A Lifestyle Intervention Study in Patients with Diabetes or Impaired Glucose Tolerance: Translation of a Research Intervention into Practice

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Objective: **The objectives of this study were to translate a research-validated lifestyle modification curriculum of the Diabetes Prevention Program (DPP) into a community-based program delivered by trained graduate students on a university campus and determine whether this delivery approach is effective in lowering risk factors of type 2 diabetes in at-risk adults.**

Methods: **A convenience sample of 29 prediabetic or type 2 diabetic patients completed a 12-month behavior modification intervention to achieve and maintain at least 7% weight loss and become more active. Changes in weight, waist and hip circumferences, blood pressure, metabolic biomarkers, physical activity levels, and medication were assessed.**

Results: **At 6 and 12 months, 39% and 56% of patients had lost ≥5% of their weight. The mean weight loss at 12 months was 6%. Significant improvements were noted in most other anthropometric measurements and diastolic BP (−4.1 mm Hg). Significant reductions in total cholesterol (−11.7%), LDL-C (−7.6%), and HDL-C (−6.5%) were observed by 6 months but not at 12 months. Fasting glucose (−12%), systolic BP (−8.4 mm Hg), and diastolic BP (−7.0 mm Hg) were significantly improved in a subgroup of participants with at least 5% weight loss. HbA1c levels were associated with percentage weight loss. Twenty-seven percent of participants on diabetes medication had their drug discontinued.**

Conclusion: **Weight-related findings of this study are comparable with those of the DPP. DPP curriculum implemented in a nonclinical setting can help some adults at-risk for or in early stages of diabetes improve anthropometric and certain metabolic outcomes. (J Am Board Fam Med 2009;22:535–543.)**

More than 20 million Americans have type 2 diabetes, and that number is expected to double by 2050.[1] A major risk factor of diabetes is excessive adiposity, which is often a consequence of poor diet and physical inactivity. Lifestyle interventions with an emphasis on behavior modification and weight reduction have been effective in lowering the incidence of diabetes.[2–4] In the landmark study, the Diabetes Prevention Program (DPP), the lifestyle therapy resulted in a 58% lower incidence of diabetes in patients compared with those in the control group.[5]

The benefits of lifestyle interventions for diabetes risk reduction are well established, yet the translation of research-based interventions into clinical practice is limited. Although health care professionals are making attempts to increase the public's awareness about the benefits of a lifestyle approach, many providers have limited time, knowledge, or confidence in their ability to influence their patients' dietary and physical activity habits. Wee et al[6] reported that the rate of physician counseling about physical activity nationwide was only 34%. Using a nationally representative sample of US adults from the 2000 National Health Interview Survey, Honda[7] determined that only 21.3% and 24.5% of patients received physician advice about diet and exercise, respectively. In one study, health care providers were generally enthusiastic about giving lifestyle advice.[8] However, lack of time and resources and low knowledge of physical activity guidelines were reported as barriers to routine advising. In a survey of 620 physicians, 54% indicated that they would spend more time addressing pa-

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tients' weight concerns if their time was sufficiently reimbursed.[9]

Behavior modification is a complex process. The current dilemma faced by health care providers and patients is that the former do not have the necessary time and resources to engage their patients in an intensive lifestyle modification program, whereas the latter are often not motivated or knowledgeable enough to make substantial behavioral changes on their own. Thus, it is prudent to explore alternative ways to translate effective research interventions into practice. It is also necessary to examine whether such interventions would work in a real-world environment as effectively as they do in the research setting.

In this 1-year study, the DPP lifestyle curriculum was delivered to individuals at risk for or in the early stages of type 2 diabetes by trained graduate students in the university setting. The primary objective was to examine the effects of the intervention on anthropometric outcomes, physical activity and fitness measures and selected biomarkers.

Table 1. Baseline Characteristics of Participants (n = 31)

Characteristic	N (%)	Mean ± SD (Range)
Age		55.8 ± 8.9 (29–66)
Sex		
Female	19 (61)	
Male	12 (39)	
Race		
White	29 (94)	
African American	1 (3)	
Asian American	1 (3)	
Diagnosed with diabetes	14 (45)	
Diagnosed with IGT	14 (45)	
Classified as "high risk"	3 (10)	
Self-reported history of smoking		
Never smoked	15 (48.6)	
Smoked in the past	14 (45.4)	
Current smoker	2 (6)	
Family history of diabetes	26 (84)	

IGT, impaired glucose tolerance.

Methods

This study, entitled "Fitness Plus," was approved by the University of Northern Iowa Institutional Review Board and all participants signed informed consent. Physician consultants and collaborators involved with this study were available to answer any medical- and health-related questions, as needed.

Participants

Participants were recruited using rolling enrollment through local physician clinics, flyers, and newsletter advertisement during the summer of 2007. Of the participants who met the inclusion criteria (n = 31), 20 were recruited through physician referral (family physicians and internal medicine specialists), 7 through a university newsletter, and 4 by word of mouth. Inclusion criteria were age 25 to 65 years and diagnosis of impaired glucose tolerance or type 2 diabetes within the past 5 years. In addition, individuals at high risk for developing diabetes were also eligible. "High risk" was defined as being overweight (body mass index ≥25); having a family history of diabetes; and having at least one of the following conditions: a history of gestational diabetes, hypertension, dyslipidemia, or a sedentary lifestyle. Exclusion criteria included those who were on insulin treatment, had any major physical disability that would interfere with moderate-intensity physical activity, had been diagnosed with diabetes for longer than 5 years (or had type 1 diabetes), or had fewer than 3 risk factors to be classified as "high risk."

Thirty-one participants initially enrolled in the study. Baseline characteristics of the participants are shown in Table 1. During the course of the study, one female and 2 male participants withdrew (Figure 1). Two participants withdrew early in the study because of time constraints and one discontinued participation for unknown reasons after completing the mid-study assessment. In addition, 2 participants did not complete the final 12-month assessment because they were affected by natural disasters (tornado and floods) that occurred in their area at that time. Thus, 29 participants (94%) completed the weight-loss phase of the program (the first 6 months), including baseline and 6 month assessments, and 26 participants (84%) completed the entire 12-month study. One participant was excluded from data analysis because of noncompliance with the study protocol. He suffered from severe chronic back pain caused by a herniated disk and was unable to do any physical activity for the duration of the program.

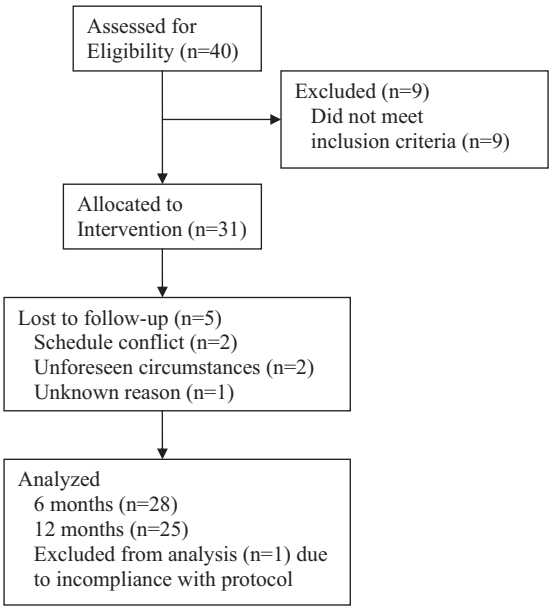

Figure 1. Flow of participants through the study.

Intervention

Three graduate students majoring in exercise science were thoroughly trained to deliver the DPP lifestyle curriculum according to the "DPP Lifestyle Intervention Manual of Operations."[10] Each student ("a health coach") was assigned approximately 10 participants for the duration of the study. The health coaches met with their participants on a weekly or biweekly basis during the first 6 months (the weight-loss phase) and once a month during the last 6 months (the weight-loss maintenance phase). In addition to a monthly visit, the health coaches made at least one monthly telephone call to each participant to discuss progress, address concerns, and provide encouragement during the maintenance phase. The health coaches met with each participant individually, except for spouses who attended educational sessions together.

The DPP lifestyle modification curriculum described elsewhere[11] consisted of 16 core sessions that each participant completed within the first 6 months. In brief, the sessions were designed to increase participants' knowledge of healthy eating and physical activity, provide options and practical suggestions for safe weight loss and positive lifestyle changes, and familiarize participants with motivational and problem-solving strategies. The primary diet-related goal was to reduce the amount of dietary fat. Each participant was assigned a weekly fat gram goal based on their initial body weight. Participants recorded their fat intake during the weight-loss phase. In addition, Fitness Plus participants had one weekly physical activity (ie, personal training) session with their health coaches during the weight loss phase. A physical activity session usually followed an educational session, or a participant could choose to return on a different day. The health coaches developed an exercise plan and worked with each participant on increasing their competence and self-efficacy in health-related fitness. In addition to dietary goals, each participant had a weekly physical activity goal, depending on their physical abilities and fitness level. Participants were asked to record the number of minutes spent in moderate-intensity physical activity between appointments.

Similar to the DPP program, the goals for the Fitness Plus participants were to lose at least 7% of their initial body weight during the first 6 months, maintain that weight loss during the last 6 months, and engage in regular physical activity of moderate intensity for at least 150 minutes a week. The Fitness Plus program followed the DPP lifestyle curriculum closely. However, there were several key differences between the 2 programs. First, some of the DPP lessons were modified. For example, an old version of the Food Guide Pyramid was presented as a model for healthy eating in one of the DPP lessons. This lesson was revised to include the current MyPyramid. Second, the Fitness Plus program had limited resources and thus did not implement some of the features of the DPP. For example, the DPP participants were provided with food scales and measuring cups and spoons, bathroom scales, and a $100 incentive. These items were not available to Fitness Plus participants. Third, the Fitness Plus intervention was delivered on a university campus by trained graduate students who were majoring in Exercise Science whereas the DPP lifestyle coaches were primarily registered dietitians. Fourth, Fitness Plus participants were allowed to take oral medications for diabetes. In contrast, individuals taking diabetes medications were excluded from the DPP, which was necessary to meet that study's objectives. Finally, the Fitness Plus program lasted 12 months whereas the DPP participants were followed for up to 5 years.

Measures

All measurements were collected at baseline and 6-month and 12-month time points. Anthropomet-

ric and blood pressure measurements were obtained by trained Fitness Plus staff according to standard protocols. Participants were weighed on a Seca 872 electronic scale (Seca Corp., Hanover, MD) in light street clothes after removing their shoes, belts, watches, and the contents of their pockets. Height without shoes was taken twice with a digital, wall-mounted stadiometer. Waist and hip circumferences were taken twice by the same investigator at all time points to prevent the chance for interobserver bias. The investigator did not have access to participants' results from previous assessments (baseline and/or 6 months) before or during the procedure. Blood pressure readings were also taken twice with a RelyOn digital sphygmometer (DuPont, Wilmington, DE) after at least a 5-minute rest. The same arm was used at each time point. For measurements taken twice, the average of the 2 values was used in the statistical analysis.

As part of the study protocol, participants were asked to provide investigators with a copy of their blood test results, including fasting lipid panel (total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein (HDL) cholesterol, total cholesterol/HDL, and triglycerides) hemoglobin A1c, and fasting glucose, which had been obtained at their local physician clinic. A central laboratory was not used. Results of laboratory tests performed within 3 months before enrollment were used as part of the baseline assessment of the participant's health status. Participants were instructed to schedule their subsequent laboratory tests at their primary care provider's clinic around the time of the 6- and 12-month assessments. These laboratory tests were part of the participant's routine follow-up with their physician. Laboratory test costs were covered by the participant's health insurance. The test results were used to assess participants' changes in health status in response to the intervention. It should be noted that certain laboratory values were not available for some participants. For example, hemoglobin A1c values were missing for some of the participants because the test is not routinely ordered for prediabetic patients. The numbers of participants whose laboratory tests were available for analysis are indicated in the Results section.

Medication usage during the study was recorded for each participant. The participants were instructed to bring their current medications and any new medications to appointments with their health coach. The medication form was updated at least once a month or at any time the participant had a change in medication. Self-reported physical activity levels were assessed using a standard, 7-day physical activity log, which was completed by each participant 1 week before each assessment. Participants were instructed to record their moderate/vigorous physical activity daily for a 7-day period. They were provided with an explanation of what comprises moderate vigorous activity and a handout with examples of activities in light-, moderate-, and vigorous-intensity categories.

Statistical Analysis

One participant was excluded from data analysis because of incompliance, as explained earlier. Thus, baseline/6 month comparisons and baseline/12 month comparisons included 28 and 25 participants, respectively. A paired *t* test was used to examine differences in the outcomes between baseline and 6 months and baseline and 12 months. A separate paired *t* test analysis was performed on a subgroup of participants who lost at least 5% of the initial weight (a threshold weight loss associated with significant health benefits) and maintained that weight loss for the duration of the study. Pearson correlation analysis was used to examine the association between weight loss and hemoglobin A1c concentrations. All outcome variables were checked for normal distribution. Log transformation was performed for glucose and triglyceride values. Statistical significance was set at $\alpha < 0.05$. Changes in medication (an increase or decrease in dosage, a new drug, or the discontinuation of a drug) were summarized using descriptive statistics. All decisions about medication changes were at the discretion of the primary physician and occurred as part of usual medical care. The medication usage analysis was limited to drugs used for diabetes, hypertension, and dyslipidemia. Changes in medication costs of drug therapy regimens for these 3 conditions were calculated using online prices.[12] All analyses were performed with SPSS statistical software version 12.0 (SPSS Inc., Chicago, IL).

Results

At 6 months, 25% of the participants (7 of 28) met the 7% weight loss goal. An additional 14% (n = 4) lost between 5% and 7%, and 50% (n =

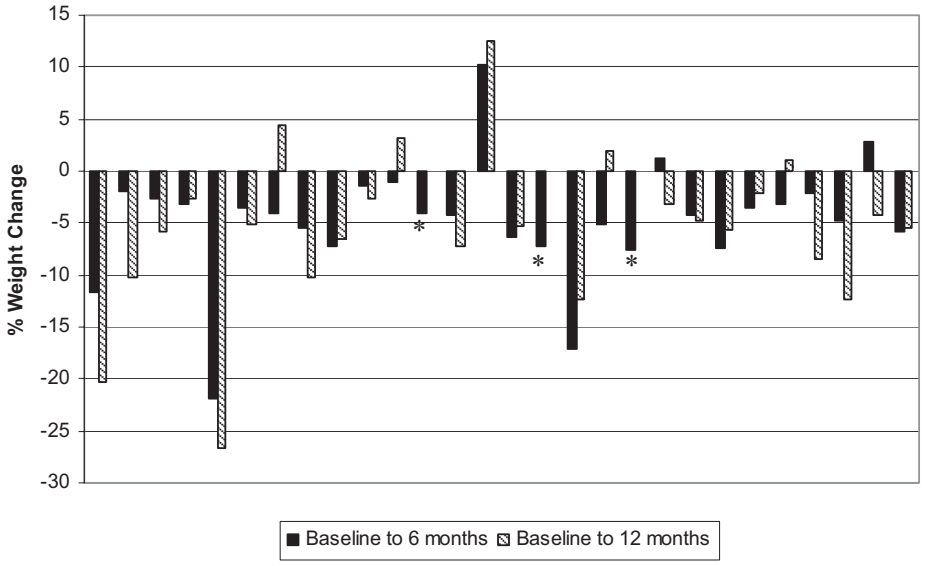

Figure 2. Change in the percentage body weight during the course of the study for each participant (n = 28). *Data for change in weight between baseline and 12 months were not available for participants who did not complete the 12-month assessment (n = 3).

14) lost between 1% and 5% of their initial weight. At 12 months, 32% (8 of 25) and 24% (n = 6) lost at least 7% and between 5% and 7% of their weight, respectively. In addition, 24% (n = 6) lost between 2% and 5%. Eleven percent (n = 3) and 16% (n = 4) gained some weight at 6 months and 12 months, respectively. The participants showed weight fluctuations during the course of the study; some continued to lose weight after the mid-study assessment whereas some regained a certain portion of the lost weight. However, as a group, Fitness Plus participants achieved an average 6-kg weight reduction at 6 months and maintained that weight loss until the end of the study (Figure 2).

The effects of the intervention on anthropometric and blood pressure measurements are summarized in Table 2. With the exception of the waist-to-hip ratio, significant reductions in all anthropometric measurements occurred between baseline and 6 months. These changes were sustained during the maintenance phase. Diastolic blood pressure was significantly lower at 6 and 12 months compared with baseline. Reduction in systolic blood pressure approached borderline significance ($P = .064$) at 6 months but not at 12 months.

Table 2. The Effects of the Intervention on Anthropometric Measurements and Blood Pressure

Outcome	Baseline (n = 28)	6 Months (n = 28)	P^*	12 Months (n = 25)	$P^\dagger$
Weight (kg)	100.2 ± 21.1 (69.1–153.3)	94.1 ± 20.2 (67.7–150.3)	<.001	94.1 ± 19.6 (66.0–148.5)	.001
BMI (kg/m^2)	36.1 ± 6.7 (26.3–53.3)	34.0 ± 6.8 (25.9–50.9)	<.001	34.0 ± 6.7 (25.5–51.9)	.001
Waist circumference (cm)	109.5 ± 16.0 (79.0–143.0)	105.0 ± 16.8 (78.0–141.0)	<.001	104.2 ± 16.1 (75.1–137.7)	.002
Hip circumference (cm)	118.5± 14.8 (97.1–156.9)	114.5 ± 14.1 (95.0–143.1)	<.001	114.6 ± 13.8 (95.5–145.3)	.001
Waist-to-hip ratio	0.93 ± 0.1 (0.7–1.2)	0.92 ± 0.1 (0.8–1.1)	.106	0.91 ± 0.1 (0.7–1.1)	.072
Systolic blood pressure (mm Hg)	130.0 ± 13.4 (104–176)	123.9 ± 16.4 (96–197)	.064	126.9 ± 15.8 (103–170)	.241
Diastolic blood pressure (mm Hg)	82.6 ± 9.6 (59–98)	77.1 ± 10.8 (60–95)	.011	78.5 ± 10.7 (64–102)	.024

Values shown as mean ± SD (range).
*Results of the paired samples *t* test, comparisons of 6-month and baseline values.
†Results of the paired samples *t* test, comparisons of 12-month and baseline values.

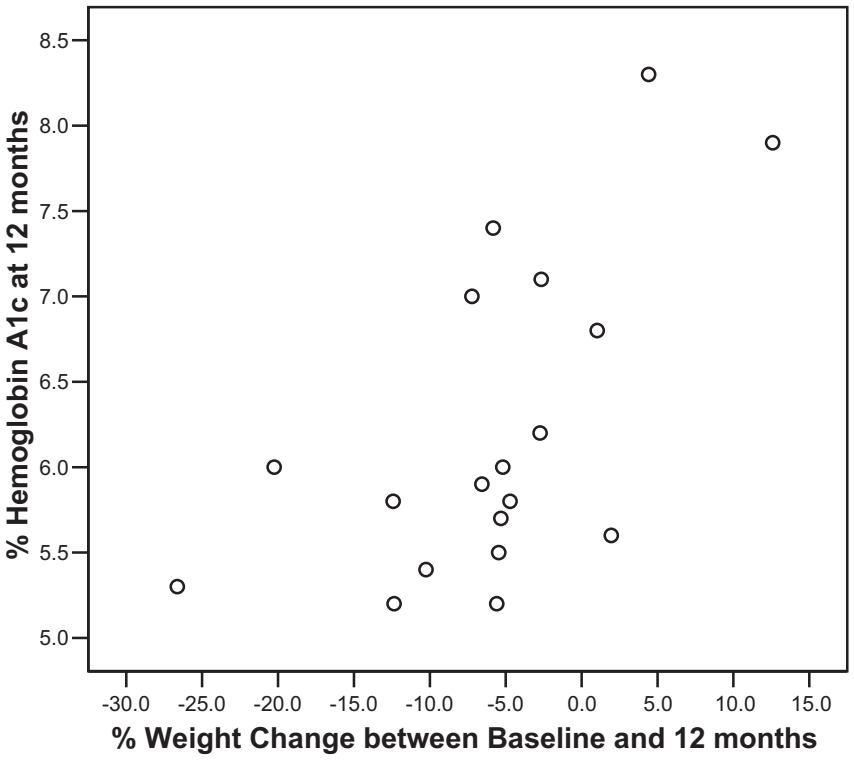

Figure 3. Correlation between the percentage of weight loss (baseline to 12 months) and hemoglobin A1c (n = 19) using Pearson correlation (r = 0.608; *P* = .006; n = 19).

At baseline, the mean blood lipid concentrations were within or near normal ranges (except for triglycerides; mean ± SD, 195 ± 163 mg/dL; n = 28) whereas fasting glucose (mean ± SD, 118.4 ± 19.6 mg/dL; n = 21) and hemoglobin A1c (mean ± SD, 6.5 ± 1%; n = 22) were mildly elevated. Significant reductions in lipid parameters, including total cholesterol (−11.7% or 21.2 mg/dL [95% CI, 6.6–35.6]; n = 28), low-density lipoprotein cholesterol (−7.6% or 7.8 mg/dL [95% CI, 1.1–14.6]; n = 27), and HDL cholesterol (−6.5% or 2.8 mg/dL [95% CI, 0.2–5.6]; n = 27) occurred between baseline and 6 months. In addition, there were suggestive declines in blood glucose (*P* = .092; n = 21) and triglyceride concentrations (*P* = .101; n = 28) but not in hemoglobin A1c (6.4% ± 0.9% at 6 months). Comparisons between baseline and 12-month values revealed no significant changes in any of the laboratory tests. Although the mean hemoglobin A1c levels did not change throughout the study, Pearson correlation analysis showed an inverse association between hemoglobin A1c levels and the percentage of body weight loss at 6 months (r = 0.499; *P* = .009; n = 26) and at 12 months (r = 0.608; *P* = .006; n = 19; see Figure 3).

A subgroup analysis of the participants (n = 14) who lost at least 5% of their initial weight and maintained the weight loss during the course of the study showed significant reductions in systolic blood pressure (−8.4 mm Hg [95% CI, 2.4–14.3] from 132 ± 11.9 at baseline), diastolic blood pressure (−7.0 mm Hg [95% CI, 1.7–12.4] from 84.4 ± 9.0) and fasting glucose concentration (−13.9 mg/dL [95% CI, 0.6–27.2] from 116.2 ± 22.2) between baseline and 12 months. Their lipid concentrations and hemoglobin A1c did not change.

At baseline, 77.8% (n = 21), 74% (n = 20), and 40.7% (n = 11) of participants were on antihypertensive, antihyperlipidemic, and diabetes medications, respectively. Medication changes pertaining to diabetes, hypertension, or hyperlipidemia occurred in 13 participants during the study period (Table 3). Some participants were able to discontinue or lower their dose of medications; at 12 months this occurred in 10% (n = 2), 27.3% (n = 3), and 10.5% (n = 2) of participants who were receiving maintenance medication at baseline (for hypertension, diabetes, and dyslipidemia, respectively). These were patients who likewise had no new medication initiated nor dosage increases of

Table 3. Frequency of Medication Changes Related to Hypertension, Diabetes, or Hyperlipidemia*

Medication	New Drug Start	Dose of Existing Drug Increased	Dose of Existing Drug Decreased	Drug Discontinuation
Antihypertensive	0	2	2	1
Diabetes	3	2	0	5
Antihyperlipidemic	4	1	2	6
Total	7	5	4	12

*Medication changes pertaining to hypertension, diabetes, or hyperlipidemia occurred in 13 participants during the study period.

concomitant drugs for these conditions. The total reduction in costs for drug therapy for these conditions among the 13 participants was $121 per month. Of note, 3 of the 4 participants who had a diabetes medication discontinued during the study remained off of their medication at 12 months.

Participants who lost at least 5% of their body weight were significantly more likely to experience a change in their medication regimen (eg, dosage decrease) for these 3 disease conditions compared with those with less weight loss (76.9% and 23.1%, respectively; $P = .018$). Four of the 5 participants who had one or more maintenance medication dosage lowered or discontinued were among participants who lost at least 5% of their body weight ($P = .192$ vs those with less weight loss).

The average amount of moderate-intensity physical activity (minutes per week) varied widely among the participants and was relatively high at each time point: 230 ± 209 at baseline, 198.4 ± 124 at 6 months, and 258 ± 215 at 12 months. The level of physical activity did not change significantly between assessments. The proportion of participants who reported at least 150 minutes of moderate-intensity activity per week was 53.6% (n = 15) at baseline and 6 months and 61.5% (n = 16) at 12 months.

Discussion

The main objective of this study was to replicate an effective research intervention in a nonclinical setting with limited resources (a typical condition of many service programs) and determine whether the intervention would remain effective in improving certain metabolic and anthropometric outcomes in individuals who were prediabetic or at an early stage of the disease. Compared with the DPP Lifestyle group,[5] Fitness Plus participants were, on average, older (50.6 ± 11.3 years vs 55.8 ± 8.90 years) and heavier (body mass index of 33.9 ± 6.8 vs 36.1 ± 6.7) at baseline. At 6 months, 25% of Fitness Plus participants achieved the 7% weight loss goal compared with 50% in the DPP program. During the final assessment, 32% of Fitness Plus participants (at 12 months) and 38% of the DPP participants (at the last visit within a 1.8- to 4.6-year follow-up) maintained a weight loss of at least 7%. The physical activity goal of at least 150 minutes per week was met by 53.6% of Fitness Plus participants and 74% of DPP participants at 6 months. The same goal was met by 61.5% of Fitness Plus participants and 58% of DPP participants at the last follow-up visit.

At least 2 other studies have implemented research-validated lifestyle interventions in a real-life setting. Absetz et al[13] reported that 12% of their 352 participants achieved a weight reduction of at least 5% and that 65% met their goal of at least 240 minutes/week of moderate-intensity physical activity by 12 months. Medical literature suggests that 5% weight loss is associated with significant metabolic benefits.[14] Similar to the Fitness Plus study, McBride et al[15] adopted the DPP lifestyle protocol for cardiac rehabilitation patients. Their results showed an average weight reduction of 4.5 kg by 12 months (compared with an average weight loss of 6 kg in our study). The authors reported significant improvements in blood pressure values, glucose, and lipids by 12 months. However, the improvements in lipid and blood pressure values were not adjusted for the use of antihyperlipidemic and antihypertensive medications.

The majority of Fitness Plus participants were on antihyperlipidemic, antihypertensive, or diabetes medication. Thus, changes in the metabolic outcomes throughout the study might have not accurately reflected the effect of the intervention. It should be noted, however, that the amount of weight loss was consistently associated with hemoglobin A1c levels at each time point. In other

words, the participants with a greater weight loss had lower levels of hemoglobin A1c at 6 and 12 months. An alternative way to assess the impact of an intervention on metabolic outcomes is by tracking changes in medication. Our intervention resulted in lower maintenance medication usage and costs for diabetes, hypertension, and hyperlipidemia. Given that all medication changes occurred during routine patient care and were not part of the study protocol, we were very encouraged with these findings. The observation that 27% of patients taking diabetes medication had their drug discontinued is especially noteworthy.

The results of physical activity assessment were somewhat unexpected. The participants reported relatively high levels of moderate-intensity activity at baseline, and the average levels remained fairly constant throughout the study. Seasonal variation in physical activity, inaccurate reporting, or misunderstanding of what counts as "moderate intensity" activity might have influenced the outcome. All participants were recruited in the summer and completed the midstudy assessment in December or January. Although the participants were provided with an explanation and examples of moderate-intensity physical activity, some of them rated the intensity of their activities based on perceived exertion rather than objective criteria, such as walking at 3 to 4 mph. Because of the limitations of self-reported data, it is prudent for any program to include some form of objective physical activity and/or fitness assessment.

Conclusion

This study used a nontraditional method of intervention delivery in the university setting by trained graduate students rather than health professionals. There was a close collaboration between the study staff and local health care providers who encouraged their patients to enroll in the Fitness Plus program and provided medical consultation as needed. This collaboration model can be replicated by other communities working to combat the growing prevalence of type 2 diabetes. It may help ease the burden on health care professionals while providing a valuable opportunity for students to gain practical experiences in dealing with lifestyle modification and weight management issues. The DPP materials are available through the DPP Study Document website.[10] Qualified professionals, such as fitness center instructors, cardiac rehabilitation personnel, or staff from community hospitals, could use these resources in their practice. Because the program involves patient education it can be delivered in any setting, including local schools and YMCAs.

The results of this study should be interpreted with caution because of the bias associated with the recruitment of volunteers, the lack of a control group, the relatively small sample size, the lack of ethnic diversity, and self-reported physical activity levels. However, the weight-related findings of this study are comparable with those of others[5,14,15] and demonstrate that the DPP curriculum implemented in a nonclinical setting can help some adults at risk for type 2 diabetes modify their lifestyle, lose weight, and improve certain metabolic outcomes.

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