, published recently, have been highlighted as:

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- •• Of major importance

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The DPP was a large randomized clinical trial that spanned across 27 sites in the United States. Study subjects included both men and women from a wide range of both age and ethnic groups (48% minority representation).

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