Long-term Weight Loss Maintenance in the Continuation of a Randomized Diabetes Prevention Translational Study: The Healthy Living Partnerships to Prevent Diabetes (HELP PD) Continuation Trial

Mara Z. Vitolins,[1] Caroline S. Blackwell,[1] Jeffrey A. Katula,[2] Scott P. Isom,[3] and L. Douglas Case[3]

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OBJECTIVE

HELP PD was a clinical trial of 301 adults with prediabetes. Participants were randomized to enhanced usual care (EUC) or to a lifestyle weight loss (LWL) intervention led by community health workers that consisted of a 6-month intensive phase (phase 1) and 18 months of maintenance (phase 2). At 24 months, participants were asked to enroll in phase 3 to assess whether continued group maintenance (GM) sessions would maintain improvements realized in phases 1 and 2 compared with self-directed maintenance (SM) or EUC.

RESEARCH DESIGN AND METHODS

In phase 3, LWL participants were randomly assigned to GM or SM. EUC participants remained in the EUC arm and along with participants in SM, received monthly newsletters. All participants received semiannual dietitian sessions. Anthropometrics and biomarkers were assessed every 6 months. Mixed-effects models were used to assess changes in outcomes over time.

RESULTS

Eighty-two of the 151 intervention participants (54%) agreed to participate in phase 3; 41 were randomized to GM or SM. Of the 150 EUC participants, 107 (71%) continued. Ninety percent of clinic visits were completed. Over 48 months of additional follow-up, outcomes remained relatively stable in the EUC participants; the GM group was able to maintain body weight, BMI, and waist circumference; and these measures all increased significantly ($P < 0.001$) in the SM group.

CONCLUSIONS

Participants in the GM arm maintained weight loss achieved in phases 1 and 2, while those in the SM arm regained weight. Because group session attendance by the participants in the GM arm was low, it is unclear what intervention components led to successful weight maintenance.

[1]Department of Epidemiology and Prevention, Division of Public Health Sciences, Wake Forest School of Medicine, Winston-Salem, NC
[2]Department of Health and Exercise Science, Wake Forest University, Winston-Salem, NC
[3]Department of Biostatistics and Data Sciences, Division of Public Health Sciences, Wake Forest School of Medicine, Winston-Salem, NC

Corresponding author: Mara Z. Vitolins, mvitolin@wakehealth.edu

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Lifestyle interventions designed to prevent diabetes have been shown to produce clinically meaningful changes in blood glucose and body weight across a number of settings (1–15). Weight loss intervention trials have likewise reported clinically significant weight loss in participants over 6–24 months (16–22). Many of these trials also reported that participants begin to regain body weight after the intensive intervention as the frequency of contact with study staff lessens (17,21,22). While short-term weight loss is achievable for many participants, long-term maintenance of that weight loss remains challenging (18,23). More-effective approaches to sustain weight loss in a larger percentage of the population are needed.

The Healthy Living Partnerships to Prevent Diabetes (HELP PD) trial successfully translated the Diabetes Prevention Program (DPP) lifestyle weight loss (LWL) intervention into a low-cost, community-based weight loss program administered and delivered through a local diabetes care center and led by community health workers (CHWs) (24). HELP PD previously reported that participants in the LWL arm of the study experienced statistically significant positive changes in body weight during the intensive 6-month phase (P1) and maintained those changes during the 18-month maintenance phase (P2) compared with the enhanced usual care (EUC) group (13,25). Positive between-group differences in fasting blood glucose, waist circumference, and other biological variables also remained relatively consistent over P1 and P2 (13,25) and were comparable to those achieved in the DPP (26).

To evaluate the long-term effects of a community-based diabetes prevention program on body weight and other metabolic parameters, participants were invited to take part in a continuation study, HELP PD phase 3 (P3). The primary goal of this analysis was to evaluate body weight changes during P3. Secondary outcomes were waist circumference, BMI, and biomarker changes (glucose, insulin) over 4 additional years in participants who consented to re-enroll. Participants in the LWL arm who consented to enroll in P3 were rerandomized to either *1*) continue CHW-led group maintenance (GM) or *2*) self-directed maintenance (SM). Participants in the EUC group were invited to re-enroll and were followed for comparison purposes. In this analysis, we examined group differences in the changes in body weight and other important biomarkers of health over the 48 months of additional follow-up in P3.

RESEARCH DESIGN AND METHODS

P1 and P2 of the HELP PD study consisted of a single-center, randomized, two-arm, controlled trial of 301 overweight and obese participants (BMI $\geq$25–39.9 kg/m^2) with elevated fasting blood glucose levels ranging between 95 and 125 mg/dL conducted in Forsyth County, North Carolina (24,27). Participants were randomly assigned to either a group-based LWL intervention or EUC. The LWL intervention was adapted from the DPP (3) for use in a group setting and for delivery by a CHW (24). P1 consisted of a 6-month intensive weight loss program with weekly group meetings, while P2 consisted of 18 months of monthly group-based maintenance meetings and phone calls. The fidelity of intervention content delivery in the LWL sessions was standardized by the development of a digital video disk series to provide information on nutrition, physical activity, and behavioral topics, and the group sessions also included presentations from local community groups to support sustainable lifestyle change. Participants randomized to the EUC condition received two individual visits with a registered dietitian/nutritionist (RDN) and monthly newsletters with information on healthy lifestyle behaviors and community resources. Data were collected at baseline and every 6 months to assess changes in key outcome measures. Details regarding the design, recruitment and baseline characteristics, key outcomes, intervention delivery, cost, and a comparison of the HELP PD results with those of the DPP have been published elsewhere (13,24–28). Approval to proceed with all phases of HELP PD was received from the institutional review board of Wake Forest University Health Sciences, and study progress was annually reviewed and approved.

At the 24-month clinic assessment visit, participants were asked whether they would like to enroll in P3, which consisted of an additional $\geq$48 months of follow-up, and asked to sign an informed consent document. Participants who did not attend the 24-month visit were contacted by telephone or mail. Because participants were recruited and randomized to HELP PD over a 20-month period (27), the enrollment process for P3 also lasted $\sim$20 months.

Participants randomized to GM were asked to continue attending any of three monthly group meetings led by CHWs from P1 and P2 under the supervision of the RDN assigned to GM. As in P1 and P2, these groups were held after work hours and were 1 h in length (24). All group meetings were held in a local diabetes care center. Participants who had not achieved the initial weight loss goal for P1 and P2 ($\geq$7% of initial body weight) were instructed to continue losing weight by meeting their specific calorie and physical activity goals. Participants who successfully achieved weight loss goals in P1 and P2 were encouraged to either maintain their weight loss or to continue to lose weight as long as their BMI did not fall to $<$20 kg/m^2. Participants were also encouraged to maintain at least 150 min/week of moderate intensity physical activity. The content of the group meetings focused on maintaining the healthy behaviors that produced weight loss and/or problem solving to overcome barriers to weight loss. The topic for each monthly group meeting was determined by the CHW for that group and reviewed and approved by the RDN supervising the intervention. In addition to group meetings, participants randomized to GM received monthly phone calls from a CHW. Participants who were randomized to SM were told that they could use any approach they desired to assist them in maintaining their weight loss and health behaviors and received individual counseling sessions with the same RDN who counseled them during P1 and P2. Participants who re-enrolled in EUC received monthly newsletters with information on local resources to support healthy lifestyle change. Participants in all three groups received individual visits with an RDN every 6 months. Depending on their date of enrollment in P3, participants received 8–11 visits with the RDN.

Outcome Measures

As in P1 and P2, anthropometry measurements and fasting blood were collected every 6 months by study staff who were also responsible for consent, enrollment, and randomization in P3 (13,25). Body

weight, the primary outcome, was measured in light clothing without shoes or outer garments. Waist circumference was measured without clothing over the skin and in the recumbent position (29). Phlebotomy was performed by trained study personnel after at least an 8-h fast in accordance with American Diabetes Association guidelines (30). All samples were analyzed in a central laboratory at Wake Forest Baptist Medical Center by technicians masked to randomization assignment. All participants received a $25 gas card at the conclusion of each clinic visit to compensate them for their time and travel. In addition, they received inexpensive study-branded items during these visits, including water bottles, tote bags, and t-shirts, to further incentivize clinic visit attendance.

Fasting glucose was measured using a timed end point method supplied by Beckman Coulter for the Synchron LX analyzer. Within-run coefficients of variation for this method are ≤3.9%, and total coefficients of variation are ≤6.45%. Insulin was assayed using the paramagnetic particle, chemiluminescent immunoassay for Access Immunoassay Systems from Beckman Coulter. There is <0.3% cross-reactivity with human proinsulin and no detectable cross-reactivity with human C-peptide; the overall within-assay variability is 3.9%, and the between-assay variability is 5.5% with this method. The HOMA of insulin resistance (HOMA-IR) was calculated using the following equation: (fasting insulin × fasting glucose) / 22.5. HOMA-IR is considered a superior method of measuring insulin resistance than fasting insulin alone because it is correlated with other measures of insulin resistance that are more invasive (31,32).

Statistical Methods

Participants were randomized to the LWL intervention or the EUC condition at the baseline visit of P1. For P3, participants who were originally randomized to LWL were rerandomized at 24 months to either GM or SM for ≥48 months of additional follow-up. Variably sized blocked randomization was used to rerandomize the LWL participants into GM or SM to ensure approximately equal accrual over time and to ensure that future randomizations could not be inferred from past assignments. The randomization sequence was generated by a study statistician and implemented through the study website. All participants had assessment visits every 6 months during all phases of the study (P1, P2, and P3). Participants recruited early during P1 continued to have assessment visits every 6 months up to 66 months after rerandomization. Those data are used in the analyses, but the primary inferences for P3 are for the 4 years after the end of the original study per protocol (P1, P2). All analyses are intention to treat; all participants were included in the analyses in the arms they were assigned regardless of their compliance with their respective arm. Mixed-effects repeated-measures models, constrained to have equal means at rerandomization for the two intervention groups (33), were used to assess changes over time (during the extended follow-up period) and to assess the differences between groups in the average change over time (mean outcome between months 30 and 72 minus the outcome at month 24). Toeplitz, compound symmetry, autoregressive, and unstructured covariance matrices were used to model the within-participant correlations over time for each outcome, and the structure resulting in the smallest Bayesian information criterion statistic was used for the final analysis for that outcome. Linear contrasts were used to assess the hypotheses of interest. Separate constrained mixed models were also run on the two rerandomized groups just during the extended follow-up period. Conclusions from these models were the same as those from the models that included all groups, so they are not described separately. Additional models were run that included age, race, sex, and marital status (married/living together vs. other arrangement). Conclusions were unchanged.

RESULTS

Re-enrollment for P3 began in September 2009 and lasted ~20 months, ending in May 2011. Follow-up visits were conducted from March 2010 through May 2015 (Fig. 1). Of the 301 participants randomized in the original HELP PD study, 261 either attended the 24-month visit or were contacted by study staff, and 189 consented to take part in P3. The timeline and rerandomization process for P3 are outlined in Fig. 1. Eighty-two of the 151 LWL participants (54%) agreed to be randomized to GM or SM; 41 were randomized to each arm. One hundred seven of the 150 EUC participants (71%) agreed to continue in the EUC in P3. There were no significant differences between the re-enrollers and those who declined. Demographic characteristics of the 189 participants who enrolled in P3 at the initial baseline visit for HELP PD are summarized in Table 1 and are similar for the three groups. Ages ranged from 36 to 80 years, with a median of 57 years; 74% were age ≥50 years. Seventy-four percent were white, 55% were female, 70% were employed full or part time, 67% were married, and 71% were obese. Seventy-one percent of the participants had two or fewer people living at home. Demographic characteristics were largely unchanged at P3 randomization (except, of course, for age) and remained similar for the three groups. Clinical measures at P1 baseline and at P3 randomization are also summarized in Table 1. These measures were all similar for the three groups at the initial baseline, but at P3 randomization, fasting glucose, insulin, and HOMA-IR were all significantly higher in the EUC participants compared with the participants randomized from the LWL arm, reflecting the success of the LWL intervention in P1 and P2.

Session attendance for the GM participants is summarized in Supplementary Table 1. As can be seen, group attendance was poor, with about one-third of the sessions attended over the first 4 years. Attendance decreased each year from 43.3% the 1st year to 26.4% the 4th year. Attendance at the regularly scheduled meetings was only 23% over the first 4 years, with make-up sessions accounting for another 10%. Two participants did not attend any sessions.

Clinical outcomes are summarized in Table 2 by arm and yearly assessment visit through 72 months of follow-up (48 months following rerandomization). Overall, 89% of the participants had a 72-month (or later) assessment visit, and 90% of the clinical assessments were completed during P3. Results during P1 and P2 have been reported previously (13,25). During P1, the LWL intervention led to reductions in weight, BMI, waist circumference, fasting glucose, insulin, and HOMA-IR, and some of that benefit was maintained during P2. Most

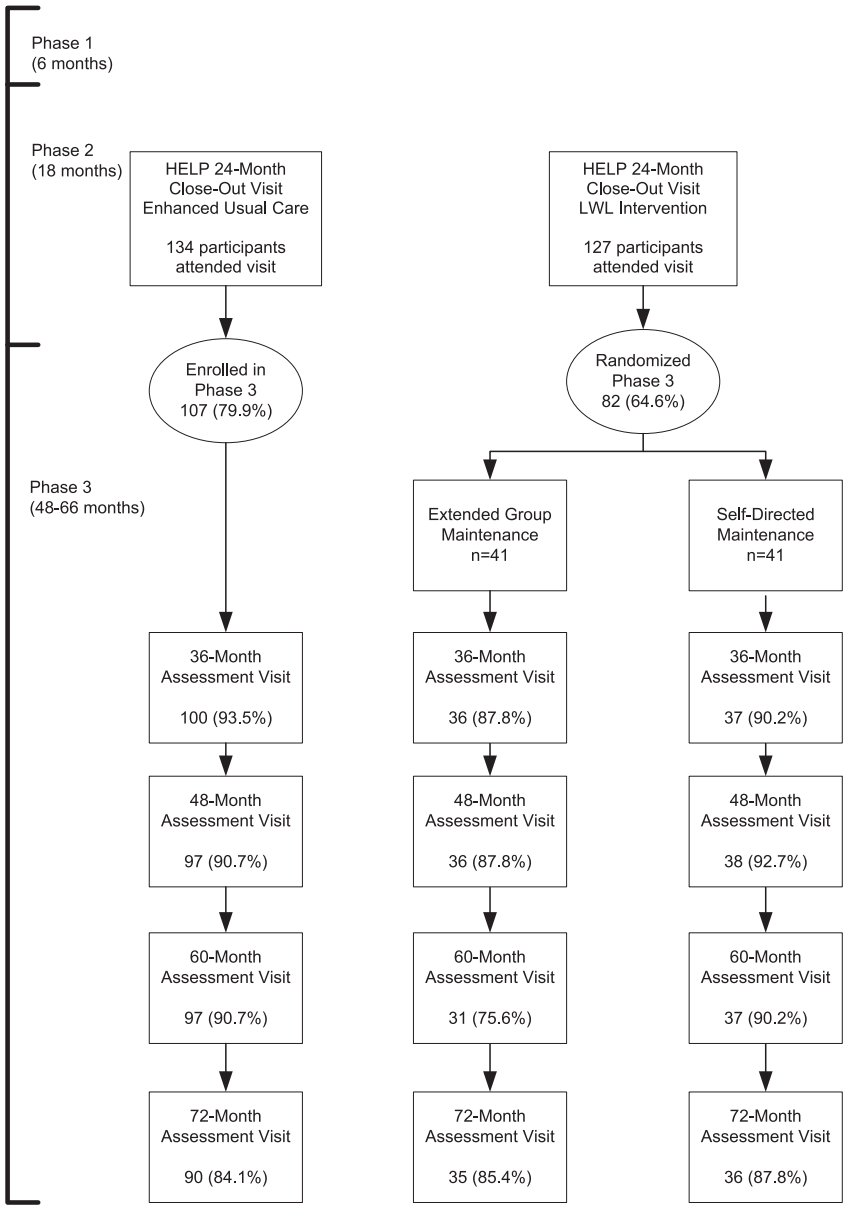

Figure 1—Study timeline and flow of participants from P3 enrollment to 72 months in HELP PD P3.

outcomes remained fairly stable for the EUC participants during P3. The GM participants were able to maintain body weight loss, BMI, and waist circumference, while those measures worsened over time in the SM participants. Least squares means from the mixed models are shown in Fig. 2 and Supplementary Figs. 1–3. As seen in Fig. 2, the change in weight between 24 and 72 months (P3) was not statistically significant for the EUC or GM groups but was highly statistically significant for the SM group ($P < 0.001$). The average change in weight during P3 (i.e., the average weight during months 30–72 relative to the weight at P3 re-enrollment at 24 months) was −0.72 kg for the EUC group, 0.68 kg for the GM group, and 3.82 kg for the SM group. The SM group differed significantly from the EUC and GM groups in average weight change ($P \leq 0.001$ for each comparison), while the EUC and GM group difference was nonsignificant. Results are similar for BMI and waist circumference (Supplementary Figs. 1 and 2). BMI and waist circumference in the SM group increased significantly, while these remained fairly stable over time in the EUC and GM groups. The average changes in BMI and waist circumference were significantly greater for the SM group ($P \leq 0.001$ for each comparison). Trends were similar for fasting glucose and HOMA-IR, although the changes over time in the SM group were not statistically significant ($P = 0.128$ for glucose, 0.301 for insulin, and 0.159 for HOMA-IR), and the groups did not differ significantly in average changes for any of these outcomes during P3 (Supplementary Fig. 3). Attendance at group sessions was not associated with change in any of the outcomes during P3 (all $P > 0.18$). Seventy-nine percent of the RDN visits were attended by EUC participants in P3. For the GM and SM groups, attendance was 49% and 58%, respectively.

A total of 59 serious adverse events were reported in P3: 8 in the GM, 6 in the SM, and 45 in the EUC arms, none of which were related to study participation (i.e., overnight hospitalization for planned surgery, events related to preexisting medical conditions). All events were reviewed and adjudicated by an independent medical safety officer outside the investigative team. Incident diabetes was defined as a fasting glucose >126 mg/dL or receipt of antidiabetes medication. The percentage of participants with diabetes at each visit is shown in Supplementary Table 2. A steady increase over time in the proportion of participants with diabetes in the EUC and SM groups is noted, while the proportion of participants with diabetes in the GM group remained low (3% at 72 months).

CONCLUSIONS

In this analysis, we examined group differences in the changes in body weight and other important biomarkers of health over the 4 years of additional follow-up in HELP PD P3. During P3, participants randomized to GM were able to better maintain the improvements in body weight, BMI, and waist circumference that they had achieved in P1 and P2 compared with participants randomized to SM, who experienced significant increases in body weight, BMI, and waist circumference over the course of P3. It is not clear what component of the GM intervention is driving the effect in P3 because attendance at group sessions was low and was not associated with change in weight. It is possible that participants randomized to the GM may have felt more accountable. Because this is the only diabetes prevention study in our knowledge to examine the

Table 1—Demographic characteristics of participants taking part in P3 at baseline of HELP PD and clinical measures at baseline and at P3 randomization

Characteristic	GM (n = 41)	SM (n = 41)	EUC (n = 107)	P value*
Sex				0.580
Male	17 (41)	18 (44)	50 (47)	
Female	24 (59)	23 (56)	57 (53)	
Race				0.112
Nonwhite	15 (37)	11 (27)	23 (22)	
White	26 (63)	30 (73)	84 (79)	
Age (years), median (range)	57 (40–80)	57 (36–75)	58 (39–76)	0.562
<50	12 (29)	10 (24)	27 (25)	
50–59	17 (41)	15 (37)	33 (31)	
≥60	12 (29)	16 (39)	47 (44)	
Marital status				0.202
Never married	2 (5)	6 (15)	5 (5)	
Married/living together	27 (66)	23 (56)	77 (72)	
Divorced, widowed, or separated	12 (29)	12 (29)	25 (23)	
Employed full or part time	29 (71)	29 (71)	74 (69)	0.815
Number in house				0.839
1	7 (17)	11 (27)	23 (22)	
2	23 (56)	18 (44)	53 (50)	
3	6 (15)	8 (20)	15 (14)	
≥4	5 (12)	4 (10)	16 (15)	
Clinical measures at P1 baseline				
Fasting blood glucose (mg/dL)	103.7 (8.9)	106.5 (17.1)	106.5 (10.1)	0.186
Weight (kg)	94.3 (15.7)	97.4 (14.6)	92.8 (17.0)	0.106
BMI (kg/m^2)	32.5 (4.4)	33.8 (3.6)	32.4 (4.3)	0.242
Waist circumference (cm)	103.7 (9.9)	107.4 (8.5)	104.3 (11.5)	0.348
Insulin (μU/mL)	14.6 (7.7)	18.4 (12.1)	17.5 (10.9)	0.521
HOMA-IR	3.8 (2.2)	5.1 (4.3)	4.7 (3.2)	0.467
Clinical measures at P3 randomization				
Fasting blood glucose (mg/dL)	102.2 (10.5)	103.6 (9.5)	108.2 (13.0)	0.002
Weight (kg)	89.3 (15.9)	92.0 (15.3)	92.4 (16.8)	0.391
BMI (kg/m^2)	30.9 (4.6)	32.0 (4.0)	32.3 (4.3)	0.181
Waist circumference (cm)	101.0 (12.1)	103.0 (8.9)	104.3 (11.1)	0.133
Insulin (μU/mL)	10.5 (8.0)	12.4 (8.0)	14.0 (9.7)	0.018
HOMA-IR	2.8 (2.4)	3.3 (2.4)	3.9 (3.0)	0.008

Data are n (%) or mean (SD). *EUC vs. combined maintenance groups.

maintenance of benefits over 6 years, comparison with other studies is difficult. However, these results are consistent with those of the Weight Loss Maintenance Trial in which participants who received personal contact after an intensive lifestyle intervention maintained greater weight loss than those randomized to a self-directed group (21).

Interestingly, while GM session attendance during P3 was low, participants in this arm were able to remain on track. Because of the low session attendance, GM participants were contacted by telephone/e-mail by the CHWs more frequently, and a reward system that was based on meeting behavioral goals was implemented. Unfortunately, in light of the low attendance rates, these approaches did not have a significant impact on group attendance but may have helped participants to meet/maintain behavioral goals.

Among the most successful strategies used by the DPP trial (34) was establishing participant accountability (35). Regular contacts with participants that included reviewing weight loss progress and goal attainment, assisting with problem solving, reinforcing success and effort, and self-monitoring dietary intake and physical activity were used to establish accountability. Because we did not have a formal assessment of accountability, we can only speculate that remaining in the intervention arm of the trial rather than actual attendance at group meetings was sufficient for the maintenance of changes in the anthropometric outcomes reported here. Our findings suggest that the appropriate dose of contact after intensive intervention to maintain weight loss may not be linked to frequency of contact but perhaps to accountability. Social support has also been linked to maintenance of behavior change in lifestyle interventions in a number of studies (23), and it is possible that the social support available from the CHW and/or other group members played a role in the maintenance of weight and other outcomes.

Furthermore, participants in the SM group were responsible for managing their own weight maintenance and were unsuccessful in doing so. As noted, a majority of the outcomes remained fairly stable after rerandomization to P3 in the EUC and GM participants, while they worsened over time in the SM participants. It might be expected that the LWL participants who agreed to continue in P3 were the more enthusiastic participants. Yet, despite this expectation, those who were rerandomized to SM did not maintain the weight loss and other biomarker improvements achieved in P1 and P2. Individual dietitian counseling for participants in SM focused on general concepts of healthy eating related to MyPlate (36) and encouraged maintenance of habits established in P1 and P2, although this did not mitigate weight regain. It is possible that to maintain weight loss, the SM group needed the established accountability of the CHW that the GM participants continued to have during P3.

The EUC participants continued to maintain their baseline body weight as they had during P1 and P2. However, the mean waist circumference measures in the EUC group increased, even though the mean body weight decreased. Central adiposity has been reported to be detrimental to health, and this finding highlights the need to collect measures beyond height and weight and the importance of including measures to assess body composition changes. Although the RDNs provided information and guidance for EUC participants to consume a diet consistent with MyPlate (36), the counseling did not include calorie restriction for weight loss.

When HELP PD participants were asked to enroll in P3, more of the EUC participants agreed to re-enroll. Only 54% of the participants in the LWL group agreed to participate in P3 compared with 71% of the EUC participants. Although not collected systematically, participants declining participation in P3 expressed

Table 2—Measures of body weight and biomarker outcomes over 6 years of follow-up by study arm

	Baseline		1 year		2 years		3 years		4 years		5 years		6 years	
Group	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)
Weight (kg)														
GM	41	94.3 (15.7)	41	87.4 (15.5)	41	89.3 (15.9)	36	88.5 (16.2)	36	87.4 (15.8)	31	87.9 (16.4)	35	88.6 (17.2)
SM	41	97.4 (14.6)	40	90.9 (15.1)	41	92.0 (15.3)	37	94.9 (16.0)	38	95.8 (15.1)	37	97.4 (16.6)	36	97.7 (17.9)
EUC	107	92.8 (17.0)	106	91.2 (16.9)	106	92.4 (16.8)	100	91.9 (16.6)	97	91.4 (17.3)	97	91.7 (17.5)	90	91.5 (18.0)
BMI (kg/m^2)														
GM	41	32.5 (4.4)	41	30.2 (4.5)	41	30.9 (4.6)	36	30.5 (4.5)	36	30.4 (4.3)	31	30.5 (4.6)	35	30.6 (4.6)
SM	41	33.8 (3.6)	40	31.7 (4.1)	41	32.0 (4.0)	37	32.8 (4.1)	38	33.4 (4.2)	37	33.7 (4.4)	36	33.8 (4.2)
EUC	107	32.4 (4.3)	106	32.0 (4.4)	106	32.3 (4.3)	100	32.1 (4.2)	97	32.0 (4.5)	97	32.0 (4.4)	90	32.0 (4.3)
Waist circumference (cm)														
GM	41	103.7 (9.9)	41	98.2 (11.4)	41	101.0 (12.1)	36	99.2 (11.8)	36	99.5 (10.9)	31	100.0 (10.9)	35	101.6 (11.8)
SM	41	107.4 (8.5)	40	102.4 (9.8)	41	103.0 (8.9)	37	105.2 (9.3)	38	106.9 (9.7)	37	108.3 (9.7)	36	108.6 (9.7)
EUC	107	104.3 (11.5)	106	103.5 (10.9)	107	104.3 (11.1)	100	104.1 (11.1)	97	104.4 (11.7)	97	105.4 (11.7)	90	105.4 (11.8)
Fasting blood glucose (mg/dL)														
GM	41	103.7 (8.9)	41	99.3 (9.7)	41	102.2 (10.5)	36	101.3 (10.3)	36	100.4 (16.2)	31	98.2 (11.6)	35	102.7 (17.3)
SM	41	106.5 (17.1)	40	101.6 (9.6)	41	103.6 (9.5)	37	105.1 (9.5)	38	105.6 (14.2)	37	109.4 (13.4)	36	110.1 (16.1)
EUC	107	106.5 (10.1)	106	103.3 (10.9)	107	108.2 (13.0)	100	108.5 (13.2)	97	107.3 (13.8)	97	107.1 (12.0)	90	108.5 (14.5)
Insulin (μU/mL)														
GM	41	14.6 (7.7)	41	8.6 (5.5)	41	10.5 (8.0)	36	9.2 (8.8)	36	9.3 (9.5)	31	10.8 (12.0)	35	9.4 (5.7)
SM	41	18.4 (12.1)	40	11.0 (5.1)	41	12.4 (8.0)	37	13.7 (9.2)	38	14.5 (12.8)	37	15.4 (9.2)	36	15.3 (8.9)
EUC	107	17.5 (10.9)	106	13.2 (8.1)	107	14.0 (9.7)	99	13.1 (8.3)	97	14.5 (9.4)	97	14.4 (9.0)	90	13.6 (8.8)
HOMA-IR														
GM	41	3.8 (2.2)	41	2.2 (1.5)	41	2.8 (2.4)	36	2.4 (2.8)	36	2.6 (3.7)	31	2.7 (3.0)	35	2.5 (2.0)
SM	41	5.1 (4.3)	40	2.8 (1.4)	41	3.3 (2.4)	37	3.6 (2.6)	38	4.0 (4.6)	37	4.3 (3.0)	36	4.3 (2.8)
EUC	107	4.7 (3.2)	106	3.4 (2.2)	107	3.9 (3.0)	99	3.6 (2.5)	97	3.9 (2.9)	97	3.9 (2.7)	90	3.7 (2.5)

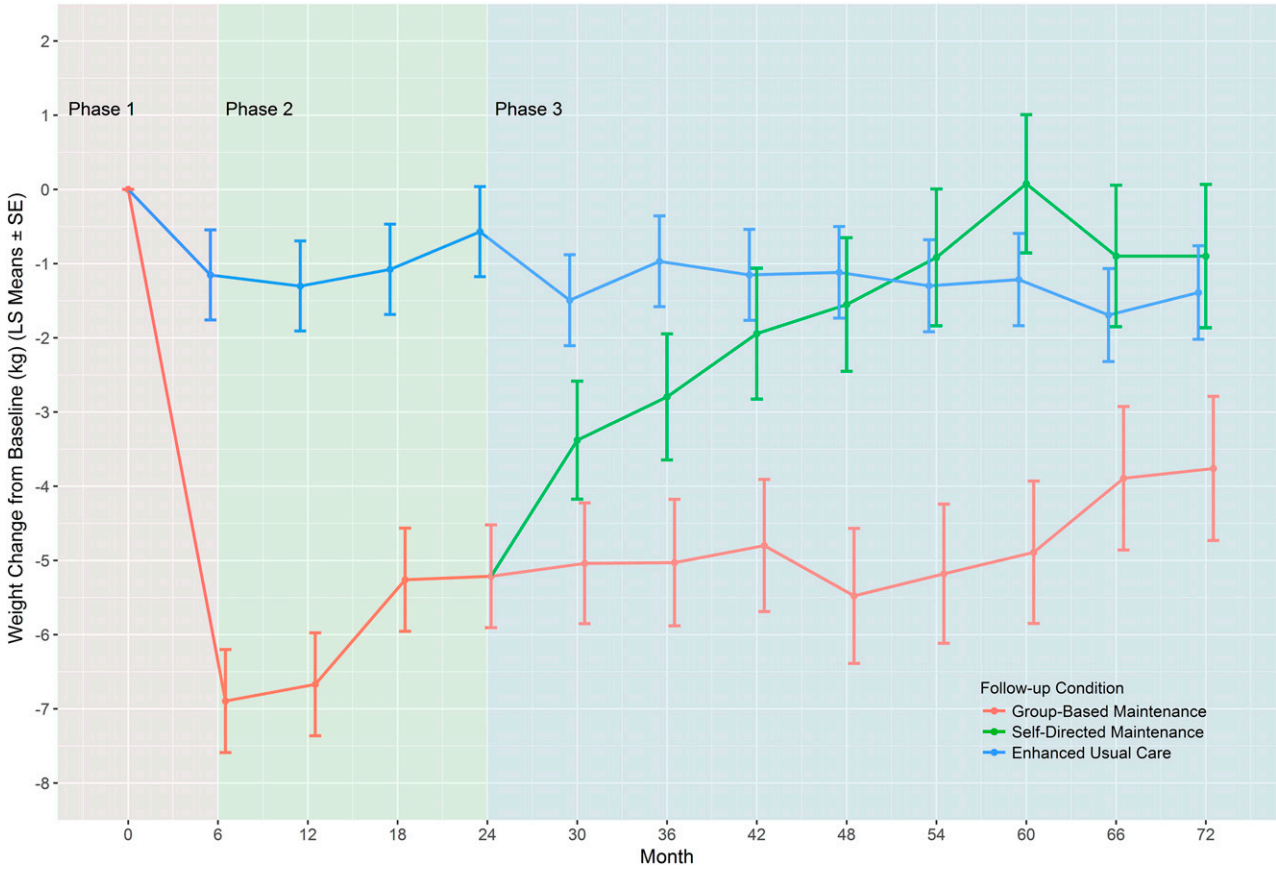

Figure 2—Changes in body weight by treatment group from baseline in HELP PD through 72 months of follow-up. LS, least squares.

several common reasons for nonparticipation: the continued time commitment should they be randomized to GM; competing work, family, or caregiver demands; and confidence in their own ability to successfully manage their weight without additional intervention. P3 occurred following a full 24 months of intervention that included 42 group sessions in the original HELP PD study. It could be that some participants had simply had enough of participating in HELP PD. Alternatively, the lower rerandomization rate in the LWL group could have been due to the participants' perceived success/failure in P1 and P2. That is, it is possible that participants who successfully lost weight did not perceive the need for further intervention. Similarly, it is also possible that participants who were not successful did not believe that further intervention would be helpful.

Although the numbers are low, we did observe a steady increase over time in the proportion of participants who were diagnosed with diabetes in both the EUC and the SM groups, while the proportion of participants with diabetes in the GM group remained low (3% at 72 months). This is encouraging and supports that community-based diabetes prevention programs, such as HELP PD, can slow progression toward the expression of diabetes if healthful behaviors and weight loss are maintained.

Limitations of this study that warrant mentioning include that not all participants re-enrolled in P3. Nonetheless, we were able to see important differences in outcomes between the groups during P3. The attendance rates of the sessions were low in GM, although participants were in contact with the CHWs. Additionally, we cannot determine the specific elements of continuing in the intervention that made the GM participants successfully maintain weight loss.

In conclusion, the current study demonstrates that long-term maintenance of beneficial changes in adiposity and metabolic functioning requires continued contact. The maintenance of weight loss is a critical public health issue, and the dangers of weight regain have been documented (37). Additional research to determine the amount of contact/accountability necessary to support weight loss maintenance is needed because it is well recognized that long-term weight loss maintenance is essential to maintain health benefits achieved through weight loss.

HELP PD P3 results suggest that continued contact may have aided in maintaining favorable lifestyle changes and played an important role in preventing weight regain typically observed after the discontinuation of traditional diabetes prevention LWL interventions. Long-term studies are warranted to determine factors required to keep adults diagnosed with prediabetes engaged in maintaining healthful diets and staying physically active to maintain weight loss, thereby reducing the risk of type 2 diabetes.

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References

1. Tuomilehto J, Lindström J, Eriksson JG, et al.; Finnish Diabetes Prevention Study Group. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J Med 2001;344:1343–1350
2. Quinn MT, McNabb WL. Training lay health educators to conduct a church-based weight-loss program for African American women. Diabetes Educ 2001;27:231–238
3. Knowler WC, Barrett-Connor E, Fowler SE, et al.; Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 2002;346:393–403
4. Absetz P, Valve R, Oldenburg B, et al. Type 2 diabetes prevention in the "real world": one-year results of the GOAL Implementation Trial. Diabetes Care 2007;30:2465–2470
5. Ratner RE. Prevention of type 2 diabetes in women with previous gestational diabetes. Diabetes Care 2007;30(Suppl. 2):S242–S245
6. Absetz P, Oldenburg B, Hankonen N, et al. Type 2 diabetes prevention in the real world: three-year results of the GOAL lifestyle implementation trial. Diabetes Care 2009;32:1418–1420
7. Whittemore R, Melkus G, Wagner J, Dziura J, Northrup V, Grey M. Translating the diabetes prevention program to primary care: a pilot study. Nurs Res 2009;58:2–12
8. Ritchie LD, Sharma S, Ikeda JP, et al. Taking Action Together: a YMCA-based protocol to prevent type-2 diabetes in high-BMI inner-city African American children. Trials 2010;11:60
9. Coleman KJ, Ocana LL, Walker C, et al. Outcomes from a culturally tailored diabetes prevention program in Hispanic families from a low-income school: Horton Hawks Stay Healthy (HHSH). Diabetes Educ 2010;36:784–792
10. Salas-Salvadó J, Bulló M, Babio N, et al.; PREDIMED Study Investigators. Reduction in the incidence of type 2 diabetes with the Mediterranean diet: results of the PREDIMED-Reus nutrition intervention randomized trial. Diabetes Care 2011;34:14–19
11. Burnet DL, Plaut AJ, Wolf SA, et al. Reach-out: a family-based diabetes prevention program for African American youth. J Natl Med Assoc 2011;103:269–277
12. Ruggiero L, Oros S, Choi YK. Community-based translation of the diabetes prevention program's lifestyle intervention in an underserved Latino population. Diabetes Educ 2011;37:564–572
13. Katula JA, Vitolins MZ, Rosenberger EL, 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;34:1451–1457
14. Ali MK, Echouffo-Tcheugui J, Williamson DF. How effective were lifestyle interventions in real-world settings that were modeled on the Diabetes Prevention Program? Health Aff (Millwood) 2012;31:67–75
15. Ackermann RT, Finch EA, Schmidt KK, et al. Rationale, design, and baseline characteristics of a community-based comparative effectiveness trial to prevent type 2 diabetes in economically disadvantaged adults: the RAPID Study. Contemp Clin Trials 2014;37:1–9
16. Appel LJ, Clark JM, Yeh HC, et al. Comparative effectiveness of weight-loss interventions in clinical practice. N Engl J Med 2011;365:1959–1968
17. Coughlin JW, Brantley PJ, Champagne CM, et al.; Weight Loss Maintenance Collaborative Research Group. The impact of continued intervention on weight: five-year results from the weight loss maintenance trial. Obesity (Silver Spring) 2016;24:1046–1053
18. Franz MJ, VanWormer JJ, Crain AL, et al. Weight-loss outcomes: a systematic review and meta-analysis of weight-loss clinical trials with a minimum 1-year follow-up. J Am Diet Assoc 2007;107:1755–1767
19. Miller ER III, Erlinger TP, Young DR, et al. Results of the Diet, Exercise, and Weight Loss Intervention Trial (DEW-IT). Hypertension 2002;40:612–618
20. Pi-Sunyer X, Blackburn G, Brancati FL, et al.; Look AHEAD Research Group. Reduction in weight and cardiovascular disease risk factors in individuals with type 2 diabetes: one-year results of the look AHEAD trial. Diabetes Care 2007;30:1374–1383
21. Svetkey LP, Stevens VJ, Brantley PJ, et al.; Weight Loss Maintenance Collaborative Research Group. Comparison of strategies for sustaining weight loss: the weight loss maintenance randomized controlled trial. JAMA 2008;299:1139–1148
22. Wadden TA, Neiberg RH, Wing RR, et al.; Look AHEAD Research Group. Four-year weight losses in the Look AHEAD study: factors associated with long-term success. Obesity (Silver Spring) 2011;19:1987–1998
23. Lemstra M, Bird Y, Nwankwo C, Rogers M, Moraros J. Weight loss intervention adherence and factors promoting adherence: a meta-analysis. Patient Prefer Adherence 2016;10:1547–1559
24. Katula JA, Vitolins MZ, Rosenberger EL, et al. Healthy Living Partnerships to Prevent Diabetes (HELP PD): design and methods. Contemp Clin Trials 2010;31:71–81
25. Katula JA, Vitolins MZ, Morgan TM, et al. The Healthy Living Partnerships to Prevent Diabetes study: 2-year outcomes of a randomized controlled trial. Am J Prev Med 2013;44(Suppl. 4):S324–S332
26. Vitolins MZ, Isom SP, Blackwell CS, et al. The healthy living partnerships to prevent diabetes and the diabetes prevention program: a comparison of year 1 and 2 intervention results. Transl Behav Med 2017;7:371–378
27. Blackwell CS, Foster KA, Isom S, et al. Healthy Living Partnerships to Prevent Diabetes: recruitment and baseline characteristics. Contemp Clin Trials 2011;32:40–49
28. Lawlor MS, Blackwell CS, Isom SP, et al. Cost of a group translation of the Diabetes Prevention Program: Healthy Living Partnerships to Prevent Diabetes. Am J Prev Med 2013;44(Suppl. 4):S381–S389
29. Williamson DFK, Kahn HS, Worthman CM, Burnette JC, Russell CM. Precision of recumbent anthropometry. Am J Hum Biol 1993;5:159–167
30. American Diabetes Association. Diagnosis and classification of diabetes mellitus. 2004;27(Suppl. 1):S5–S10
31. Matthews DR, Hosker JP, Rudenski AS, Naylor BA, Treacher DF, Turner RC. Homeostasis model assessment: insulin resistance and beta-cell function from fasting plasma glucose and insulin concentrations in man. Diabetologia 1985;28:412–419
32. Katsuki A, Sumida Y, Gabazza EC, et al. Homeostasis model assessment is a reliable indicator of insulin resistance during follow-up of patients with type 2 diabetes. Diabetes Care 2001;24:362–365
33. Liang KY, Zeger SL. Longitudinal data analysis of continuous and discrete responses for pre-post designs. Sankhya Ser B 2000;62:134–148
34. Diabetes Prevention Program (DPP) Research Group. The Diabetes Prevention Program (DPP): description of lifestyle intervention. Diabetes Care 2002;25:2165–2171
35. Marrero DG. Changing patient behavior. Endocr Pract 2006;12(Suppl. 1):118–120
36. U.S. Department of Agriculture. ChooseMyPlate.gov website [Internet]. Available from https://www.choosemyplate.gov. Accessed 2 June 2017
37. Beavers KM, Case LD, Blackwell CS, Katula JA, Goff DC Jr, Vitolins MZ. Effects of weight regain following intentional weight loss on glucoregulatory function in overweight and obese adults with pre-diabetes. Obes Res Clin Pract 2015;9:266–273