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Translating Findings from Lifestyle Intervention Trials of Cardiovascular Disease and Diabetes to the Primary Care Setting

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Abstract Preventing or delaying type 2 diabetes and cardiovascular disease is a key public health issue. Large, randomized, clinical trials have shown that intensive lifestyle interventions can be used to prevent or delay type 2 diabetes and to improve cardiovascular disease risk factors, but the key question that remains is how to best translate the results from these large, clinical trials into interventions that can be effectively delivered in primary care and community-based settings. Several effective approaches have been identified and tested. New research examining specific physical activity or dietary behaviors also has identified new behavioral targets for interventions.

Keywords Type 2 diabetes · Cardiovascular disease · Lifestyle intervention · Translation research · Dietary counseling · Physical activity

Introduction

Large, randomized, clinical trials (RCT) conducted in both Europe and the United States have demonstrated that type 2 diabetes can be prevented or delayed through the modification of behaviors, such as dietary intake and physical activity with resulting weight loss. The methods to promote lifestyle modification in these trials were both costly to conduct and required a significant time commitment from both the participants and intervention staff.

The Finnish Diabetes Prevention Study (DPS) was a multicenter RCT designed to assess the feasibility and effects of an intensive lifestyle intervention (ILI) to prevent type 2 diabetes compared with a control treatment in high-risk individuals [1]. The goals given to the ILI participants were to reduce weight by at least 5 % from baseline, to consume less than 30 % of total calories from fat, to consume less than 10 % of total calories from saturated fat, to consume at least 15 g of fiber per 1,000 kcal of dietary intake, and to engage in moderate activity for at least 30 minutes per day [2]. The participants in the ILI group had a 58 % lower incidence of type 2 diabetes compared with the control group during the average 3.2 years of follow-up [1].

The Diabetes Prevention Program (DPP) was a multicenter RCT study conducted in the United States with the goal to determine whether ILI or treatment with the antihyperglycemic drug metformin prevent or delay the onset of type 2 diabetes in overweight or obese participants with impaired glucose tolerance [3]. Both treatments were compared to a placebo group. The two goals for ILI were to achieve and maintain a reduction in weight from baseline of at least 7 % and to engage in at least 150 minutes per week of moderate-intensity activity, such as brisk walking [4]. To achieve the weight loss goal, ILI participants were advised to adopt a low-fat (<25 % of total calories from fat), hypocaloric diet. Similar to the Finnish DPS study, the ILI in the DPP reduced the incidence of type 2 diabetes by 58 % compared with the placebo group during an average of 2.8 years of follow-up.

The Look AHEAD study is an ongoing clinical trial comparing the long-term effects of an ILI targeting modest

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weight loss (7 % from baseline) compared with diabetes support and education in individuals with type 2 diabetes on time to the incidence of a major CVD event [5]. The approach to weight loss was through a hypocaloric, low-fat diet (<30 % of total caloric intake) and 175 minutes per week of moderate-intensity physical activity. Results for weight loss and CVD risk factors at 1 year and 4 years postrandomization have been published [6, 7]. At both time points, the ILI showed significantly greater weight loss and improvement in CVD risk factors compared to diabetes support and education.

The translation of these efficacious interventions into effective interventions in primary care settings requires a modification of the approach to delivery. In this review, we examine recent reports of efforts to translate these large lifestyle intervention RCTs into effective, clinically feasible interventions. We also examine related research and developments that may influence the process of translating lifestyle intervention RCTs in the future.

Common Modifications to Translate Lifestyle Interventions

In randomized clinical trials featuring ILI, the intervention often is delivered during individual meetings between a participant and the lifestyle interventionist [1, 3]. One of the key modifications in efforts to translate the DPP or DPS is to deliver the intervention through group sessions [8, 9••, 10] or a combination of group and individual sessions [11••]. Other common modifications include reducing the number of education sessions [12••] and using nonmedical personnel to deliver the intervention [8, 13–15].

Translations of Diabetes Prevention Randomized Clinical Trials

Online communication has expanded tremendously in the past few years. The effective utilization of online communication has the potential to enable delivery of lifestyle interventions to geographically disbursed populations at low cost. A pilot study of a translation of the DPP into a clinic-based, Internet-delivered intervention showed modest weight loss from baseline in those completing the program (45 of 50 participants enrolled) [16]. The intervention was delivered in this pilot study by nurse educator lifestyle interventionists. By design, this intervention automated the delivery of lifestyle intervention curriculum, which allowed the interventionist to focus on individually tailored advice for participants as well as to provide ongoing support to the participants [17]. An advantage of this approach is that it allows individuals who for reasons due to geography, access to transportation, or schedule are not able to participate in traditional, in-person lifestyle interventions to have access to intensive support to make lifestyle changes.

The Diabetes Education & Prevention with a Lifestyle Intervention Offered at the YMCA (DEPLOY) study, based on the DPP protocol, utilized the existing infrastructure of the YMCA to deliver group-based lifestyle interventions in overweight or obese participants at high risk of type 2 diabetes [8]. This relatively small, cluster-randomized trial showed initial success with significantly greater weight loss in the intervention compared with the control participants, and these differences were sustained at 12 months after randomization. This program has been expanded from the original two YMCA sites to YMCAs across the United States [18]. In a follow-up analysis, 72 % of the original DEPLOY participants enrolled in an extension study [19]. At 28 months, the lifestyle intervention participants maintained an average 6 % weight loss from baseline. A recently published meta-analysis concluded that translations of the DPP resulted in an average weight loss of 4 % from baseline at 12 months [20]. Furthermore, the authors of the meta-analysis concluded that studies, such as DEPLOY, demonstrate that translation of lifestyle interventions like the DPP can be successful even when using nonmedical personnel to deliver the intervention.

The Diabetes in Europe–Prevention using Lifestyle, Physical Activity, and Nutritional intervention (DE-PLAN) is a project to translate the findings from the Finnish DPS into primary care-based lifestyle interventions to prevent type 2 diabetes in Europe [21•]. This objective is broken down into two subgoals: the first is to assess type 2 diabetes risk in European populations; the second is to implement and evaluate a lifestyle intervention program to prevent type 2 diabetes in high-risk individuals. Recently the results from two DE-PLAN studies have been reported: one in Greece [10] and one in Spain [11••]. A feature of DE-PLAN is that individual centers have the flexibility to individualize certain aspects of the intervention based on local needs and capabilities. For example, centers can choose to use individual- or group-based intervention delivery [21•].

The intervention in Greece was a 1-year single group intervention with the same five prevention goals as the Finnish DPS. Eligibility for this trial was determined partially by using the FINDRISC score developed from the Finnish DPS, rather than solely on the basis of glucose tolerance test results. Some of the participants were normal glucose tolerant at enrollment. The participants met with a dietician twice per month in small groups (6–10 individuals per group). The dropout rate was >30 % (66/191 enrolled did not return for the follow-up OGTT at 1 year postrandomization). The individuals completing the program lost an average 1 kg (95 % confidence interval (CI), −8.2 to 10.2 kg) of body weight, which was a statistically significant change from baseline. Greater adherence to the sessions was associated with greater weight loss [10]. The percentage of participants with normoglycemia was higher at study end

(46.4 % at study end vs. 32 % at baseline), although 5.6 % of participants developed type 2 diabetes during the course of the year.

The nonrandomized translation study in Spain was a 4-year study and included groups receiving standard care or an ILI with the ILI participants allowed to choose between individual-based or group-based intervention [11••]. The behavioral goals for the ILI participants were a low-fat, high-fiber Mediterranean diet, 30 minutes per day of moderate intensity physical activity, and at least 3 % weight reduction. The intervention was delivered in a primary care setting and included 2–4 individual or group sessions (5–15 participants per group) with telephone or text message follow-up at 6- to 8-week intervals. The primary outcome was incidence of type 2 diabetes during the 4-year trial in the standard care participants compared with the ILI participants. The ILI participants had a significantly lower incidence of diabetes compared with the standard care participants (4.6 cases vs. 7.2 cases per 100 person-years; a 36.5 % relative risk reduction).

Together, these translations from the Finnish DPS suggest that effective lifestyle interventions to prevent type 2 diabetes can be feasibly implemented in primary care settings, but that retention can be a challenge. Also, neither study was randomized, making unbiased evaluation of the programs difficult. This is a common challenge in translations of lifestyle intervention RCTs, and a goal of translation studies must be to evaluate the programs as rigorously as possible to identify the interventions most likely to have real, broad-based impacts on type 2 diabetes incidence.

Ongoing Lifestyle Interventions Translated from Clinical Trials

American Indians and Alaska Natives (AI/AN) have been shown to be at particularly high risk for type 2 diabetes [22]. The DPP ILI was shown to be efficacious in AI/AN participants [3]. The Special Diabetes Program for Indians – Diabetes Prevention Program is a demonstration project to translate the DPP ILI into community- and clinic-based interventions to reduce the incidence of type 2 diabetes in AI/AN communities. The effectiveness of the program has not yet been reported, but baseline and process data have identified behavioral indicators, such as self-reported physical activity at baseline and self-assessed diet quality, which correlate with the Transtheoretical Model stage of behavior change [23].

A simple pedometer was used in the DPP [4], as well as the Look AHEAD study [5], to help encourage some participants to achieve the physical activity goal by providing objective feedback of daily ambulation. Since then, a randomized, clinical trial utilizing a physical activity plan that was specifically designed around using a pedometer to motivate daily walking has shown significant impacts on glucose tolerance in individuals with impaired glucose tolerance [24]. Currently, an investigation examining whether this brief, pragmatic intervention conducted in primary care settings can increase ambulatory activity and delay or prevent the progression to type 2 diabetes is underway [25•]. The translation study will use a group-based approach to deliver the intervention with an initial session lasting approximately 3 hours, which is led by two trained educators. In addition to pedometer steps per day recommendations, the participants also are encouraged to reduce saturated fat intake. In this trial, participants also will have the opportunity to meet as a group with the trained educator at 12 and 24 months after the initial session [25•]. Strengths of this intervention include a plan to measure objectively changes in ambulatory and other dimensions of physical activity using a triaxial accelerometer, as well as a detailed systematic approach for evaluating quality assurance in the delivery of the intervention by the trained educators.

Cardiovascular Disease Prevention Translation Studies

The Look AHEAD study is still underway [5], but the lifestyle intervention strategy of promoting habitual physical activity and modest weight loss through fat and calorie restriction is already being employed in primary care and community settings to prevent macrovascular complications of type 2 diabetes [26, 27]. The effects of these interventions on cardiovascular outcomes will not be known for some time. Process measures of these trials have been reported, and rates of retention, weight loss, and self-reported physical activity are somewhat lower but still comparable to what has been observed in lifestyle intervention RCTs. Among participants in the Special Diabetes Program for Indians–Healthy Heart program, those who were older, had a higher body mass index, and reported higher levels of activity had higher retention. Site characteristics predicting higher retention include older age of the program staff, a higher percentage of female staff, and having a site where at least 75 % of program staff had completed graduate or professional school [27].

Recent Research Potentially Impacting Lifestyle Intervention in Primary Care

The physical activity goal of the largest lifestyle intervention RCTs to prevent type 2 diabetes or CVD usually has been to achieve a specified weekly duration of physical activity at an intensity similar to brisk walking [1, 3, 5]. The participants were encouraged to self-monitor physical activity behavior, and only bouts of activity at least 10 minutes in length were counted toward the weekly goal [4, 5]. More recent research has demonstrated that other types of activity have health benefits related to type 2 diabetes and cardiovascular disease, although none of these studies have shown that promoting these other types of activity leads to prevention or delay of type 2 diabetes or cardiovascular disease.

Bouts of brisk walking shorter than 10 minutes have been shown to have a significant beneficial acute impact on postprandial triglycerides and resting blood pressure in healthy young men [28]. This was a repeated measures design where the order of three different conditions was randomized. The key findings were that a total of 30 minutes of walking a day, comprised of 3-minute bouts, resulted in significantly lower triglyceride concentrations than a control condition. Triglyceride concentrations were not different after a day of 30 minutes of walking in 3-minute bouts compared with 30 minutes of walking in a single bout. The findings were similar for resting blood pressure.

Physical inactivity also has received attention recently for its possible consequences on type 2 diabetes and cardiovascular disease risk. The total amount of objectively measured sedentary time [29–31], as well as the breaks in sedentary time [32], has been related to glucose response and insulin sensitivity. A study recently experimentally manipulated interruptions in sitting time and found that interrupting sitting time with short 2-minute bouts of light or moderate activity resulted in significantly lower glucose and insulin responses to an oral glucose challenge [33].

The dietary intervention component of the DPP ILI emphasized a hypocaloric, low-fat diet [3], whereas the Finnish DPS ILI [1] also encouraged a hypocaloric, low-fat diet, but additionally provided specific recommendations on saturated fat and fiber intake. The optimal dietary approach for diabetes and cardiovascular disease prevention is still controversial. Diets of varying macronutrient composition and the effects on diabetes incidence or risk markers have been examined.

Another pattern of dietary intake that has received considerable attention is intake of refined carbohydrates, specifically regular consumption of sugar sweetened beverages (SSB). A meta-analysis of 11 studies, including 310,819 participants, found that those consuming approximately one to two servings per day of SSB had a 26 % greater risk of developing diabetes than those consuming none or <1 serving per month) [34]. Future lifestyle interventions are likely to include specific goals related to limiting the intake of SSBs.

Similar to the DPP, the ongoing Look AHEAD study has employed hypocaloric, low-fat dietary recommendations. The results of the Look AHEAD study when completed may provide more evidence regarding the efficacy of a low-fat diet as part of a strategy to prevent CVD in adults with type 2 diabetes. Several smaller trials have compared the effect of low fat versus low carbohydrate diets on glycemic control and CVD risk factors.

One study showed in 105 adults with type 2 diabetes that despite a rate weight loss that was initially higher in those consuming the low-carbohydrate diet, both diets had a similar weight reduction at 1 year (3.4 %), with no significant changes in HbA1C and blood pressure [35]. However, there was a significant increase in HDL in the low-carbohydrate group. In a subset analysis, the low-fat diet significantly decreased C-reactive protein (CRP) at 6 months, whereas the low-carbohydrate diet significantly decreased markers of endothelial function [36]. In another 1-year trial comparing four popular weight loss diets, including a low-carbohydrate Atkins diet and a low-fat Ornish diet in 160 adults aged 22 to 72 years, there was a similar significant reduction in body weight (2.1–3.3 kg) and LDL/HDL ratio (~10 %) in all diets, with no effects on blood pressure or glucose after 1 year [37]. The effects on blood lipids, insulin, and CRP were independent of the type of diet but dependent on weight loss reductions. Similarly, another RCT in overweight/obese participants with type 2 diabetes specifically tested the effects of a high monounsaturated fat (MUFA) (46 % of energy as carbohydrate and 38 % as fat) or high-CHO diet (54 % energy as carbohydrate and 28 % as fat) for 1 year [38]. Both groups had similar energy intake, weight loss, and improvements in body composition, blood pressure, HDL cholesterol, and glucose control.

Although lower carbohydrate diets consistently appear to have overall beneficial effects on triglyceride and HDL-cholesterol levels, the long-term efficacy and safety of these diets has been questioned. The Food and Nutrition Board of the Institute of Medicine has established a minimum daily carbohydrate requirement for adults of 130 g per day [39] to meet the brain's requirement for glucose, because the brain is the only truly carbohydrate-dependent organ in that it oxidizes glucose completely to carbon dioxide and water. This assumes the consumption of an energy-sufficient diet with an acceptable macronutrient distribution, for which carbohydrate has been established as 45–65 % of energy intake. Therefore, there are health concerns if low-carbohydrate diets are followed for many years.

Another dietary strategy is the Mediterranean-style diet like that used in the DE-PLAN translation study reported by Costa et al. (2012), in which macronutrient distribution is similar to that recommended by the Institute of Medicine. A Mediterranean diet consists of moderate amounts of fat, particularly monounsaturated fat (mainly from olive oil), high intake of fruits, vegetables, legumes, nuts, cereals, and whole-grains; moderate intake of fish, poultry and wine and relatively low red meat consumption.

In a meta-analysis, adherence to the Mediterranean diet was significantly associated with a reduced risk of cardiovascular mortality [40]. Another meta-analysis of 16 RCTs found a significant favorable difference in body weight (−1.75 kg; 95 % CI −2.86 to −0.64 kg) between the Mediterranean and control diets (mostly low fat diets), which was more profound if the Mediterranean diet was accompanied by energy restriction (−3.88 kg; 95 % CI −6.54 to −1.21 kg) and increased physical activity (−4.01 kg; 95 % CI −5.79 to −2.23 kg) [41]. In addition, the Mediterranean diet was associated with a lower risk of type 2 diabetes and those following this diet with high adherence had significantly improvements in glucose control.

Other Factors Impacting Translation of Lifestyle Intervention to Primary Care Settings

Objective feedback about physical activity in the form of steps recorded on a simple pedometer has been an optional toolbox approach [4, 5] or even the primary tool to modify physical activity behavior [24, 25•]. More sophisticated devices like heart rate monitors and accelerometers have been used to assess objectively multiple dimensions of physical activity and inactivity. There is a distinction between objective feedback and assessment. Objective feedback provides real-time feedback to a participant about physical activity behavior. Objective assessment of physical activity is for researchers to evaluate physical activity and does not necessarily include real-time feedback to the participant. In the DPP and Finnish DPS, assessment of behavioral change (including physical activity behavior) according to the goals of the intervention was assessed by self-report [2, 4]. Intervention-related response bias can make it difficult to determine the actual magnitude of behavior change using a subjective physical activity assessment method like self-report [42–44]. Additionally, lifestyle interventions encouraging specific physical activity behaviors can have an impact on other lifestyle behaviors not assessed by self-report tools. For example, participation in an exercise intervention can potentially influence nonexercise activity [45, 46] or eating behavior [47]. Tools to measure objectively multiple components of physical activity behavior can provide considerable insight into changes in physical activity behavior in response to lifestyle advice. Some objective measures were available at the time of the DPP and Finnish DPS, but broad use of these tools has not been feasible due to cost and other factors. More recently, physical activity monitors have become available that are less expensive and feasible for use in lifestyle intervention research. This development can be useful for translation projects. One use of these devices in translation projects is to evaluate the magnitude of the behavioral response to an intervention. Since reduced intensity of the intervention, either through fewer intervention sessions, limited individual attention from the lifestyle interventionist, or both is a frequent aspect of translation projects, a key question of lifestyle intervention translation projects often "is the intensity of the intervention sufficient to change behavior and will this beneficially impact health?" Physical activity monitors can help answer this question in a way that is not biased by response bias.

Recently, the cost of objective assessment tools has lowered considerably and this in part, along with the widespread use of devices like smartphones, has made it feasible to provide objective feedback to participants using highly sophisticated tools, such as triaxial accelerometry and heart rate monitors that were largely previously only available for objective assessment. New innovations in smartphones also come into play with self-monitoring, particularly as it relates to weight and diet self-monitoring.

In the DPP, the adherence to self-monitoring (diet, physical activity, or weight) was a significant predictor of achieving the weight loss goal [48]. Self-monitoring was done using paper and pencil logbooks. In the case of dietary self-monitoring, participants were asked to record the fat and calorie grams of the foods that they consumed. This required determining the caloric and fat gram contents of foods, by referring to a provided reference book or through reading nutrition labels. Applications on smartphones now facilitate self-monitoring dietary intake. Some applications will even allow the user to scan bar codes on prepared foods or food ingredients to record the nutrition information. These innovations obviously can make it much easier for participants to self-monitor dietary intake and may increase accuracy as well. It is not clear what effect these new innovations will have on success in lifestyle interventions.

Another recent innovation related to smartphones is the increase and relatively widespread use of social media. The applications for self-monitoring also frequently include an option for the user to share results. This can potentially facilitate more frequent communication between the lifestyle interventionist and participant. A lifestyle interventionist can communicate specific feedback based on the self-monitoring records (or lack of records) shared by a participant. A study already described in this review utilized online communication to automate the delivery of a translation of the DPP [17]. Determining the effectiveness of automation and the use of online social media to communicate in lifestyle interventions requires additional research.

Conclusions

The translation of clinical trial research into primary care and community settings is a dynamic process. Large RCTs, such as Look AHEAD, Finnish DPS, and DPP, which evaluated the impact of lifestyle interventions on disease incidence are costly and take years to plan, implement, and disseminate. Research that evaluates the impacts of lifestyle intervention on risk factors for disease can be completed much more quickly but do not provide the more definitive results of studies with disease incidence as the outcome. Developing strategies to reduce the incidence of type 2 diabetes or CVD in large groups or even regional or national populations requires translating findings from studies with both disease incidence and risk factors for disease as endpoints.

Existing translational studies demonstrate that ILIs like the DPP and Finnish DPS can be translated to lifestyle interventions that can be implemented in clinic- and community-based settings, but the magnitude of changes (for example weight loss) is typically more modest than seen in the initial RCT. Thus, a challenge for translational studies is to raise the health impact of these studies closer to the levels observed in tightly controlled RCTs.

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