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Translating the Diabetes Prevention Program into the Community

The DEPLOY Pilot Study

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Abstract

Background—The Diabetes Prevention Program (DPP) found that an intensive lifestyle intervention can reduce the development of diabetes by more than half in adults with prediabetes, but there is little information about the feasibility of offering such an intervention in community settings. This study evaluated the delivery of a group-based DPP lifestyle intervention in partnership with the YMCA.

Methods—This pilot cluster-randomized trial was designed to compare group-based DPP lifestyle intervention delivery by the YMCA to brief counseling alone (control) in adults who attended a diabetes risk-screening event at one of two semi-urban YMCA facilities and who had a BMI ≥24 kg/m^2, ≥2 diabetes risk factors, and a random capillary blood glucose of 110–199 mg/dL. Multivariate regression was used to compare between-group differences in changes in body weight, blood pressures, HbA1c, total cholesterol, and HDL-cholesterol after 6 and 12 months.

Results—Among 92 participants, controls were more often women (61% vs 50%) and of nonwhite race (29% vs 7%). After 6 months, body weight decreased by 6.0% (95% CI=4.7, 7.3) in intervention participants and 2.0% (95% CI=0.6, 3.3) in controls (p<0.001; difference between groups). Intervention participants also had greater changes in total cholesterol (−22 mg/dL vs +6 mg/dL controls; p<0.001). These differences were sustained after 12 months, and adjustment for differences in race and gender did not alter these findings. With only two matched YMCA sites, it was not possible to adjust for potential clustering by site.

Conclusions—The YMCA may be a promising channel for wide-scale dissemination of a low-cost approach to lifestyle diabetes prevention.

Introduction

More than 60 million Americans have prediabetes, defined by impaired glucose tolerance (IGT) or impaired fasting glucose (IFG). People with prediabetes are at increased risk for developing diabetes,[1–5] cardiovascular events,[6–9] and other obesity-related adverse health outcomes. Because the prevalence of obesity is increasing in all segments of the population, the burden of prediabetes and diabetes will continue to escalate.[10] Identifying strategies to prevent diabetes on a national scale is indeed a public health priority.

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The Diabetes Prevention Program (DPP) and other large randomized trials have demonstrated that a structured diet and physical activity intervention achieving modest weight loss in overweight adults with IGT can significantly reduce the progression to diabetes.[11,12] However, the DPP involved enrollment criteria and an intensive lifestyle intervention that are challenging to implement and sustain in busy healthcare settings.[13,14] In this context, there has been an ongoing need for real-world adaptations of the DPP lifestyle intervention that balance fidelity to DPP procedures with new design elements that optimize effectiveness, minimize cost, and improve sustainability.[15] Because healthcare settings have a limited capacity to offer intensive behavioral interventions,[16] success in achieving this goal is likely to require involvement by community organizations with greater expertise and resources for offering intensive lifestyle programs.

With exceptional reach into diverse U.S. communities and a long history of implementing successful health promotion programs, the YMCA is a capable community partner. Over the past 4 years, the YMCA of greater Indianapolis has participated with researchers at Indiana University School of Medicine (IUSM) to design, implement, and evaluate a group-based adaptation of the highly successful DPP lifestyle intervention. This pilot study was conducted to test the hypotheses that YMCA wellness instructors could be trained to implement a group-based lifestyle intervention with fidelity to the DPP model and that adults at high risk for developing diabetes who were assigned to receive this intervention could achieve changes in body weight comparable to the DPP.

Methods

Design

This study, known as Diabetes Education & Prevention with a Lifestyle Intervention Offered at the YMCA (DEPLOY), was a matched-pair, group-randomized pilot intervention trial involving two YMCA facilities in greater Indianapolis. Using data from a 2003 YMCA primary market area analysis of communities surrounding six local YMCAs, two facilities located in semi-urban communities with similar racial and socioeconomic characteristics were selected. These two sites volunteered to partner with the IUSM to implement and evaluate a community-based approach to identify and educate adults at risk for developing type 2 diabetes and to offer YMCA resources to help prevent the development of diabetes by promoting modest weight loss and increased physical activity. Before implementing this initiative, one of the two YMCA sites was randomly assigned to receive training and support for delivering a formal, group-based adaptation of the DPP lifestyle intervention at the YMCA facility. The Indiana University–Purdue University Indianapolis IRB approved the study protocol.

Participants

The goal of this study was to recruit participants who resembled DPP participants without imposing tests that are difficult to perform or sustain in a community setting. An approach was selected that combines a questionnaire and capillary whole-blood glucose testing to predict the risk for IGT or undiagnosed diabetes in a community setting.[17] This approach involved four major steps: (1) an invitation to adults with diabetes risk factors to attend a community-based screening and education event at the YMCA; (2) a determination of BMI; (3) completion of the 7-item American Diabetes Association (ADA) diabetes risk assessment[17,18]; and (4) collection of a drop of whole blood by finger stick to assess casual capillary blood glucose (CCBG) concentration for people with a BMI ≥24 kg/m^2 and an ADA risk score ≥10.

In three separate waves between August 2005 and May 2006, a 1-page letter was mailed to 7500 randomly selected households within approximately 5 miles of each YMCA facility. This letter introduced the concept of prediabetes and offered information about the effectiveness of

lifestyle modification to prevent or delay the onset of diabetes. The flier listed common risk factors for prediabetes and encouraged adults who were affected by one or more of these risk factors to attend one of several diabetes risk-screening events at the nearest participating YMCA.[17,18]

All people attending the screening events were assessed for diabetes risk. CCBG was determined using a One-Touch Ultra handheld glucose meter.[19] People with a CCBG ≥200 mg/dL were informed that they were at high risk for diabetes and should see a healthcare provider immediately to undergo formal confirmatory testing and follow-up. People with an ADA risk score ≥10 and CCBG of 110–199 mg/dL (100–199 mg/dL if fasting ≥9 hours) were informed that they were at increased risk of developing diabetes and were potentially eligible for the study. These participants were referred to an onsite research assistant and were enrolled if they provided written, informed consent and were free of any comorbidity expected to limit lifespan to <3 years or to contraindicate the gradual adoption of light/moderate physical activity (e.g., a recent cardiovascular event, severe chronic obstructive pulmonary disease, advanced arthritis, poorly controlled hypertension).

Measures

All measures were collected by the IUSM research team during risk-assessment events held at the YMCA sites at baseline and after 4–6 and 12–14 months of study enrollment. The primary study outcome was percent change in body weight after 4–6 months. Body weight was measured using a calibrated, beam-balanced scale with participants wearing light clothing and no shoes. Secondary outcomes included changes in body weight at 12 months; changes in blood pressure, and point-of-care tests for HbA1c, total cholesterol, and HDL-cholesterol (HDL-c). HbA1c was assessed from a fingerstick capillary whole-blood sample using a DCA 2000 analyzer.[20,21] Total cholesterol and HDL-c were measured from capillary whole blood using a Cholestech LDX® lipid analyzer.[22,23] Blood pressures were assessed with an aneroid sphygmomanometer with appropriate-sized cuff and participants seated and relaxed for at least 5 minutes.

Intervention and Controls

Study participants were allocated to the DPP intervention or standard advice alone (controls) depending on the location of the YMCA at which they attended a screening event (i.e., group allocation). To avoid raising expectations about assignment to intervention or control groups at the time of enrollment, participants were told simply that the study would provide them with (1) access to additional resources from the YMCA to reduce diabetes risk through lifestyle modification, and (2) repeat diabetes risk testing with brief counseling again after 6 and 12 months.

The educational and motivational components of both interventions began during the screening events. All screening participants received personalized advice about their risk for developing diabetes, and those without contraindications were advised that modest weight loss (5%–10%) via caloric restriction and the gradual adoption of moderate physical activity (equivalent to brisk walking for 30 minutes daily) were generally safe and effective in preventing or delaying the onset of diabetes. Brief advice at the screening events typically took between 2 and 5 minutes and was supplemented by use of Small Steps, Big Rewards educational materials available from the National Diabetes Education Program (NDEP).[24,25]

Eligible screening participants who consented to enroll in the study met briefly with a YMCA employee before leaving the screening event to learn about YMCA resources that might help them to reduce their risk for developing diabetes. At the intervention site, the YMCA employee discussed how to access the group-based DPP intervention. Enrollment in this program was

highly encouraged but not a requirement for study participation. At the control site, the YMCA offered information about other existing wellness programs to help participants achieve modest weight loss through gradual lifestyle changes. Thus, participants in both the intervention and control groups received similar testing, brief counseling, NDEP materials, limited access to the YMCA to help with weight-loss attempts, and repeat testing and brief counseling again after 6 and 12 months of enrollment. However, only participants at the DPP intervention site were offered free-of-charge access to a new group-based diabetes prevention intervention.

Group-Based Diabetes Prevention Program

Participants at the intervention site who elected to participate in the new diabetes prevention program were assembled into groups of 8–12 people who could meet at a mutually agreeable time. Procedures for the group-based program were modeled closely after publicly available DPP materials,[26,27] with some adaptation to improve the sustainability of the program by the YMCA.[28] Briefly, the intervention core curriculum involved 16 classroom-style meetings focused on building knowledge and skills for goal setting, self-monitoring, and problem-solving. Program sessions lasted 60–90 minutes, and the entire core curriculum was delivered over 16–20 weeks. Goals upon completion of the program included a 5%–7% reduction in baseline body weight and 150 minutes per week of moderate-level physical activity similar to brisk walking. Although ongoing intervention activities are an essential component of successful weight maintenance,[29] this small pilot study was designed to demonstrate feasibility, so maintenance activities following the core curriculum sessions involved only monthly, large-group meetings at the YMCA, during which guest presenters discussed topics such as healthy restaurant eating and food shopping. Before implementing any of the program sessions, YMCA staff completed a structured two-and-one-half day group-instructor training curriculum administered by experienced DPP investigators. The YMCA selected instructor candidates based on their good communication skills and prior experience in group education or programming.

Several approaches were used to ensure that intervention sessions were delivered with fidelity to the DPP model. These approaches were based on similar strategies used during the DPP, and were developed by a training core of DPP project staff, YMCA personnel, and the principal investigator. Quality assurance began with the structured training and certification process described above, adapted from the DPP manual of operations. During implementation, group instructors had regular access to the DPP training team to discuss issues about lesson content, group moderation, or the medical questions of participants. The training core reviewed session logs (attendance and lesson checklists) submitted by the group instructors for any potential departure from the DPP lesson model. Fidelity, in this context, was discussed during the weekly meetings of the project team but was not assessed quantitatively during this study.

Statistical Analyses

Ordinary least squares multivariate regression was used to compare the between-group differences for percent change in body weight and for absolute change in HbA1c, systolic blood pressure, and total and HDL-c. Because this was a small pilot study involving only two matched YMCA sites, it was possible that between-group baseline differences in the two sampling populations could lead to confounding. Moreover, between-group differences in the baseline values of outcome variables could introduce bias from regression to the mean. To minimize these potential sources of bias, baseline values for the dependent variable were included in each regression model.[30] Because there was an 11% between-group difference in the percentage of participants who were men and a 22% difference in the percentage of participants of nonwhite race, sensitivity analyses were performed in which gender and (separately) race were added as a covariate to each model. Adding gender or race (white versus nonwhite) as a covariate did not change the magnitude or significance of any of the study outcomes, so only

the results of models adjusted for baseline differences in the dependent variable are presented. All analyses were performed using SAS version 9.1 and include all participants who completed data collection, regardless of their level of intervention participation. As this was a pilot study involving only two YMCA sites, it was not possible to adjust SEs for potential clustering by YMCA site, and missing data were not imputed.

Results

Baseline Characteristics

A total of 535 adults were assessed during the YMCA-based diabetes risk screening events. Among all people screened, 143 had a high-risk ADA questionnaire and met the glucose-level criteria for the study. After the exclusion of 12 participants because of conditions that might preclude participation in a community-based physical activity program, 131 were eligible and 92 (70%) enrolled (Figure 1). At baseline, intervention and control participants were similar with respect to age, but control participants were more often female (61% vs 50%) and of nonwhite race (29% vs 7%) (Table 1).

Program Participation

Of the 46 participants in the intervention arm, 35 (76%) participated in at least one of the YMCA group lifestyle sessions. These 35 participants completed an average of 75% of the 16 core curriculum visits. Thus, the 46 participants allocated to the intervention arm attended an average of 57% (76% × 75%) of the maximum possible core curriculum sessions.

Outcomes at 4–6-Month Follow-Up

The 4–6-month follow-up visit was completed by 85% of intervention participants and 83% of controls. Participants who attended the follow-up evaluation were not significantly different in age, gender, or race from nonrespondents to the follow-up evaluation. At the 4–6-month follow-up visit, there was a clinically meaningful and significant between-group difference in the primary outcome of percent change in body weight (Table 2). Compared to baseline levels, body weight decreased by 6.0% (95% CI=4.7, 7.3) in intervention participants and 2.0% (95% CI=0.6, 3.3) in control participants ($p<0.001$ for the difference between groups). This equated to a mean weight loss of 5.7 kg (12.5 lbs) for intervention participants and 1.8 kg (4.0 lbs) for controls. There was also a significant and clinically meaningful between-group difference in the change in total cholesterol concentration (−21.6 mg/dL intervention vs +6 mg/dL controls; $p<0.001$). There were no significant between-group differences in any of the other cardiometabolic risk measures over this relatively short period of follow-up.

Outcomes at 12–14-Month Follow-Up

At the 12–14-month follow-up visit, there was still a clinically meaningful and significant between-group difference in the primary outcome of percent change in body weight (Table 2). Compared to baseline levels, follow-up body weight decreased by 6.0% (95% CI=3.8, 8.3) in intervention participants and 1.8% (95% CI= +0.3, −3.9) in controls ($p=0.008$ for between-group difference). This equated to a mean weight loss of 5.7 kg (12.5 lbs) for intervention participants and 1.6 kg (3.6 lbs) for controls. There was also still a significant and clinically meaningful between-group difference in the change in total cholesterol concentration (−13.5 mg/dL intervention vs +11.8 mg/dL controls; $p=0.002$). Although none of the differences in remaining cardiometabolic risk measures reached significance, HDL-c appeared to exhibit a trend ($p=0.095$) toward greater elevation among intervention participants (+1.9 mg/dL) versus controls (−1.4 mg/dL).

Conclusion

This study found that YMCA wellness instructors can be trained to deliver a group-based DPP lifestyle intervention and achieve changes in body mass after 6 and 12 months that are comparable to the DPP study. This level of effectiveness was observed even in the context of a modest (57%) overall attendance level. This is the first study to demonstrate that the YMCA is a promising vehicle for the dissemination of the DPP lifestyle intervention into the community. In the DPP, 5 kg (about 5%) of weight loss was associated with a 58% reduction in incident diabetes.[31] In this pilot study, people at high risk for developing diabetes achieved and maintained a mean 6% reduction in baseline body weight and significant reductions in total cholesterol. Given these results, delivery of the DPP via the YMCA warrants further study as a model for the wide-scale dissemination of an evidence-based strategy to lower diabetes and cardiometabolic risk for millions of Americans with prediabetes.

This was a small pilot feasibility study, and it has some notable limitations. First, the study involved only two matched YMCA facilities and allocated participants by randomizing these sites to deliver a group-based DPP intervention or to offer only brief counseling and information about existing YMCA programs. This study design was chosen for two reasons: (1) the YMCA did not feel comfortable declining program access to some participants at a single site when others (possibly a neighbor or close friend) would receive the program free of charge, and (2) it was desirable not to inform control participants that other individuals might receive a more-intensive lifestyle intervention. This minimized treatment contamination and some potential bias attributable to treatment awareness. However, group allocation may have increased the possibility of unmeasured confounding because it increased the probability of baseline differences between individual participants in the two treatment groups. In addition, it is possible that weight loss and other outcomes are correlated within neighborhoods (or YMCAs), and this could increase the probability that treatment differences were significant. Sensitivity analyses found that outcomes did not differ significantly with statistical adjustment for baseline differences in potential confounders such as gender and race. However, it was not possible to adjust for all potential confounders in this study or to control for the correlation of weight-loss outcomes within YMCA sites because this small pilot study involved only one site in each treatment group. Because the differences in weight outcomes were strongly significant ($p<0.001$ at 6 months), these findings clearly warrant further study of the group-based delivery of the DPP lifestyle intervention by trained YMCA wellness instructors.

Another interesting finding was the modest but significant weight loss observed by control participants. One explanation for this finding is that the study recruited and retained motivated people with an increased likelihood of achieving short-term weight loss with brief advice alone. Because 16% of the participants did not complete data collection at 6 months for the primary weight-loss outcome, the effectiveness of the intervention may have been over-estimated if weight loss was lower in nonrespondents. It is also possible that a community-marketing approach, followed by the formal testing of diabetes risk, brief activation by trained professionals, and follow-up for retesting after 6 and 12 months, may be sufficient to help some individuals with prediabetes to lose and maintain modest weight loss. Although brief counseling with limited follow-up alone is not typically sufficient as a strategy to maintain weight loss even in motivated volunteers,[29] it is possible that the knowledge of prediabetes risk is particularly activating, and that formal advice supplemented by NDEP materials can support lifestyle change in select individuals. Because even modest weight reduction translates into meaningful reductions in diabetes risk,[31] further research is needed to understand the impact of diabetes-risk perceptions on individuals' receptivity to brief lifestyle counseling.

Despite the clear effectiveness of an intensive lifestyle intervention to prevent the development of diabetes, there are no existing models for delivering such an intervention to a large and

growing population of American adults with prediabetes. This study provides evidence that the YMCA could offer one solution for how to deliver a DPP lifestyle intervention in community settings and to achieve weight-loss levels that translate into considerable reductions in diabetes risk. The YMCA may also offer additional benefits for successful DPP translation because it is accessible to broad segments of the population and it sets fees for program access that are based on cost-recovery alone. Much of the difficulty in disseminating the original DPP lifestyle intervention has been the relatively high cost of one-on-one delivery by behavioral experts.[32] In this study, the hourly wage of YMCA group instructors was approximately one half that of behavioral experts in the DPP. Moreover, the group-delivery approach reduces overall personnel costs by an additional 50% by offering sessions to 8–12 participants simultaneously. Finally, the YMCA has a national policy to turn no person away due to inability to pay for membership or program access. Under this policy, the YMCA uses charitable donations to subsidize access to programs by people in underserved areas and low-income households.

This study was not designed to compare different approaches for optimizing enrollment in a YMCA-based diabetes prevention intervention. However, the relatively low level of participation with community-based diabetes risk screening events verifies the findings from the DPP and other studies[33] that a household mailing approach alone may engage only a limited subset of people who are at risk for diabetes. Future research should assess and compare the use of multiple recruitment channels, in both healthcare and nonhealthcare sectors, to optimize the reach of DPP translation activities in conjunction with low-cost intervention delivery by a community partner such as the YMCA.

By lowering the cost of and expanding the accessibility to diabetes-prevention services, the YMCA may serve not only to increase the number of individuals with prediabetes who have access to and can pay for evidence-based diabetes prevention; it may also provide a compelling model for health-plan reimbursement. This provides yet another compelling reason to develop and test novel strategies that link community-based program delivery with existing clinical services that could help to identify and activate more adults with prediabetes. Some health plans already pay for fitness facility access and other community wellness benefits, but short-term cost recovery and uncertainty about health benefits from these policies limits their sustainability.[34–36] If the YMCA can continue to develop and support a model for the formal training of program group instructors and can ensure the quality and consistency of the program as it has with other national lifestyle programs,[37] health plans may be more willing to pay the fees associated with a DPP intervention delivered at the YMCA for enrollees with prediabetes. In one prior prediction model, a health plan could pay 100% of the costs of the group lifestyle intervention as delivered in this study and recover all costs within 3 years (after which the plan would save costs each year from avoided health outcomes).[15] In this context, the costs and cost effectiveness of community-based models for DPP translation should be a primary focus of future studies.

There are currently more than 2500 YMCA facilities serving more than 10,000 rural, suburban, and inner-city communities in the U.S. alone. Given the encouraging benefits of group-based diabetes prevention in the YMCA on body weight and total cholesterol, combined with a potential for broad reach and cost effectiveness, the national dissemination of the DPP intervention in partnership with the YMCA provides hope in the battle against a growing national diabetes epidemic.

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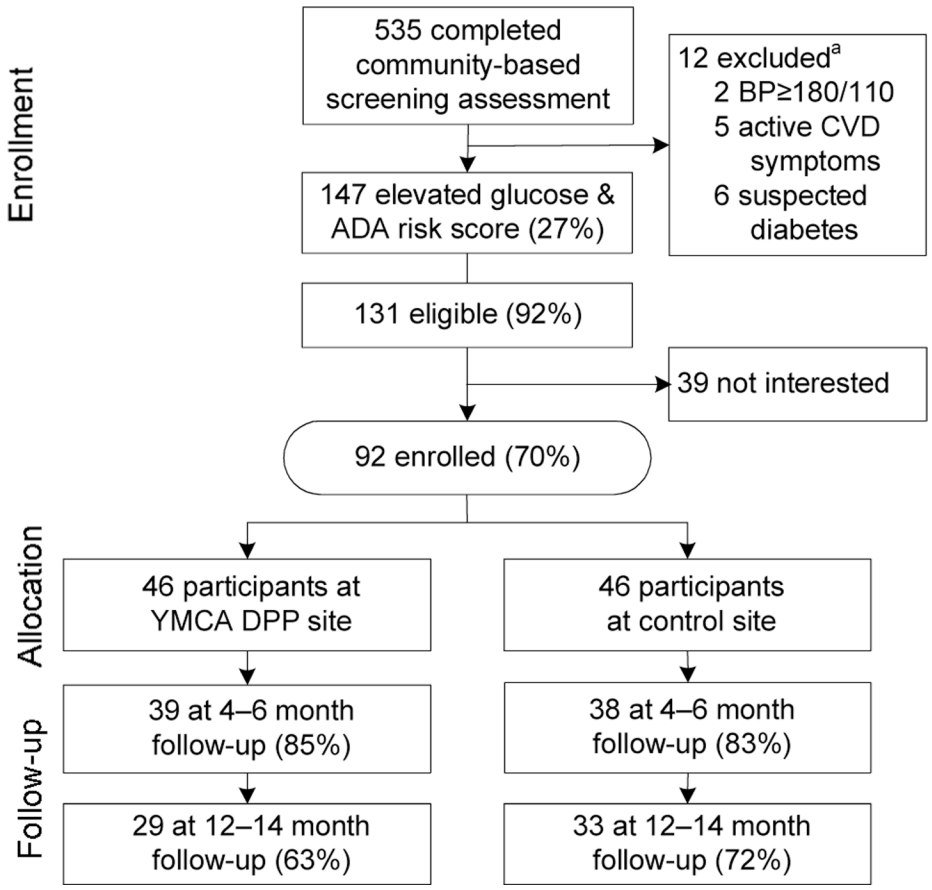

Figure 1. Trial flow

*One participant met more than one exclusion criterion.

Table 1

Baseline participant characteristics[a]

Characteristic	Standard advice (*n*=46)	Group DPP (*n*=46)
Age (years)	60.1 (10.5)	56.5 (9.7)
Women (%)	28 (61)	23 (50)
Race/Ethnicity[b](%)		
Hispanic	2 (4)	1 (2)
African American	9 (20)	2 (4)
White	32 (71)	43 (93)
Other	4 (9)	1 (2)
Comorbidity score[c]	3.6 (2.3)	2.6 (2.2)
Weight (kg)	90.9 (17.3)	94.5 (16.4)
BMI (kg/m^2)	30.8 (5.1)	32.0 (4.8)
HbA1c (mg%)	5.6 (0.5)	5.5 (0.5)
Total cholesterol (mg/dL)	178 (34)	197 (41)
HDL-cholesterol (mg/dL)	48 (16)	43 (14)
Systolic blood pressure (mmHg)	132 (15)	133 (18)
Diastolic blood pressure (mmHg)	81 (8)	82 (10)

[a] Mean (SD) unless otherwise specified

[b] Participants may have selected more than one category.

[c] Seattle Index of Comorbidity[38]; range 0–23, higher score reflects greater comorbidity.

DPP, The Diabetes Prevention Program

Table 2

Main outcome effects[a]

Outcome	Standard advice	Group DPP	*p*-value
4–6 months	*n*=38	*n*=39	
% change in weight	−2.0 (−3.3, −0.6)	−6.0 (−7.3, −4.7)	<0.001
% change BMI	−2.3 (−3.7, −0.8)	−5.8 (−7.3, −4.4)	0.001
Change HbA1c (mg%)	−0.1 (−0.2, 0.01)	−0.1 (−0.2, 0.01)	0.96
Change total cholesterol (mg/dL)	+6.0 (−2.8, 14.8)	−21.6 (−29.9, −13.3)	<0.001
Change HDL-cholesterol (mg/dL)	+2.1 (−1.3, 5.4)	+1.1 (−2.1, 4.2)	0.68
Change systolic blood pressure (mmHg)	−2.3 (−6.1, 1.6)	−1.9 (−5.6, 1.9)	0.88
12–14 months	*n*=33	*n*=29	
% change in weight	−1.8 (−3.9, 0.3)	−6.0 (−8.3, −3.8)	0.008
% change BMI	−1.4 (−3.6, 0.8)	−6.7 (−9.1, −4.4)	0.002
Change HbA1c (mg%)	0.0 (−0.1, 0.2)	−0.1 (−0.2, 0.1)	0.28
Change total cholesterol (mg/dL)	+11.8 (1.3, 22.4)	−13.5 (−24.3, −2.8)	0.002
Change HDL-cholesterol (mg/dL)	−1.4 (−4.4, 1.3)	+1.9 (−1.0, 4.7)	0.10
Change systolic blood pressure (mmHg)	−2.7 (−8.0, 2.7)	−1.6 (−7.3, 4.1)	0.78

[a] Mean (95% CI)

DPP, The Diabetes Prevention Program