Can a Practical and Scalable Lifestyle Intervention Produce Meaningful Weight Loss in Primary Care Patients?

Ma J, Yank V, Xiao L, et al. Translating the Diabetes Prevention Program lifestyle intervention for weight loss into primary care: a randomized trial. JAMA Intern Med 2013;173:113–121.

Study Overview

Objective. To determine whether two Diabetes Prevention Program (DPP)–like lifestyle interventions result in greater weight loss than usual care among primary care patients at high risk for type 2 diabetes (T2DM).

Study design. Randomized controlled trial with blinded analyses, 2 intervention arms, and 1 control arm.

Setting and participants. The Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care (E-LITE) trial was conducted at a single primary care clinic in Silicon Valley, CA. Recruitment and enrollment took place between 2009 and 2010 and patients were followed for up to 15 months after randomization.

Patients were eligible if they were 18 years of age or older, overweight (BMI ≥ 25 kg/m^2), and had laboratory evidence of pre-diabetes (fasting plasma glucose [FPG] 100–125 mg/dL) or metabolic syndrome. Patients who had more severe illnesses (medical or psychiatric) were excluded, along with those who were pregnant or were unlikely, due to a planned life event, to be able to participate in a 15-month trial. 241 patients were ultimately enrolled.

Eligible patients were randomized to 1 of 3 study arms. The first intervention arm (n = 79) consisted of an in-person DPP-like curriculum delivered in 90- to 120-minute weekly group visits (8–10 people) conducted by a lifestyle coach who was a registered dietitian, over 12 weeks, followed by a 12-month maintenance phase during which regular email contact between participants and their health coach continued to occur. In addition to learning the adapted DPP curriculum, at each of the weekly in-person visits participants did food tastings at check-in and participated in 30 to 45 minutes of physical activity led by a contracted fitness instructor.

The second intervention arm (n = 79) consisted of a self-directed, DVD-based lifestyle change curriculum, also delivered over 12 weeks, and also followed by a 12-month maintenance phase during which email contact between participants and a health coach occurred. The participants in the self-directed intervention group did have an initial in-person group visit with the lifestyle coach for orientation to study websites and where they received study materials, including a pedometer and scale.

Throughout the 15-month trial, all intervention participants (self-directed and in-person) received bi-weekly

email reminders about healthy lifestyle change from the lifestyle coach, as well as a monthly, standardized email containing motivational messages. Additionally, all intervention participants had the option of sending specific questions to the coach with the assurance that a response would be provided within 1 to 2 days. The in-person group had an additional point of email contact during maintenance—namely, the lifestyle coaches sent at least 1 personalized email each month to all in-person participants with specific feedback on their progress.

Participants in the usual care arm of the study (n = 81) received no written, DVD, or in-person materials about weight management or lifestyle change and continued to receive usual care through their primary care providers.

Main outcome measures. The primary outcome of interest was change in BMI at 15 months. BMI was calculated by in-person weight and height measured at baseline, with only weight measurement repeated at 3, 6, and 15 months by blinded research assistants. Secondary outcomes included change in waist circumference, FPG levels, blood pressure, and serum lipid levels. Fasting blood samples were taken at baseline and 6 and 15 months.

The investigators used intention-to-treat analysis to compare outcomes between groups and did not exclude any patients who enrolled in non–study-related weight management or lifestyle change programs during follow-up. They analyzed continuous outcomes using mixed linear models and categorical outcomes using mixed logistic models, accounting for the repeated measures design of their study and possible clustering effects at the level of a patient's primary care provider. In addition to analyzing between-group outcomes, they also examined whether patient sex had an effect on the impact of treatment.

Results. The 3 study groups were similar at baseline on all measured characteristics. As a whole, the study participants were late middle-aged adults (mean age, 52.9y, SD 10.6y), and 46.5% were female. There was not considerable racial or ethnic diversity in the group—78% were non-Hispanic white, 17% were Asian/Pacific Islander, and 4% were Hispanic. Notably, the patient population as a whole was very well off, with 48.1% reporting annual incomes over $150k. The lowest income category reported by the investigators was $75k, and only 12% of patients fell in that group. Additionally, this was a highly educated group, with 97% of participants holding a college or advanced degree. Mean BMI was in the obese range (32 [SD 5.4] kg/m^2), and just over half (54.4%) of patients were pre-diabetic. A larger proportion of patients (86.7%) qualified as having the metabolic syndrome at baseline. Patient follow-up and retention were very good, with 15-month weight measures available (either through direct study measurement or EMR extraction) for 80.5% of participants.

Participants in both intervention arms achieved greater decreases in BMI than those in the usual care arm. The most successful group in terms of 15-month weight loss was the in-person coaching group, which achieved a mean decrease of 2.2 (0.3 SE) BMI units compared with baseline, followed by the self-directed group (–1.6 units [0.3 SE]), with the usual care group achieving the smallest weight loss (–0.9 units [0.3 SE]). The in-person group's weight loss was significantly greater than both the usual care group ($P < 0.001$) and the self-directed group ($P = 0.03$). The self-directed group had significantly greater 15-month weight loss than the usual care group as well ($P = 0.02$). The investigators also presented their results framed in the context of what was deemed to be a successful weight loss by the original DPP—a 7% decrease in body weight [1]. When using that metric, there was also a significant difference between the intervention arms and the usual care group. Namely, compared with 14.4% of patients achieving success in usual care, 37% did so in the in-person arm ($P = 0.003$) and 35.9% did so in the self-directed arm ($P = 0.004$).

For the non–weight-based outcome measures, there were no significant differences between participants in the in-person and self-directed intervention groups; however, there were some statistically significant differences between intervention and usual care participants. Waist circumference, FPG level, and total cholesterol levels all decreased significantly more in both groups of intervention participants than they did in controls. Effects on blood pressure were less pronounced, with only the in-person vs. usual care diastolic blood pressure change comparison reaching statistical significance ($P = 0.04$). Improvement in HDL did not differ across the groups, nor did decreases in serum triglycerides or LDL. Total cholesterol levels increased marginally over the 15-month period in all groups, but did so significantly less in the intervention (for in-person, $P = 0.05$, for self-directed, $P = 0.04$) than usual care arms.

Interestingly, when the impact of the interventions

on weight was examined according to participant sex, the investigators found differences between men and women. Namely, women in the in-person intervention lost significantly more weight (–6.9kg [SD 1.1]) and maintained the weight loss better than those in the self-directed intervention arm (–3.9kg [SD 1.2]) or the usual care arm (–3.0kg [SD 1.1]), such that at 15 months there was no statistical difference in weight loss between women in the self-directed arm and those in usual care. For men, however, both intervention groups lost and maintained significantly more weight than the usual care group, with mean (SD) weight loss of 5.6 (1.1) kg in the in-person arm, 5.1 (1.0) kg in the self-directed arm, and 2.0 (1.1) kg in the usual care arm (*P* value for in-person vs. usual care = 0.002, for self-directed vs. usual care = 0.007).

Conclusion. Both interventions (in-person > self-directed) led to decreases in BMI, waist circumference, and FPG in intervention participants relative to usual care controls. The researchers conclude that this study provides evidence to support a broadening of the kind of reimbursable lifestyle interventions in primary care to include non–face-to-face interventions (eg, email or DVD-based), as these may be easier to incorporate into many primary care practices and also may be effective ways of promoting weight loss and reduction of diabetes risk.

Commentary

Worldwide, the number of patients at risk for diabetes has increased substantially as our population has become more obese [2]. Once developed, diabetes has devastating micro- and macrovascular consequences, leading to substantial morbidity and mortality [3]. Health care providers and US public health professionals have therefore dedicated years of work to helping at-risk patients prevent the development of this costly and often debilitating chronic disease.

One of the most well-known studies in this area was the Diabetes Prevention Program, in which overweight patients with impaired fasting glucose were randomized to receive metformin, placebo, or an intensive lifestyle intervention [1]. The study followed patients for up to 3 years, during which lifestyle intervention patients showed the greatest decrease in risk of developing diabetes (58% reduction in risk with a compared to placebo), even exceeding the effects observed in the group with metformin [1]. Although the trial is often held up as an example of the power of lifestyle change to prevent disease, the time-and resource-intense intervention has proven difficult to replicate in the real world of busy and overburdened primary care practices.

A number of subsequent studies have reinforced the idea that moderate (5%–10%) weight loss can have a substantial impact on diabetes prevention. However, weight management is not easily incorporated into primary care [4,5]. Lack of reimbursement for many preventive services, particularly for those related to weight management, combined with short visit times, make it difficult for primary care providers to integrate even a moderate-intensity lifestyle counseling intervention into routine practice [4]. Furthermore, for younger and middle-aged working adults, many of whom are raising children, finding the time to attend the necessary in-person sessions might be prohibitively difficult (or expensive).

The investigators in this study tested the impact of a simplified DPP-like curriculum. They sought to test 2 different adaptations of the DPP—both perceived to be more realistic for use in primary care than the original program—against the usual paradigm of little or no weight management counseling in clinic. One of the major strengths of this study was the fact that it had a robust design—a randomized trial with blinding during the data collection phase for key outcomes of weight and blood measurements. These features decreased the likelihood of bias that could have been introduced in a nonrandomized or observational design of treatment effects, and due to measurement bias if research assistants had not been blinded. Furthermore, the intention-to-treat analysis allowed the investigators to maintain the integrity of that original randomization process, preserving the distribution of potential confounders between the comparison groups at the analysis phase. In the paper, the investigators also mention that this intention-to-treat analysis created a more realistic picture of expected effects, as they analyzed data from all patients, including those who sought outside weight management programs during the course of the study.

Another strength of this study was that patients were followed for a full year after completing the initial intensive phase of the intervention. Many patients regain weight at the end of such intense interventions, so this was important for determining at least the moderate-term durability of that initial intense weight-loss phase. This maintenance phase, although still somewhat

resource-intensive, was entirely based on electronic communication, which would likely be much easier for both patients and providers to achieve in a busy real-world setting than a maintenance phase based on less-frequent in-person visits. The trial design also featured the use of 2 intervention arms, one of which was more intense and required a lot of in-person visits, and the other of which was almost entirely self-directed and could be done at home. Both arms were less intense than the original DPP curriculum but have very clear differences in terms of how scalable and implementable they are for real practices. For mobility-limited patients, or those for whom the costs of numerous in-person visits are high, or whose jobs prohibit visits during normal office hours, the testing of a purely in-home, DVD-based program is a very important addition to the trial.

Where this trial succeeded in maintaining internal validity, it does have some limitations in terms of generalizability. The patient population was a wealthy and highly educated group (50% with annual incomes exceeding $150k and 98% college degree or higher) with few racial/ethnic minorities (4% Hispanic, no African Americans). Higher income and education levels might facilitate not only the health literacy needed to understand the curriculum but also the self-efficacy and financial resources necessary to comply with it.

Additionally, although the interventions tested here were less intense than the original DPP, they still may have been more intense than could realistically be expected to be adopted for most primary care practices, from both the provider and patient perspective. For most working Americans, the time investment needed to participate in 12 weeks of 90- to 120-minute classes may not be realistic. Additionally, the patients in this trial were slightly older (mean age 53 years), perhaps based on the overall makeup of the clinic population, but also perhaps because younger adults who are working and actively engaged in child-rearing would not enroll in such a time-intensive intervention (self-directed or not). Finding interventions that are realistic for adults from different socioeconomic backgrounds and stages of life is one key component to developing easily implementable programs for real-world primary care practices. As the authors point out, they were not able to assess cost-effectiveness, which, for practices and payers considering whether or how to reimburse this kind of care, would be a critical piece of information.

In terms of secondary outcomes, this study had a limited ability to look at the downstream impact of weight loss on diabetes incidence due to lack of longer-term follow-up. However, they did examine a number of intermediate blood measures that might predict later diabetes or cardiovascular outcomes. For many of those outcomes, there were not significant differences between the intervention and control arms. This finding could be due to a lack of power or could be because both groups were already being treated with medication (eg, antihypertensives, lipid-lowering agents) at baseline and through follow-up, although that information is not presented or reviewed in the manuscript.

Applications for Clinical Practice

This study tested 2 primary-care based lifestyle interventions for weight management in a group of patients at high risk for developing diabetes. They found that both interventions helped patients lose weight and maintain that weight loss during a 1-year maintenance phase. Although the interventions were less intense than many in prior studies, they may still be daunting for most primary care practices to consider implementing without major changes to the way this kind of care is reimbursed. Furthermore, retesting of these interventions in a more representative population would be important before widespread adoption could be undertaken.

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References

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