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The Feasibility, Acceptability, and Preliminary Effectiveness of a Promotora-Led Diabetes Prevention Program (PL-DPP) in Latinas:

A Pilot Study

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Abstract

Purpose—The purpose of this pilot study is to test the feasibility, acceptability, and preliminary effectiveness of a Promotora-Led Diabetes Prevention Program (PL-DPP) in Hispanic women (Latinas).

Methods—Twenty Latina adults with prediabetes were enrolled in this single-arm pilot trial of PL-DPP. Participants underwent a year-long lifestyle intervention consisting of 24 sessions divided into 14 weekly core sessions and 10 post-core sessions offered either biweekly or monthly. Each session was led by a promotora in Spanish. The primary outcome was weight change over the 12-month study period.

Results—The study participants were socioeconomically challenged, middle-aged Latinas with limited access to health care. Eighteen participants (90%) completed at least 12 sessions, and 1 was lost to follow-up. Overall, participants reported high levels of satisfaction with PL-DPP. At 12 months, the participants achieved a mean weight loss of 10.8 pounds, which corresponded to 5.6% of initial body weight. Significant pre-post reductions in waist circumference, diastolic blood pressure, LDL cholesterol, and insulin levels were also observed. Modest reductions in A1C and fasting plasma glucose were not significant.

Conclusions—The PL-DPP demonstrated feasibility, acceptability, and preliminary effectiveness in a high-risk population of Latinas. Future research examining this intervention in a

randomized clinical trial should explore factors impacting its effects using both qualitative and quantitative methods.

Over 29 million American adults have diabetes, which causes significant morbidity and mortality while accounting for \$244 billion in annual health care spending.^{1,2} In addition, the Centers for Disease Control and Prevention estimates that 86 million Americans have prediabetes and are at high risk for progressing to overt diabetes.² Previous research suggests that Latinos have the highest risk of developing diabetes compared to African Americans and non-Hispanic whites.³ Furthermore, 1 study reported that Hispanic women (hereafter referred to as Latinas) have a 52% lifetime risk of diabetes compared to 45% among Hispanic men.⁴ Indeed, Latinas should be a high priority for further research that seeks to understand and intervene upon possible causes for these inequalities, which relate to a likely interplay of genetic, biologic, behavioral, sociocultural, and environmental characteristics.

Now considered the gold standard for evidence-based interventions to prevent or delay type 2 diabetes, the Diabetes Prevention Program (DPP) clinical trial demonstrated that a structured lifestyle program involving the adoption of moderate physical activity and modest weight loss can reduce the development of type 2 diabetes by 58% among adults with prediabetes.⁵ This program was designed to help participants lose weight by reducing caloric intake, altering the macronutrient composition of their diets, and promoting regular physical activity. Many groups have adapted the DPP lifestyle program and delivered it in diverse settings and populations with varied success.⁶

One promising model for delivering this lifestyle intervention in community settings involves using lay health workers as group leaders.⁷⁻¹⁵ Such a workforce may promote the cost-effectiveness and potential scalability of the program while increasing its responsiveness to diverse target populations. However, few existing DPP translations using lay health workers have included Latino participants,¹²⁻¹⁴ and no studies to date have focused exclusively on Latinas. Thus, little is currently known about how best to adapt approaches for dietary modification and physical activity promotion to maximize behavioral changes among this high-risk population. Latinas are also an important influence on the health behaviors of family members and have a respected position of authority in their culture.¹⁶ Interventions focused on Latinas may therefore have multiplicative effects within their families¹⁷ and even more broadly in their communities.¹⁸

The overall objective of this pilot study was to test the feasibility, acceptability, and preliminary effectiveness of a culturally appropriate adaptation of the DPP lifestyle program for Latinas, delivered by lay community health workers (hereafter referred to as promotoras). The primary aim was to evaluate pre-post changes in weight and the following cardiometabolic markers from baseline to 12 months: waist circumference, blood pressure, and plasma glucose, insulin, hemoglobin A1C, and lipids. Additionally, the authors sought to assess the feasibility and acceptability of this intervention model by tracking participant attendance and soliciting their qualitative feedback after completing the program. In an exploratory aim, associations among changes in psychosocial measures and weight were examined.

Methods

Study Design

The authors conducted a pilot trial of the Promotora-Led DPP (PL-DPP) to prepare for a larger randomized controlled trial of this intervention, which is currently underway (NCT 02088034). The current pilot trial included only 1 experimental arm, in which all participants received the PL-DPP. Outcomes were assessed at 12 months and analyzed as changes from baseline. The study protocol was approved by the institutional review boards at the Temple University School of Medicine and Northwestern University Feinberg School of Medicine.

Participants and Setting

The authors recruited participants during health fairs conducted by Latino-serving nonprofit organizations and community gatherings held at a local church in Philadelphia. The study team brought a table to these community-based events where they completed initial screening activities. In addition, recruitment efforts were conducted in 2 primary care clinics serving the target population. All women who expressed interest in participating were asked to complete the American Diabetes Association's (ADA) 7-item Diabetes Risk Assessment Questionnaire.¹⁹ Those with an ADA risk score of 5 or greater underwent fasting lab work at Temple University's Center for Obesity Research and Education. Eligibility criteria included Latina ethnicity, Spanish language fluency, age at least 20 years, and body mass index of 25 kg/m² or higher. In addition, all participants were required to have prediabetes, defined according to the most recent ADA criteria²⁰: fasting plasma glucose from 100 to 125 mg/dL (5.55–6.94 mmol/L) and/or hemoglobin A1C from 5.7–6.4 (38.8–46.4 mmol/mol). Those with any of the following exclusion criteria were not eligible to participate: current or planned pregnancy during the study period, diabetes at baseline, chronic conditions that could affect ability to participate (eg, uncontrolled cardiovascular disease, pulmonary disease with oxygen dependence, or arthritis limiting regular physical activity), medical comorbidities that could influence body weight (eg, HIV, cancer, or uncontrolled thyroid disease), and medications that could affect weight or glucose metabolism (eg, systemic corticosteroids, topiramate, bupropion, or quietapine). The authors enrolled 20 participants in this pilot study, which was implemented in 2 community-based organizations serving Latinos.

Description of the PL-DPP Intervention

The PL-DPP intervention was based on the Group Lifestyle Balance (GLB) program, which is a widely used and effective modification of the original DPP lifestyle intervention. This program has been described in depth elsewhere, and complete program materials are available online in English and Spanish.²¹ In short, the GLB program is a group-based lifestyle intervention focused on 2 primary goals for its participants—achieving 7% weight loss from baseline and engaging in 150 minutes per week of moderate physical activity. The instructional content of the GLB program focuses on the determinants of energy balance, including dietary changes and physical activity. This information is delivered in a year-long, 22-session curriculum that incorporates strategies for improving these health behaviors and

achieving the program goals. The first 12 sessions are administered weekly, and the following 10 sessions are spaced out to biweekly and then monthly delivery.

The PL-DPP protocol was developed by modifying the Spanish language GLB participant handouts. In addition, the investigators translated the English GLB trainers guide into Spanish and modified it for the promotoras' use. The authors conducted a qualitative study to guide the development of the PL-DPP protocol,²² which informed the creation of targeted messages about healthy behavior change in the Latino family context as well as culturally appropriate tools for dietary self-monitoring. In addition, this formative phase uncovered a need to spend additional time with topics related to dietary education and self-management. Based on feedback from the promotoras, the second and third GLB sessions were each divided into 2 separate sessions. Therefore, the PL-DPP program included 24 sessions over the 12-month period, with the first 14 sessions delivered weekly. All sessions were conducted in Spanish and were attended by 1 of the authors (V.A.A.), who ensured fidelity to the GLB protocol by confirming that all of the content in each participant handout was covered. Each session was led by 1 promotora, with another promotora serving as an assistant. To facilitate adherence to the PL-DPP protocol, the participants received self-monitoring materials also used in the original DPP, such as self-monitoring log books, pocket handbooks providing information about the fat and calorie content of common foods, measuring cups for cooking, a scale for weighing themselves, and a pedometer for monitoring daily steps.

Importantly, PL-DPP was designed for delivery by promotoras, who are lay health workers enabling emotional and role support for behavioral changes in ways that are culturally salient. This intervention model has proved particularly effective for chronic disease management among many racial and ethnic minority populations.²³ Promotora interventions have been studied extensively in diabetes management and have been shown to increase social support, improve self-management behaviors, and improve intermediate health outcomes among participants.^{24,25} The 2 promotoras who led PL-DPP sessions in this pilot study were initially chosen to conduct health education efforts based on their dedication to the community and natural leadership skills. Nonprofit partners serving the target population helped identify individuals with these characteristics, who were then interviewed by members of the study team to determine their suitability. Although these promotoras had no more than a high school education, they were highly familiar with the communities in which this study was implemented, having worked with the investigative team for 8 years and conducted several group-based lifestyle interventions prior to implementing PL-DPP. In addition, they received 18 hours of training from local and national diabetes prevention experts, including 1 of the developers of the GLB curriculum. After completing these training events, the promotoras delivered all 24 PL-DPP sessions to members of the investigative team who supervised them and gave feedback before implementing the study protocol with participants. Those who trained the promotoras on the protocol had advanced degrees in psychology, medicine, or public health.

Measures

Anthropomorphic and Cardiometabolic Measures—The primary outcome was the change in weight from baseline to 12 months, which was measured using a commercial-grade weight scale. Height was measured using a wall-mounted stadiometer to allow for calculation of body mass index (BMI). The following were secondary cardiometabolic outcomes: waist circumference (assessed as the average of 2 values measured with a measuring tape around the top of the iliac crests at end-expiration), systolic and diastolic blood pressures (each assessed as the average of 2 values measured with an aneroid sphygmomanometer with participants seated for 5 minutes prior), A1C, fasting glucose, insulin, and lipids. All plasma specimens were analyzed in the same Quest diagnostics laboratory.

Psychosocial Measures—In exploratory analyses for this pilot study, the authors examined 6 psychosocial covariates as potential mediators or moderators of the programs' preliminary efficacy. Each of the following measures is considered valid and has been widely used in the literature.^{26–31} Health literacy is defined as an individual's ability to understand and act on health information, which has been found to promote weight loss efforts.³² This construct was assessed in the current study using the Short Test of Functional Health Literacy in Adults, which consists of 36 items included in 2 prose passages ($\alpha = 0.97$).³³ Health-related quality of life (HRQL) is an individual measure of mental and physical health functioning assessed here with the SF-36³⁴ because of its negative association with chronic diseases like obesity and diabetes.³⁵ In a large body of research evaluating the SF-36 mental and physical health functioning scores, reliability statistics usually exceed 0.90.³⁶ Social support was assessed using the 12-item Multidimensional Scale of Perceived Social Support ($\alpha = 0.88$).^{31,37} Given the association between perceived stress and incident diabetes,³⁸ this construct was examined with the Perceived Stress Scale ($\alpha = 0.85$).²⁶ Because of their associations with both weight and glycemic control,^{39,40} depressive and anxiety symptoms were determined by the Beck Depression Inventory ($\alpha = 0.91$) and the GAD-7 ($\alpha = 0.92$), respectively.^{41,42} All survey instruments were administered to participants in Spanish using previously validated translations of these scales.

Feasibility and Acceptability Measures—The participants' attendance and attrition rates were considered key outcomes related to feasibility. In addition, the authors developed a brief questionnaire to explore the acceptability of the PL-DPP among participants. This tool consisted of 8 statements reflecting perceptions of the program and assessed their level of agreement with each statement on a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree). In addition, the authors asked participants the following open-ended question to guide future modifications of the PL-DPP intervention: "What would you change about the PL-DPP program?"

Statistical Analysis—Descriptive statistics were used to characterize the study cohort with respect to sociodemographic features (Table 1), physical and laboratory measurements (Table 2), and psychosocial measures (Table 3). Measures of intervention acceptability were assessed descriptively using summary statistics (Table 4). Primary and secondary outcome metrics were reassessed at 12 months to estimate mean changes in these indicators during

the study period. Primary and secondary outcome analyses included paired *t* tests for changes in anthropomorphic and laboratory measures (Table 2) and changes in psychosocial factors from baseline to 12 months (Table 3). In exploratory analyses, the authors used Pearson's sample correlation coefficient (*r*) to evaluate the association between the 12-month change in participants' psychosocial measures and the primary outcome—12-month change in weight. Because of the preliminary and exploratory nature of these analyses, no adjustments were made for multiple comparisons. All analyses were conducted using Stata 13.⁴³

Results

Baseline Characteristics

The study participants were middle-aged Latinas with limited access to health care, low educational attainment, and a mean household income below the federal poverty level (Table 1). All of the women were foreign born and primary Spanish speakers, with an average duration of US residence of almost 20 years. Over half of participants had a family history of diabetes, and one-quarter had a personal history of gestational diabetes (Table 1). At baseline, 18 participants were obese (BMI ≥ 30 kg/m²), and the same number had abdominal obesity, defined by a waist circumference of at least 88 cm.⁴⁴ All participants had prediabetes by either A1C or fasting plasma glucose, but only half of them had prediabetes by both criteria. More participants qualified for the study based on A1C criteria alone, which resulted in a mean fasting glucose level below the diagnostic threshold of 100 mg/dL (5.55 mmol/L). The participants had normal mean values for other cardiometabolic markers (Table 2).

Changes in Anthropomorphic and Cardiometabolic Outcomes

From baseline to 12 months, the participants achieved a clinically meaningful and statistically significant mean change in body weight of 10.8 pounds (4.9 kg) (Table 2). This corresponded to a 5.6% reduction in body weight (95% CI, 3.3%-8.0%). Forty-two percent of pilot participants achieved the 7% weight loss goal, and 58% achieved at least 5% weight loss. In addition to weight, there were also clinically meaningful and statistically significant pre-post reductions in waist circumference, diastolic blood pressure, LDL cholesterol, and fasting insulin levels (Table 2). There was a modest pre-post reduction in systolic blood pressure that did not achieve statistical significance. Pre-post changes in A1C and fasting plasma glucose were not significant (Table 2). However, 6 participants (30%) reverted to normoglycemia by 12 months based on changes in their serum fasting glucose.

Changes in Psychosocial Measures

Mean scores for perceived stress, anxiety, and depression all decreased from baseline to 12 months (Table 3). The reduction in depressive symptoms was statistically and clinically significant. Participants' scores for health literacy, health-related quality of life, and perceived social support improved during the study period. Changes were marginally significant for health literacy (*P* = .05) but not for other measures.

Associations Among Changes in Psychosocial Measures and Changes in Body Weight

Pre-post changes in perceived stress and anxiety showed statistically significant correlations with weight changes. Pre-post changes in depressive symptoms were modestly correlated with weight changes but did not achieve statistical significance (Table 3).

Feasibility and Acceptability of PL-DPP

Of the 20 individuals enrolled, participants completed an average of 71% of the sessions. Only 1 participant was lost to follow-up during the 12-month study, representing an attrition rate of 5%. Of the 19 participants who completed 12-month follow-up, 3 (15% of total sample) attended all 24 PL-DPP sessions, and 18 (90% of total sample) completed at least 12 sessions, which has been reported as an attendance threshold associated with weight loss.^{7,45} Indeed, session attendance in PL-DPP was significantly associated with weight loss ($P = .02$). Participants deemed the intervention highly acceptable (Table 4). The most common response to the open-ended question about what participants would change about the program was “nothing” ($n = 11$). Examples of some suggestions for improvement included the following: lengthen duration of program ($n = 1$), incorporate cooking demonstrations ($n = 2$), and include group-based exercise during sessions ($n = 2$).

Conclusions

In a sample of Spanish-speaking Latinas, the PL-DPP demonstrated preliminary weight loss effectiveness. The 12-month mean change in weight was both clinically and statistically significant in this single-arm pilot study. In addition, all other intermediate cardiometabolic outcomes improved from baseline to 12 months, except triglycerides. Depressive symptoms also improved significantly. In exploratory analyses, weight loss was associated with improvement in anxiety and perceived stress. High attendance rates, low attrition, and consistently positive feedback among PL-DPP participants all provide preliminary evidence of the intervention's feasibility and acceptability.

This is the first study to examine a culturally tailored version of the Diabetes Prevention Program focused exclusively on Latinas. The PL-DPP study population is also unique with respect to its low educational attainment and household income—socioeconomic factors that are consistently associated with poor metabolic health.⁴⁶ The mean weight loss achieved during this pilot PL-DPP intervention (5.6% of initial body weight) exceeds the pooled weight loss among lay health worker-led studies in a recent meta-analysis of DPP translations (3.2%).⁶ The 12-month mean change in weight in the current study (10.8 lbs) exceeds that observed in similar studies implemented among Latinos, the highest of which was 7.2 pounds.^{12–14} In addition, the preliminary effectiveness of the PL-DPP is supported by significant improvements in other cardiometabolic markers that were either unchanged in these studies or not reported. The change in weight and cardiometabolic risk factors found in this pilot feasibility study are approaching those observed in the most successful DPP translations.^{7,10,47,48}

Several factors may help explain the preliminary effectiveness of the PL-DPP program. The attendance rate was high compared to similar studies in the literature, and session attendance

is a consistent predictor of success in behavioral weight loss programs.^{7,45} Unlike some other similar studies, the PL-DPP protocol maintained a high level of fidelity to the original DPP content and format, including the total number and spacing of sessions. Cultural tailoring of the protocol may have increased its responsiveness to the target population's values and needs. Other studies have found that cultural appropriateness enhances the effectiveness of behavioral interventions,⁴⁹ which may have been the case here. In addition, the promotoras' experience prior to delivering the PL-DPP may also have contributed to its preliminary success. Unlike many community health worker programs,⁵⁰ those delivering the intervention in this pilot study had worked as a team for 8 years and conducted similar interventions during this time. In addition, the promotoras received training from local and national experts in diabetes prevention before implementing this pilot program.

Exploratory analyses suggest that psychological factors may play a role in the PL-DPP. Participants' mean depressive symptoms decreased significantly during the study period. There were also modest decreases in participants' perceived stress and anxiety symptoms from baseline to 12 months. Although these changes were not statistically significant, their associations with weight loss were. It is premature to conclude that these psychosocial factors improved as a result of the PL-DPP intervention or to determine whether they served as mediators or moderators of the study effects. However, previous studies have demonstrated shared physiologic and behavioral mechanisms underlying both diabetes and mental health outcomes, including hypothalamic-pituitary-adrenal (HPA) axis activation, inflammation, autonomic dysfunction, sleep dysregulation, unhealthy diets, and physical inactivity.⁵¹ Indeed, stress, negative mood, and HPA reactivity have been shown to increase calorie consumption in women.^{52,53} In addition, behavioral strategies for treating metabolic and mental health disorders involve teaching the same skills, such as goal setting, self-monitoring, and problem solving, that are associated with improved outcomes in both areas.⁵⁴ These observations suggest that adding a focus on stress reduction to the PL-DPP intervention may cause further improvements in cardiometabolic and mental health, given the participants' high burden of depressive symptoms.

This pilot feasibility study has several limitations. The study population was small, which limits the external generalizability of the findings. However, the characteristics of the PL-DPP pilot participants were similar to those reported in larger studies the authors have conducted in the same population,⁵⁵ which has a higher burden of diabetes risk factors than national estimates for Latinas.⁵⁶ The lack of a control group hinders making any causal inference between the PL-DPP intervention and the observed cardiometabolic improvements. However, it is unlikely that a control group in this study would have demonstrated clinically significant weight loss given that placebo participants in the original DPP trial lost only 0.3 kg at 12 months,⁵⁷ and observational cohort studies have consistently reported increasing trajectories of weight and cardiometabolic risk factors over time. The multiple analyses conducted on secondary outcomes raises the possibility that some of the findings may be spurious. However, our confidence in their general accuracy is increased as they are consistent with reports from DPP and other translational studies.^{58,59} Fidelity was measured qualitatively by 1 of the authors, who observed each session and compared the material presented by the promotoras with that included in participant handouts. Future research with the PL-DPP will include more formal fidelity assessments. As with any

nonrandomized and uncontrolled study, there also may have been unmeasured confounders that contributed to changes in the outcomes over time.

This pilot study has yielded important data about the preliminary feasibility, acceptability, and effectiveness of the PL-DPP that informs a larger, ongoing randomized trial of this intervention. The findings reported here suggest that delivery of the DPP by promotoras represents a promising approach for diabetes prevention in socioeconomically disadvantaged Latinas, a particularly high-risk population. Some of the most effective DPP translations including only black and white participants were led by lay people.^{7,10} Future research should explore the characteristics and processes of lay worker programs that promote their success, including selection and training protocols, strategies for engaging participants longitudinally, and creating links between communities and health care settings. Such research could inform best practices to guide the broad dissemination of promotora or lay health worker models for diabetes prevention nationwide.

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References

1. Dall TM, Yang W, Halder P, et al. The economic burden of elevated blood glucose levels in 2012: diagnosed and undiagnosed diabetes, gestational diabetes mellitus, and prediabetes. *Diabetes Care*. 2014; 37(12):3172–3179. [PubMed: 25414388]
2. Centers for Disease Control and Prevention. Number of Civilian, Noninstitutionalized Persons with Diagnosed Diabetes, United States, 1980–2011. Atlanta, GA: National Center for Health Statistics, National Health Interview Survey, Division of Diabetes Translation; 2013.
3. Cowie C, Rust K, Ford E, et al. Full accounting of diabetes and pre-diabetes in the US population in 1988–1994 and 2005–2006. *Diabetes Care*. 2009; 32(2):287–294. [PubMed: 19017771]
4. Narayan K, Boyle JP, Thompson T, Sorensen S, Williamson D. Lifetime risk for diabetes mellitus in the United States. *JAMA*. 2003; 290(14):1884–1890. [PubMed: 14532317]
5. Knowler W, Barrett-Connor E, Fowler S, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med*. 2002; 346(6):393–403. [PubMed: 11832527]
6. Ali M, Echouffo-Tcheugui J, Williamson D. How effective were lifestyle interventions in real-world settings that were modeled on the diabetes prevention program? *Health Affairs*. 2012; 31(1):67–75. [PubMed: 22232096]
7. Ackermann RT, Finch EA, Brizendine E, Zhou H, Marrero DG. Translating the Diabetes Prevention Program into the community: the DEPLOY pilot study. *Am J Prev Med*. 2008; 35(4):357–363. [PubMed: 18779029]
8. Faridi Z, Shuval K, Njike VY, et al. Partners reducing effects of diabetes (PREDICT): a diabetes prevention physical activity and dietary intervention through African-American churches. *Health Educ Res*. 2010; 25(2):306–315. [PubMed: 19261690]
9. Jiang LH, Manson SM, Beals J, et al. Translating the Diabetes Prevention Program into American Indian and Alaska Native communities: results from the Special Diabetes Program for Indians

- Diabetes Prevention demonstration project. *Diabetes Care*. 2013; 36(7):2027–2034. [PubMed: 23275375]
10. Katula J, Vitolins M, Rosenberger E, et al. One-year results of a community-based translation of the Diabetes Prevention Program Healthy-Living Partnerships to Prevent Diabetes (HELP PD) Project. *Diabetes Care*. 2011; 34(7):1451–1457. [PubMed: 21593290]
 11. Mau MK, Keawe'aimoku Kaholokula J, West MR, et al. Translating diabetes prevention into native Hawaiian and Pacific Islander communities: the PILI 'Ohana Pilot project. *Prog Community Health Partnersh*. 2010; 4(1):7–16. [PubMed: 20364073]
 12. Ockene IS, Tellez TL, Rosal MC, et al. Outcomes of a Latino community-based intervention for the prevention of diabetes: the Lawrence Latino diabetes prevention project. *Am J Public Health*. 2012; 102(2):336–342. [PubMed: 22390448]
 13. Parikh P, Simon E, Fei K, Looker H, Goytia C, Horowitz CR. Results of a pilot diabetes prevention intervention in East Harlem, New York City: Project HEED. *Am J Public Health*. 2010; 100:S232–S239. [PubMed: 20147680]
 14. Ruggiero L, Oros S, Choi YK. Community-based translation of the diabetes prevention program's lifestyle intervention in an under-served Latino population. *Diabetes Educ*. 2011; 37(4):564–572. [PubMed: 21690435]
 15. West DS, Bursac Z, Cornell CE, et al. Lay health educators translate a weight-loss intervention in senior centers: a randomized controlled trial. *Am J Prev Med*. 2011; 41(4):385–391. [PubMed: 21961465]
 16. Weiler DM, Crist JD. Diabetes self-management in a Latino social environment. *Diabetes Educ*. 2009; 35(2):285–292. [PubMed: 19204101]
 17. Moreno JP, Johnston CA. Considering the impact of acculturation on lifestyle interventions for Latinos. *Am J Lifestyle Med*. 2015; 9(1):40–42.
 18. Sobralske MC. Health care seeking among Mexican American men. *J Transcult Nurs*. 2006; 17(2): 129–138. [PubMed: 16595400]
 19. American Diabetes Association. *Diabetes Risk Test*. Alexandria, VA: American Diabetes Association; 2011.
 20. American Diabetes Association. *Diagnosis and classification of diabetes mellitus*. *Diabetes Care*. 2014; 37(1):S81–S90. [PubMed: 24357215]
 21. University of Pittsburgh: Diabetes Prevention Support Center. [Accessed February 6, 2015] 2015. <http://www.diabetesprevention.pitt.edu>
 22. O'Brien MJ, Shuman SJ, Barrios DM, Alos VA, Whitaker RC. A qualitative study of acculturation and diabetes risk among urban immigrant Latinas: implications for diabetes prevention efforts. *Diabetes Educ*. 2014; 40(5):616–625. [PubMed: 24872386]
 23. O'Brien MJ, Squires AP, Bixby RA, Larson SC. Role development of community health workers: an examination of selection and training processes in the intervention literature. *Am J Prev Med*. 2009; 37(6 suppl 1):S262–S269. [PubMed: 19896028]
 24. Ingram M, Torres E, Redondo F, Bradford G, Wang C, O'Toole ML. The impact of promotoras on social support and glycemic control among members of a farmworker community on the US-Mexico border. *Diabetes Educ*. 2007; 33:172S. [PubMed: 17620398]
 25. Shepherd-Banigan M, Hohl SD, Vaughan C, Ibarra G, Carosso E, Thompson B. The promotora explained everything. *Diabetes Educ*. 2014; 40(4):507–515. [PubMed: 24793637]
 26. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav*. 1983; 24(4):385–396. [PubMed: 6668417]
 27. Mills SD, Fox RS, Malcarne VL, Roesch SC, Champagne BR, Sadler GR. The psychometric properties of the Generalized Anxiety Disorder-7 Scale in Hispanic Americans with English or Spanish language preference. *Cultur Divers Ethnic Minor Psychol*. 2014; 20(3):463–468. [PubMed: 25045957]
 28. Parker RM, Baker DW, Williams MV, Nurss JR. The test of functional health literacy in adults. *J Gen Intern Med*. 1995; 10(10):537–541. [PubMed: 8576769]
 29. Penley JA, Wiebe JS, Nwosu A. Psychometric properties of the Spanish Beck Depression Inventory-II in a medical sample. *Psychol Assess*. 2003; 15(4):569–577. [PubMed: 14692850]

30. Ware JE, Gandek B. Overview of the SF-36 health survey and the international quality of life assessment (IQOLA) project. *J Clin Epidemiol*. 1998; 51(11):903–912. [PubMed: 9817107]
31. Zimet GD, Dahlem NW, Zimet SG, Farley GK. The multidimensional scale of perceived social support. *J Per Assess*. 1988; 52(1):30–41.
32. Davis TC, Bass PF, Arnold CL, et al. Provider and patient intervention to improve weight loss: a pilot study in a public hospital clinic. *Patient Educ Couns*. 2008; 72(1):56–62. [PubMed: 18346861]
33. Baker D, Williams M, Parker RM, Gazmararian J, Nurss J. Development of a brief test to measure functional health literacy. *Patient Educ Couns*. 1999; 38(1):33–42. [PubMed: 14528569]
34. Ware J, Sherbourne CD. The MOS36-Item Short-Form Health Survey (SF-36): I. Conceptual-framework and item selection. *Med Care*. 1992; 30(6):473–483. [PubMed: 1593914]
35. Kolotkin RL, Meter K, Williams GR, Kolotkin GR. Quality of life and obesity. *Obes Rev*. 2001; 2(4):219–229. [PubMed: 12119993]
36. Ware JE Jr. SF-36 health survey update. *Spine*. 2000; 25(24):3130–3139. [PubMed: 11124729]
37. Zimet G, Powell SS, Farley G, Werkman S, Berkoff K. Psychometric characteristics of the Multidimensional Scale of Perceived Social Support. *J Per Assess*. 1990; 55(3–4):610–617.
38. Novak M, Björck L, Giang KW, Heden-Stahl C, Rosengren L, Wilhelmsen A. Perceived stress and incidence of type 2 diabetes: a 35-year follow-up study of middle-aged Swedish men. *Diabetic Med*. 2013; 30(1):e8. [PubMed: 23075206]
39. Katon WJ. The comorbidity of diabetes mellitus and depression. *Am J Med*. 2008; 121(11, suppl 2):S8–S15. [PubMed: 18954592]
40. Lustman PJ, Clouse RE. Depression in diabetic patients: the relationship between mood and glycemic control. *J Diabetes Complicat*. 2005; 19(2):113–122. [PubMed: 15745842]
41. Beck AT, Ward CH, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. *Arch Gen Psychiatry*. 1961; 4:561–571. [PubMed: 13688369]
42. Spitzer R, Kroenke K, Williams J, Lowe B. A brief measure for assessing generalized anxiety disorder—the GAD-7. *Arch Intern Med*. 2006; 166(10):1092–1097. [PubMed: 16717171]
43. Stata 13 [computer program]. Version 13. College Station, TX: StataCorp LP; 2013.
44. Grundy SM, Cleeman JI, Daniels SR, et al. Diagnosis and management of the metabolic syndrome: an American Heart Association/National Heart, Lung, and Blood Institute scientific statement. *Circulation*. 2005; 112(17):2735–2752. [PubMed: 16157765]
45. Venditti EM, Bray GA, Carrion-Petersen ML, et al. First versus repeat treatment with a lifestyle intervention program: attendance and weight loss outcomes. *Int J Obes*. 2008; 32(10):1537–1544.
46. Brown AF, Ettner SL, Piette J, et al. Socioeconomic position and health among persons with diabetes mellitus: a conceptual framework and review of the literature. *Epidemiologic Rev*. 2004; 26(1):63–77.
47. Amundson HA, Butcher MK, Gohdes D, et al. Translating the diabetes prevention program into practice in the general community: findings from the Montana Cardiovascular Disease and Diabetes Prevention Program. *Diabetes Educ*. 2009; 35(2):209–210, 213–214, 216–220. [PubMed: 19321807]
48. Vanderwood KK, Hall TO, Harwell TS, Butcher MK, Helgerson SD. Implementing a state-based cardiovascular disease and diabetes prevention program. *Diabetes Care*. 2010; 33(12):2543–2545. [PubMed: 20805260]
49. Kreuter M, Lukwago S, Bucholtz DC, Clark E, Sanders-Thompson V. Achieving cultural appropriateness in health promotion programs: targeted and tailored approaches. *Health Educ Behav*. 2003; 30(2):133–146. [PubMed: 12693519]
50. Shediac-Rizkallah MC, Bone L. Planning for the sustainability of community-based health programs: conceptual frameworks and future directions for research, practice and policy. *Health Educ Res*. 1998; 13(1):87–108. [PubMed: 10178339]
51. Holt RIG, De Groot M, Lucki I, Hunter CM, Sartorius N, Golden SH. NIDDK international conference report on diabetes and depression: Current understanding and future directions. *Diabetes Care*. 2014; 37:2067–2077. [PubMed: 25061135]

52. Adam TC, Epel ES. Stress, eating and the reward system. *Physiol Behav.* 2007; 91(4):449–458. [PubMed: 17543357]
53. Epel E, Lapidus R, McEwen B, Brownell K. Stress may add bite to appetite in women: a laboratory study of stress-induced cortisol and eating behavior. *Psychoneuroendocrinology.* 2001; 26(1):37–49. [PubMed: 11070333]
54. Fisher EB, Chan JCN, Nan H, Sartorius N, Oldenburg B. Co-occurrence of diabetes and depression: Conceptual considerations for an emerging global health challenge. *J Affect Disord.* 2012; 142:S56–S66. [PubMed: 23062858]
55. Wanat KA, Kovarik CL, Shuman S, Whitaker RC, Foster GD, O'Brien MJ. The association between obesity and health-related quality of life among urban Latinos. *Ethn Dis.* 2014; 24(1):14–18. [PubMed: 24620443]
56. Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999–2008. *JAMA.* 2010; 303(3):235–241. [PubMed: 20071471]
57. Ackermann RT, Edelstein SL, Narayan KM, et al. Changes in health state utilities with changes in body mass in the Diabetes Prevention Program. *Obesity.* 2009; 17(12):2176–2181. [PubMed: 19390518]
58. Rubin RR, Knowler WC, Ma Y, et al. Depression symptoms and antidepressant medicine use in diabetes prevention program participants. *Diabetes Care.* 2005; 28(4):830–837. [PubMed: 15793181]
59. Trief P, Cibula D, Delahanty L, Weinstock R. Depression, stress, and weight loss in individuals with metabolic syndrome in SHINE, a DPP translation study. *Obesity.* 2014; 22(12):2532–2538. [PubMed: 25251749]

Table 1

Baseline Characteristics of the Participants

Characteristic	Mean \pm SD ^a
Age, y	44.5 \pm 13.0
Education, y	10.8 \pm 3.9
Duration of US residence, y	18.9 \pm 14.0
Household income, dollars	16 271 \pm 7061
Employed, n (%)	8 (40)
Married or living with partner, n (%)	14 (70)
Parous, n (%)	20 (100)
Foreign born, n (%)	20 (100)
Country/region of birth, n (%)	
Mexico	8 (40)
Central America	3 (15)
Caribbean	8 (40)
Other	1 (5)
Spanish as primary language, n (%)	20 (100)
Has insurance coverage, n (%)	6 (30)
Has a usual source of health care, n (%)	7 (35)
Family history of diabetes, n (%)	11 (55)
Personal history of gestational diabetes, n (%)	5 (25)

^aParticipant characteristics displayed as mean \pm SD unless stated otherwise.

Table 2
Change in Anthropomorphic and Cardiometabolic Outcomes Over 12 Months

Outcome	Mean Baseline Value ± SD	Mean 12-Month Value ± SD ^a	Pre-Post Change (95% CI)	P Value ^b	Effect Size
Weight, lbs	195.5 ± 47.3	184.7 ± 46.7	-10.8 (-5.6, -16.0)	<.001	-.23
Body mass index, kg/m ²	36.5 ± 7.6	34.6 ± 8.0	-1.9 (-1.0, -2.9)	<.001	-.25
Waist circumference, cm	104.3 ± 13.3	100.0 ± 14.1	-4.3 (-2.3, -6.4)	<.001	-.32
Systolic blood pressure, mm Hg	114.1 ± 17.0	110.3 ± 16.2	-3.8 (-9.2, 1.5)	.15	-.22
Diastolic blood pressure, mm Hg	74.7 ± 9.0	68.5 ± 9.5	-6.2 (-3.4, -8.9)	<.001	-.69
Total cholesterol, mg/dL	178.9 ± 41.9	170.8 ± 44.9	-8.1 (-19.2, 3.0)	.14	-.19
mmol/L ± SD	4.63 ± 1.09	4.42 ± 1.16	-0.21 (-0.50, 0.08)		
LDL cholesterol, mg/dL	108.0 ± 39.1	98.8 ± 30.7	-9.2 (-16.1, -2.2)	.01	-.24
mmol/L ± SD	2.80 ± 1.01	2.56 ± 0.80	-0.24 (-0.4, -0.06)		
HDL cholesterol, mg/dL	45.5 ± 9.0	46.5 ± 9.7	1.0 (-1.3, 3.3)	.38	.11
mmol/L ± SD	1.18 ± 0.23	1.20 ± 0.25	0.03 (-0.03, 0.09)		
Triglycerides, mg/dL	131.9 ± 87.9	135.7 ± 103.9	3.8 (-34.8, 42.4)	.84	.04
mmol/L ± SD	1.49 ± 0.99	1.53 ± 1.17	0.04 (-0.39, 0.48)		
Hemoglobin A1C, %	5.8 ± 0.2	5.7 ± 0.5	-0.1 (-0.3, 0.2)	.70	-.50
mmol/mol ^c	39.9	38.8	-1.1		
Fasting glucose, mg/dL,	95.4 ± 12.7	93.0 ± 8.1	-2.4 (-8.5, 3.8)	.43	-.19
mmol/L ± SD	5.29 ± 0.70	5.16 ± 0.45	-0.13 (-0.47, 0.21)		
Insulin, μU/mL	11.3 ± 9.6	8.2 ± 7.6	-3.1 (-4.9, -1.2)	.003	-.32
pmol/L ± SD	78.5 ± 66.7	56.9 ± 52.8	-21.6 (-34.0, -8.3)		

^aOne participant was lost to follow-up. The mean 12-month values reflect data from 19 participants who completed the 12-month assessment.

^bP values correspond to paired *t* tests assessing the significance of changes in anthropomorphic and cardiometabolic outcomes from baseline to 12 months.

^cStandard deviations and 12-month change of hemoglobin A1C could not be converted to SI units due to their small values (ie, <3%).

Table 3
Correlations Among Changes in Psychosocial Measures and Weight Change Over 12 Months

Psychosocial Measure	Mean Baseline Value ± SD	Mean 12-Month Value ± SD ^a	Pre-Post Change (95% CI)	P Value ^b	Effect Size	Correlation With Weight Change ^c	P Value ^d
Health literacy ^e	28.3 ± 9.6	30.2 ± 9.0	1.9 (0.6, 3.8)	.05	.20	-.12	.61
Health-related quality of life ^f							
Physical component summary	43.5 ± 9.8	44.9 ± 10.9	1.4 (-2.1, 4.9)	.41	.14	-.03	.89
Mental component summary	45.1 ± 9.5	46.5 ± 9.7	1.4 (-2.8, 5.6)	.49	.15	-.31	.19
Perceived social support ^g	60.3 ± 16.2	66.4 ± 13.8	6.2 (-1.1, 13.4)	.09	.38	-.01	.96
Perceived stress ^h	22.4 ± 10.0	22.3 ± 7.2	-0.11 (-4.2, 4.0)	.95	-.01	.46	.049
Depression ⁱ	16.5 ± 13.0	11.3 ± 10.9	-5.2 (-9.3, -1.2)	.01	-.40	.38	.11
Anxiety ^j	5.84 ± 6.08	3.89 ± 5.72	-1.95 (-4.79, 0.89)	.16	-.32	.49	.03

^a One participant was lost to follow-up. The mean 12-month values reflect data from 19 participants who completed the 12-month assessment.

^b P values correspond to paired t tests assessing the significance of changes in psychosocial measures from baseline to 12 months.

^c Correlations were tested between the pre-post change in each psychosocial measure and the pre-post change in weight using the Pearson correlation coefficient.

^d P values correspond to the test for significant (nonzero) correlations between the pre-post change in each psychosocial measure and weight loss.

^e Scored from 0 to 36 using the Short Test of Functional Health Literacy in Adults, with higher numbers indicating higher levels of health literacy.

^f Scored using the SF-36 norm-based scoring algorithm based on population values (mean = 50, SD= 10), with higher numbers indicating higher levels of physical and mental health functioning, respectively.

^g Scored from 12 to 84 using the Multidimensional Scale of Perceived Social Support, with higher numbers indicating higher levels of perceived social support.

^h Scored from 0 to 40 using the Perceived Stress Scale, with higher numbers indicating higher levels of perceived stress.

ⁱ Scored from 0 to 63 using the Beck Depression Inventory, with higher numbers indicating more depressive symptoms.

^j Scored from 0 to 21 using the GAD-7, with higher numbers indicating more anxiety symptoms.

Table 4

Participant Feedback About the Promotora-Led Diabetes Prevention Program (PL-DPP) Intervention

Statement of PL-DPP Acceptability	Mean Score \pm SD ^a
I am satisfied with the program	4.9 \pm 0.3
The information presented in the program was useful	4.8 \pm 0.4
The length of the program was adequate	4.2 \pm 1.3
The content was presented in an organized manner	4.9 \pm 0.3
The content was clearly presented	4.9 \pm 0.3
The promotora who led my group was well prepared for our sessions	4.8 \pm 0.4
The promotora who led my group was knowledgeable	4.9 \pm 0.3
The promotora was responsive to my questions and comments	4.8 \pm 0.4

^aThe response options for each statement were: 1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = strongly agree.

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