One-Year Results of a Community-Based Translation of the Diabetes Prevention Program

Healthy-Living Partnerships to Prevent Diabetes (HELP PD) Project

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OBJECTIVE—Although the Diabetes Prevention Program (DPP) and the Finnish Diabetes Prevention Study (FDPS) demonstrated that weight loss from lifestyle change reduces type 2 diabetes incidence in patients with prediabetes, the translation into community settings has been difficult. The objective of this study is to report the first-year results of a community-based translation of the DPP lifestyle weight loss (LWL) intervention on fasting glucose, insulin resistance, and adiposity.

RESEARCH DESIGN AND METHODS—We randomly assigned 301 overweight and obese volunteers (BMI 25–40 kg/m^2) with fasting blood glucose values between 95 and 125 mg/dL to a group-based translation of the DPP LWL intervention administered through a diabetes education program (DEP) and delivered by community health workers (CHWs) or to an enhanced usual-care condition. CHWs were volunteers with well-controlled type 2 diabetes. A total of 42.5% of participants were male, mean age was 57.9 years, 26% were of a race/ethnicity other than white, and 80% reported having an education beyond high school. The primary outcome is mean fasting glucose over 12 months of follow-up, adjusting for baseline glucose.

RESULTS—Compared with usual-care participants, LWL intervention participants experienced significantly greater decreases in blood glucose (−4.3 vs. −0.4 mg/dL; $P < 0.001$), insulin (−6.5 vs. −2.7 μU/mL; $P < 0.001$), homeostasis model assessment of insulin resistance (−1.9 vs. −0.8; $P < 0.001$), weight (−7.1 vs. −1.4 kg; $P < 0.001$), BMI (−2.1 vs. −0.3 kg/m^2; $P < 0.001$), and waist circumference (−5.9 vs. −0.8 cm; $P < 0.001$).

CONCLUSIONS—This translation of the DPP intervention conducted in community settings, administered through a DEP, and delivered by CHWs holds great promise for the prevention of diabetes by significantly decreasing glucose, insulin, and adiposity.

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The Diabetes Prevention Program (DPP) and the Finnish Diabetes Prevention Study (FDPS) demonstrated that the incidence of type 2 diabetes could be reduced by almost 60% in patients with prediabetes through weight loss resulting from changes in diet and physical activity (1,2). Despite these promising findings, the prevalence of type 2 diabetes continues to increase (3). Furthermore, although diabetes mortality has declined 8.3% in the last decade, diabetes-related complications continue to increase, resulting in rising disease burden (4).

Several recent translations (5–13) of the DPP and FDPS have demonstrated encouraging effects across diverse settings, including primary care settings (6,9,11–13), cardiac rehabilitation programs (10), churches (8), YMCAs (5), and health care facilities (7). The personnel who implemented the intervention included nurses (6,11,12), registered dietitians and exercise physiologists (7,10), health care professionals (9,13), volunteer medical personnel (8), and YMCA trainers (5). Evaluating these translated interventions is challenging because of the differences in outcome measures, sample sizes, and study designs. Although these interventions typically produced ~6% weight loss, the studies tended to have small sample sizes, often did not include comparison conditions, and lacked randomized allocation to treatment conditions. No translational study to date has reported significant reductions in blood glucose in individuals with prediabetes. Therefore, additional translational research is needed that uses innovative, cost-effective systems to deliver effective lifestyle interventions targeting patients at risk for diabetes. Numerous studies have tested the use of community health workers (CHWs) in the management of diabetes (14), but no studies to date have tested the use of CHWs in implementing lifestyle interventions designed to prevent diabetes.

This report presents the first-year results of the Healthy-Living Partnerships to Prevent Diabetes (HELP PD) Project on glucose, insulin resistance, and adiposity (15). The HELP PD project was designed to translate the methods of the DPP into the community via key modifications to enhance feasibility and dissemination: the delivery of a group-based lifestyle weight loss (LWL) intervention via a partnership between an existing community-based diabetes education program (DEP) and CHWs.

RESEARCH DESIGN AND METHODS

—The design, methods (15), recruitment procedures, and participant characteristics (16) have been described

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elsewhere. In brief, the HELP PD project is a randomized controlled trial that tests the effect of a community-based translation of the DPP LWL intervention versus a comparison condition of enhanced usual care on fasting blood glucose, other metabolic outcomes, adiposity, psychosocial variables, health-related quality of life, and health care costs and use. Data were collected at baseline and every 6 months up to 24 months of follow-up. The institutional review board of Wake Forest Baptist Medical Center approved the study, and all participants provided signed informed consent.

The eligibility criteria targeted a sample at risk for diabetes representative of the local community. Recruitment (16) was accomplished primarily through mass mailings to targeted ZIP codes. Interested individuals contacted a study telephone number and were provided basic information about participation, including additional steps in the screening and randomization process and the time commitment and expectations associated with participation before completing a telephone-screening questionnaire. Participants were required to have evidence of prediabetes on two occasions, with a confirmatory fasting glucose between 95 and 125 mg/dL, and to have a BMI $\geq$25.0 kg/m^2 and $\leq$39.9 kg/m^2 (17). Candidates were screened for other comorbid conditions that would make physical activity unsafe or limit participation in the study. These conditions included recent history of an acute cardiovascular disease event, clinical history of type 2 diabetes, uncontrolled hypertension, cancer or other conditions limiting life expectancy, chronic use of medicines known to influence glucose metabolism (i.e., corticosteroids), and major psychiatric or cognitive problems, including depression. The Physical Activity Readiness Questionnaire was administered to identify people with contraindications to exercise, who were required to obtain a medical clearance from their physician prior to randomization. Participation in a supervised program for weight loss or another research study that would interfere with HELP PD also was an exclusion criterion.

Outcome measures

Fasting blood glucose, insulin, and anthropometry were assessed at baseline and randomization and at the 6- and 12-month visits by trained study staff. Phlebotomy was performed after at least an 8-h fast, in accordance with American Diabetes Association guidelines (18). All biochemical measurements were performed in a central laboratory by technicians masked to the intervention assignment.

Fasting glucose, the primary outcome measure, was measured using a timed–end point method supplied by Beckman Coulter for the Synchron LX Analyzer, a method accepted by the Centers for Disease Control and Prevention. Within-run coefficients of variation for this method were $\leq$3.9% and total coefficients of variation were $\leq$6.45%.

Insulin was assayed using the paramagnetic particle chemiluminescent immunoassay for the Access Immunoassay Systems (Beckman Coulter). There is $<$0.3% cross-reactivity with human proinsulin and no detectable cross-reactivity with human C-peptide. Low- and high-level human serum quality-control samples were run during each 24-h time period. The overall within-assay variability was 3.9%, and the between-assay variability was 5.5%.

Insulin resistance was examined using the homeostasis model assessment of insulin resistance (HOMA-IR) index (HOMA IR = [{fasting insulin $\times$ fasting glucose}/22.5]) (19). HOMA-IR is a better measure of insulin resistance than is fasting insulin alone and is highly correlated with other, more complex and invasive measures of insulin resistance from the frequently sampled intravenous glucose tolerance test and the euglycemic clamp (20,19).

Anthropometric measurements were taken with participants wearing lightweight clothing and without shoes. Measurements were taken twice during each exam, and means were used in analyses. Seca Accu-Hite wall-mounted stadiometers were used to measure height to the nearest 0.5 cm. Weight was measured using a Cardinal Detecto digital scale (758 C Series) to the nearest 0.1 kg. BMI was calculated as weight in kilograms divided by the square of height in meters. Waist circumference was assessed, to the nearest 0.1 cm, using a Gulick II 150-cm anthropometric tape with the participant in a recumbent position (21).

Community-based implementation

Our translation of the DPP involved conducting the LWL intervention in community-based sites via a local DEP and CHWs. Study investigators and staff conducted study administration, but the registered dietitians employed by the DEP managed the day-to-day operations of the intervention as well as the training and monitoring of the CHWs. CHWs were community members with type 2 diabetes, well-controlled HbA_{1c}, and a history of healthy eating and physical activity. CHWs were recruited through our DEP by the study investigators and registered dieticians. CHWs were responsible for conducting the intervention group sessions, managing participants, and entering data on each participant's body weights obtained at group sessions. CHWs were compensated $100 per week during the first 6 months for weekly sessions and $200 per month during the second 6 months for monthly sessions. CHW training consisted of a 36-h program conducted over the course of 6–9 weeks and involved experiential learning, didactic instruction, peer mentoring, and observation. Ten CHWs were trained in two groups of five; one group before recruitment started and another group 4 months into recruitment.

LWL intervention

The LWL intervention targeted decreased caloric intake (goal of 1,200–1,800 kcal per day) and increased caloric expenditure through moderate physical activity (goal $\geq$180 min per week). The primary objective was to produce a total weight loss of 5–7% during the first 6 months of treatment. During the second 6 months, participants were encouraged to continue to meet or maintain their weight loss goals as long as their BMI did not fall below 20 kg/m^2. This approach was consistent with the recommendations of the American Diabetes Association, the North American Association for the Study of Obesity, and the American Society for Clinical Nutrition (22).

Participants met weekly for CHW-led group sessions during the first 6 months. Fourteen different groups of 8–12 participants were conducted at various community sites (e.g., parks and recreation centers). Participants also received three personalized consultations with a registered dietician (during months 1, 3, and 6). During months 7–12, participants received two scheduled contacts with the CHW each month, one group session and one telephone contact. Intervention content standardization was supported by a DVD series developed by the research team to cover nutrition and physical activity basics, energy balance, healthy eating, goal setting, and problem solving. We also included presentations from local community experts (e.g., the YMCA, local

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grocery stores, and specialty athletic footwear stores).

Enhanced usual care

The usual-care condition was designed to exceed the usual care provided to patients with prediabetes and to enhance retention. Usual care consisted of two individual sessions with a nutritionist during the first 3 months involving healthy eating and physical activity education to support weight loss. Usual-care participants also received a monthly newsletter with topics related to healthy lifestyles and information about community resources.

Power

The HELP PD project targeted the recruitment of 300 participants. The DPP found a 4 mg/dL difference in fasting glucose at 2 years. The correlation between glucose values at baseline and follow-up was estimated to be between 0.45 and 0.6 in two studies, with larger ranges in baseline glucose than found in our study. Therefore, we assumed a more modest correlation of $r = 0.2$. The DPP reported a cross-sectional SD of 8.3 mg/dL (1). The estimated SD for a follow-up measure after adjusting for the baseline value is $8.3 \times$ the square root of $(1 - 0.2^2) = 8.132$. This value of the adjusted SD was used in the NQuery program to determine sample size in a two-group trial. The trial was designed to have at least 80–90% power to detect differences in fasting glucose of 3–3.5 mg/dL. The required number of evaluable subjects per group to have 80% power to detect a difference of 3 mg/dL is 117. The required number of evaluable subjects per group to have 90% power to detect a difference of 3.5 mg/dL is 115. Allowing for up to 80% loss to follow-up over 2 years, the total required number of subjects needed to be randomly assigned to meet these two goals is 294 and 288, respectively. With a total sample size of 300 subjects randomly assigned, we estimate that the trial has 81% power to detect a 3 mg/dL difference between groups and 91% power to detect a 3.5 mg/dL difference.

Data analysis

Although the study was originally designed with 24 months of follow-up, the analyses reported here are based on the first 12 months. To compare our results with those of other diabetes prevention translational studies, the vast majority of which report 12-month outcomes, the investigators received approval to unblind the first-year results and amend the protocol to conduct independent analyses of results in the first and second years of follow-up rather than the originally planned approach of analyzing the 2 years together.

Our randomization procedure involved a permuted block design with

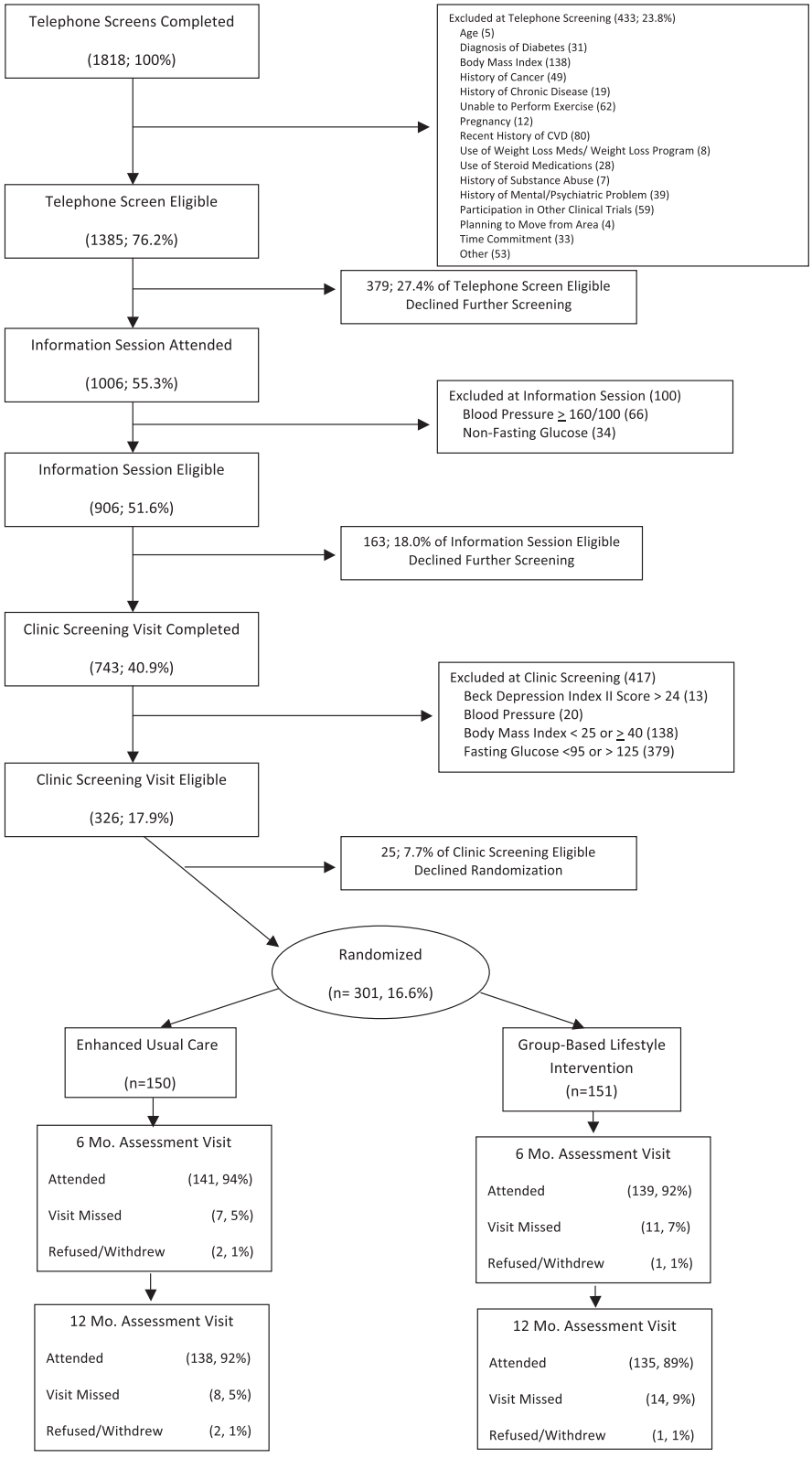

Figure 1—*Flow of participants from screening to completion of the final follow-up assessment.*

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varying block size to reduce the time randomly assigned individuals had to wait for intervention groups to develop and ensure a degree of balance. Arithmetic means and SDs are presented for continuous variables. For baseline comparisons between the LWL intervention and usual-care groups, *t* tests were used for continuous variables and the Fisher exact test was used for categorical variables. The primary hypothesis for this report involved comparing the main effect of the LWL intervention versus the usual-care control on fasting glucose. We used general linear models for repeated-measures ANCOVA (SAS PROC MIXED) to compare the main effect of the intervention on the 6- and 12-month values measured during the 1-year follow-up period. For each outcome measure, the baseline value for that outcome was used as a covariate. The test for intervention effect is based on the least square means of the estimated main effect of intervention (estimate of the average of the 6- and 12-month means). We tested for group and visit interactions and none were significant. We used the intention-to-treat approach and included all postrandomized values according to the group to which they were assigned. We performed secondary analyses, making a reasonable exception to this rule by deleting observations at visits where the subject was taking hypoglycemic medication. Inferences for comparisons were tested at a 5% two-sided level of significance. An unstructured variance model was used for intrasubject longitudinal covariance.

RESULTS—The participant screening, enrollment, and follow-up experience is depicted in Fig. 1. The 301 participants included a relatively well-educated, biracial group of middle-aged and older men and women with an average BMI of 32.8 kg/m^2 (Table 1). Over the first year of the intervention, participants attended 67.7% of all potential group intervention sessions. Including make-up visits (either in person or via telephone), participants completed 79.4% of all potential sessions. During the first 6 months, 72.4% of planned sessions were attended and 11.0% were made up with a CHW (combined attendance = 83.4%). In months 7–12, 49.2% of planned sessions were attended and 13.9% were made up (combined attendance = 63.1%). Information was available regarding the primary outcome, fasting glucose, for 280 (93.4%) participants at month 6 and 273 (90.2%) participants at month 12, with no substantive difference in data completeness between groups.

Table 2 displays changes in measures of adiposity, fasting glucose, and insulin resistance by treatment group. Relative to usual-care participants, LWL intervention participants lost a net of 6.0% of their body weight and 5.0 cm in waist circumference ($P < 0.001$ for both comparisons). Similar results were observed for absolute weight loss and BMI.

On the basis of the adjusted average of the 6- and 12-month means, fasting glucose decreased by 4.3 mg/dL in the LWL intervention participants versus a decrease of 0.4 mg/dL in the usual-care participants ($P < 0.001$). In secondary analyses that examined 6- and 12-month assessments separately, fasting glucose had decreased by 4.0 mg/dL in the LWL intervention versus an increase of 1.0 mg/dL in the usual-care intervention ($P < 0.001$) at 6 months. At 12 months, fasting glucose had decreased by 4.6 mg/dL in the LWL intervention versus a decrease of 1.8 mg/dL in the usual-care intervention ($P = 0.02$). Relative to usual-care participants, LWL intervention participants also demonstrated substantial decreases in fasting insulin and HOMA-IR ($P < 0.001$ for both comparisons).

Supplementary Table A1 contains data on adverse events, serious adverse events, and the number of new cases of diabetes by treatment group. No differences were found in these events between treatment groups.

CONCLUSIONS—These results indicate that the HELP PD project was successful in translating the DPP LWL intervention into a community-based approach that induced significant reductions in blood glucose, insulin, HOMA-IR, body weight, waist circumference, and BMI over 12 months in overweight and obese patients with prediabetes. To our knowledge, this study is the largest to date to successfully translate the DPP into the community and is the only DPP translational study to document significant changes in fasting blood glucose, insulin, and insulin resistance using a randomized controlled design.

The glucose-lowering effect of the HELP PD intervention compares favorably with the effects documented in the DPP and FDPS (−4 and −5 mg/dL, respectively, albeit over longer follow-up periods [DPP follow-up = 2.8 years and FDPS follow-up = 3.2 years]). Our future analyses will examine the sustainability of the HELP PD effect over 24 months. The effect of the HELP PD intervention on adiposity also compares favorably to other studies. A review (23) of nine randomized controlled trials examining weight loss interventions in individuals with prediabetes reported a pooled estimate of

Table 1—*Baseline sample characteristics*

Variable	LWL intervention	Usual care	Total	*P**
n	151	150	301	
Sex				1.00
Male	64 (42.4)	64 (42.7)	128 (42.5)	
Female	87 (57.6)	86 (57.3)	173 (57.5)	
Race				0.43
African American	39 (25.8)	35 (23.3)	74 (24.6)	
White	111 (73.5)	111 (74.0)	222 (73.8)	
Other/refused	1 (0.7)	4 (2.7)	5 (1.6)	
Age (years)	57.3 ± 10.1	58.5 ± 9.0	57.9 ± 9.5	0.28
Educational attainment				0.97
High school or less	29 (19.2)	32 (21.3)	61 (20.3)	
Associate degree or other	49 (32.5)	47 (31.3)	96 (31.9)	
Bachelor's degree	37 (24.5)	37 (24.7)	74 (24.6)	
Beyond Bachelor's degree	36 (23.8)	34 (22.7)	70 (23.3)	
Weight (kg)	94.4 ± 14.7	93.0 ± 16.2	93.7 ± 15.5	0.44
BMI (kg/m^2)	32.8 ± 3.9	32.6 ± 4.1	32.7 ± 4.0	0.54
Glucose (mg/dL)	105.4 ± 12.5	105.7 ± 10.0	105.5 ± 11.3	0.79
Insulin (μU/mL)	16.7 ± 9.7	16.7 ± 10.0	16.7 ± 9.8	0.95
HOMA-IR	4.4 ± 3.0	4.4 ± 2.9	4.4 ± 2.9	0.99

Data are *n* (%) or means ± SD. **t* Tests were used for continuous variables, and the Fisher exact test was used for categorical variables.

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Table 2—*Measures of adiposity and metabolic outcomes of HELP PD at 6 and 12 months by treatment group*

Variable	Baseline	6 months	12 months	Adjusted means over the follow-up period*	*P*
Weight (kg)					
Control group	92.67 ± 1.37	91.55 ± 1.38	90.93 ± 1.37	92.12 ± 0.29	
Intervention group	94.41 ± 1.24	87.14 ± 1.22	87.44 ± 1.28	86.39 ± 0.30	
Difference				−5.73 ± 0.42	<0.001
BMI (kg/m^2)					
Control group	32.42 ± 0.35	31.96 ± 0.34	31.95 ± 0.36	32.15 ± 0.10	
Intervention group	32.81 ± 0.34	30.38 ± 0.35	30.52 ± 0.36	30.25 ± 0.10	
Difference				−1.90 ± 0.14	<0.001
Waist (cm)					
Control group	104.22 ± 0.91	103.37 ± 0.90	103.45 ± 0.89	103.70 ± 0.27	
Intervention group	104.83 ± 0.79	98.67 ± 0.84	99.22 ± 0.90	98.65 ± 0.27	
Difference				−5.05 ± 0.38	<0.001
Glucose (mg/dL)					
Control group	105.92 ± 0.83	106.97 ± 0.77	104.16 ± 0.99	105.36 ± 0.53	
Intervention group	105.58 ± 1.07	101.69 ± 0.81	101.11 ± 0.84	101.60 ± 0.54	
Difference				−3.76 ± 0.76	<0.001
Insulin (μU/mL)					
Control group	16.92 ± 0.84	15.54 ± 1.07	12.81 ± 0.64	14.09 ± 0.41	
Intervention group	16.73 ± 0.82	10.73 ± 0.61	9.76 ± 0.46	10.34 ± 0.41	
Difference				−3.75 ± 0.58	<0.001
HOMA-IR					
Control group	4.50 ± 0.24	4.18 ± 0.30	3.33 ± 0.18	3.73 ± 0.12	
Intervention group	4.48 ± 0.26	2.77 ± 0.18	2.48 ± 0.13	2.65 ± 0.12	
Difference				−1.08 ± 0.17	<0.001
Percentage weight loss					
Control group	0.00 ± 0.00	−1.18 ± 0.29	−1.33 ± 0.39	−1.25 ± 0.31	
Intervention group	0.00 ± 0.00	−7.52 ± 0.48	−7.21 ± 0.57	−7.37 ± 0.31	
Difference				−6.11 ± 0.44	<0.001

Data are means ± SE. *Least square means from a repeated-measures ANCOVA using the baseline value as a covariate; *P* values represent the between-group comparison of the average of the 6- and 12-month means.

−2.8 kg of weight loss (−3.3% of initial body weight) calculated from four studies with 1 year of follow-up. The DPP (1) and FDPS (2) reported weight loss of −5.5 kg (−4.9%) and −4.2 kg (−4.7%), respectively. In addition, the DPP documented a weight loss of −6.0 kg at 12 months of follow-up. Participants in the HELP PD LWL intervention lost an average of −7.1 kg (7.3%) at 12 months. However, trials consistently show that approximately one-third of the weight lost during the first 6 months of behavioral weight loss interventions is typically regained by 1 year, and weight returns to baseline in 3–5 years (24). Our future analyses will determine whether weight loss is sustained over 24 months of follow-up.

Previous diabetes prevention translational studies have reported 12-month weight losses ranging from −0.45 kg (8) to −5.7 kg (5), but other than Boltri et al. (8), none have reported significant changes in fasting blood glucose. The DEPLOY (Diabetes Education and Prevention with a Lifestyle Intervention Offered at the YMCA) study (5) delivered a group-based translation of the DPP LWL intervention via YMCAs to 77 participants with elevated glucose and reported significant decreases in weight (−5.7 kg) and BMI (−6.7%) but no differences between groups in changes in cardiometabolic outcomes (e.g., HbA_{1c}). Likewise, the Weight Loss through Living Well (WiLLoW) study (11), using a nonrandomized controlled cohort design, delivered a group-based DPP LWL intervention to overweight patients via primary care practices and reported a 12-month weight change of –5.7 kg but did not report changes in cardiometabolic outcomes. Kramer et al (9) assessed the impact of a group-based DPP LWL intervention in patients at risk for diabetes (n = 42) delivered via primary care practices using a one-group design and reported significant 12-month changes in weight (−4.2 kg [−4.5%]), waist circumference (−7.1 cm [−6.8%]), and BMI (−1.6 [−4.8%]), but changes in glucose (−1.5 mg/dL [−1.4%]) were not significant. At a national level, Saaristo et al. (13) implemented the FDPS lifestyle intervention in 2,798 individuals with elevated risk for diabetes in 400 primary care settings and reported a mean of −1.2 kg of weight loss. Although this study did not report changes in fasting glucose, the results indicate that the reduction in incidence of diabetes (assessed using an oral glucose tolerance test) was strongly related to weight loss (relative risk of diabetes was 0.31 in the group who lost 5% weight, 0.72 in the group who lost 2.5–4.9% weight, and 1.10 in the group who gained 2.5% compared with the group who maintained weight). The results presented here suggest that the HELP PD project approach may be a more powerful translation of the DPP than previously published approaches.

Fasting insulin and HOMA-IR, two measures of insulin resistance, responded

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favorably to the intervention. Insulin resistance is a key link between obesity and the risk of both diabetes and cardiovascular disease (25). The beneficial effects on insulin resistance provide support for the hypothesis that the intervention may have beneficial effects on the risk for cardiovascular disease beyond the effects on blood glucose.

The HELP PD project made several key modifications to the DPP intervention to create a model that can be translated for use in any community with a DEP. The intervention was delivered in a group format by CHWs in community-based settings and was overseen by registered dieticians employed by a local DEP, thereby minimizing the contributions of research resources and maximizing the responsibilities of community-based staff. The results of the current study indicate that this model is effective at inducing meaningful metabolic changes in individuals at high risk for diabetes.

Although the >3,000 American Diabetes Association–recognized DEPs in the U.S. are well positioned to implement this intervention, several limitations exist. First, the HELP PD project was conducted in only one community located in the southeastern U.S. It is unknown whether this approach can be effectively disseminated to other communities. In addition, a training program must be developed to prepare personnel. Finally, reimbursement policies must be developed to support the cost of program delivery. Economic analysis of the HELP PD program is underway and may help inform policy development. Despite these limitations, the results of the HELP PD program indicate that empowering community members through partnerships with existing DEPs may effectively translate diabetes prevention efforts and ultimately alter the course of the obesity and diabetes epidemics.

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