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Healthy Living Partnerships to Prevent Diabetes (HELP PD): Design and Methods

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Abstract

Although the Diabetes Prevention Program (DPP) developed a lifestyle weight loss intervention that has been demonstrated to prevent type 2 diabetes in high-risk individuals, it has yet to be widely adopted at the community level. The Healthy Living Partnership to Prevent Diabetes study (HELP PD) was designed to translate the DPP approach for use in community settings as a cost-effective intervention led by Community Health Workers (CHW's) and administered through a Diabetes Care Center (DCC). Approximately 300 overweight and obese (BMI 25-40 kg/m^2) individuals with prediabetes (fasting blood glucose 95-124 mg/dl) were randomly assigned to either a lifestyle weight loss intervention (LW) or an enhanced usual care comparison condition (UC). The goal of LW is ≥7% weight loss achieved through increases in physical activity (180 min/wk) and decreases in caloric intake (approximately 1500 kcal/day). The intervention consists of CHW-led group-mediated cognitive behavioral meetings that occur weekly for 6 months and monthly thereafter for 18 months. UC consists of 2 individual meetings with a registered dietitian and a monthly newsletter. The primary outcome is change in fasting blood glucose. Secondary outcomes include cardiovascular risk factors, health-related quality of life, and social cognitive variables. Outcomes are masked and are collected every 6 months. The cost-effectiveness of the program will also be assessed. A community-based program that is administered through local DCC's and that harnesses the experience of community members (CHW's) may be a promising strategy for the widespread dissemination of interventions effective at preventing type 2 diabetes in high risk individuals.

Keywords

translational research; randomized controlled trial; weight loss; prevention; type 2 diabetes; obesity

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1. Introduction

The prevalence of Type II diabetes continues to increase in both older and younger adults [1-3]. Although evidence suggests that diabetes mortality has declined in the last ten years by 8.3%, diabetes-related complications continue to increase resulting in rising disease burden [4]. These realities exist despite the success of large scale clinical trials, such as the Diabetes Prevention Program (DPP) and the Finish Diabetes Prevention Study (DPS), demonstrating that weight loss resulting from changes in diet and physical activity can decrease the incidence of diabetes [5;6].

It has been argued that the lack of large-scale implementation of effective diabetes prevention programs is due to a general lack of understanding of translational research [7;8]. That is, although compelling evidence exists demonstrating the efficacy of lifestyle interventions in clinical settings [9], whether these strategies can be successfully implemented in the community is an unanswered question. Although recent projects have attempted to translate the DPP intervention, sample sizes have been small and the degree of translatability is unknown [10-14]. The overall goal of the Healthy Living Partnerships to Prevent Diabetes (HELP PD) project is to translate the methods of the DPP into the community setting by incorporating several key translations of prior research to enhance logistical and fiscal feasibility and long term dissemination: the use of a group-based intensive lifestyle behavioral intervention employing professional and community health workers (CHWs) and delivery of the intervention in the community setting via innovative expansion of an existing Diabetes Education Program (DEP) in collaboration with CHWs as empowered community partners.

2. Primary Research Goals

The primary hypothesis being tested in HELP PD is that a lifestyle intervention (addressing healthy eating, physical activity, and weight loss) administered through a community-based diabetes prevention program model will have a beneficial and clinically meaningful impact on glucose and insulin metabolism, and markers of the metabolic syndrome. It compares, in overweight and obese volunteers with elevated fasting glucose, the effects of two study conditions: a lifestyle intervention designed to induce weight loss through decreased caloric intake and increased physical activity, led by CHWs versus a control condition of usual care that includes two individual consultations with a registered dietitian and the primary outcome will be change in fasting blood glucose.

Other research goals include comparisons of physical activity, dietary intake, weight, waist circumference, insulin, triglycerides, HDL-C, blood pressure, and health-related quality of life. Additionally, we are monitoring the incidence of diabetes and serious adverse events, as participant safety concerns. A secondary aim involves an economic evaluation of the program in order to determine the cost effectiveness of the intervention in terms of the primary and major secondary (diabetes prevention) outcomes. We are also investigating whether intervention effects on outcomes (e.g., fasting glucose) differ by selected characteristics of participants (age, gender, and ethnicity) and/or are mediated through changes in constructs from social cognitive theory, behavior change (i.e., diet and physical activity), and/or biological impact measures (weight, waist).

3. Study Design

3.1. Overview

A total of 300 participants with pre diabetes (fasting blood glucose = 95 mg/dl ≤ FBG ≤ 125) were recruited over 2 years and randomized to either a CHW led lifestyle intervention or an

enhanced usual care intervention. Our comparison intervention condition is an individual education program that builds on an increased awareness of existing community resources and is designed to exceed the usual care provided to similar community members and to enhance retention. Comparison participants receive two individual sessions with the study education intervention RD. The lifestyle intervention is based on the DPP intervention and designed to produce modest, yet achievable (5-7%), weight loss through healthy eating and increased physical activity. The lifestyle intervention sessions are conducted in group format and coordinated and facilitated by the CHWs. The contact schedule occurs in 2 phases, with an early 6-month intensive phase (1 group session per week) followed by an 18-month maintenance phase (1 group session per month). This contact schedule enables us to examine the maintenance of weight loss and behavior. The main outcome is fasting blood glucose. Follow-up exams occur every 6 months to assess weight, laboratory parameters (e.g., insulin, lipid profiles), and other measures of the intervention effect (e.g., health-related quality of life).

3.2. Eligibility

The principles guiding the selection of the following inclusion and exclusion criteria were to ensure the enrollment of participants who meet 3 major criteria: 1) high risk for developing diabetes, 2) no medical contraindications to participate in a lifestyle intervention including unsupervised physical activity and weight loss, and 3) ethical randomization, i.e., there are no compelling reasons that potential participants should be referred for immediate weight loss (see Table 1 for a complete list of eligibility criteria). We also sought to exclude individuals with behavioral or psychiatric conditions (e.g., substance abuse, schizophrenia) who are unlikely to be compliant with the intervention. We selected criteria which would be more easily implemented in the community than those used in DPP. Specifically, inclusion was based on fasting blood glucose, rather than results of an oral glucose tolerance test, to enhance the logistical feasibility, translation, and dissemination. An upper limit for BMI was chosen in deference to recommendations that persons with BMI $\geq$40 kg/m^2 be evaluated for bariatric surgery [15]. Eligibility was established through a multi-step process involving telephone and in-person screening.

3.3. Recruitment

Recruitment of study participants began in the spring of 2007 and concluded in April 2009. Potential participants were identified through a variety of approaches appropriate for a translational study. Our recruitment strategies included mass mailings to targeted zip codes, in-person presentations to community organizations, community health fair and workplace screening, and participant and provider referrals. A tiered screening process was developed to maximize the potential for screening those most likely to qualify for randomization. Interested potential participants were telephone screened, then invited to a study information session that includes a study video developed to be used in conjunction with the informed consent process. During this session, a glucometer is used to assess a random blood sample, blood pressure was measured, and the Physical Activity Readiness Questionnaire (PAR-Q) was administered. Participants who were interested and eligible following the information session were then scheduled for a clinic visit at the General Clinical Research Center (GCRC). At these visits, height, weight, blood pressure, and fasting glucose were assessed to determine eligibility. Eligible participants were then scheduled for a randomization visit.

3.4. Informed Consent

Approval of protocol and consent forms by the institutional review board was obtained prior to the start of recruitment. All participants completed an informed consent and HIPAA authorization prior to the screening process.

3.5. Randomization

Eligible participants were randomly assigned, if equal probability, to either the lifestyle intervention or the enhanced usual care arm using a web-based data management system that verifies eligibility. Although neither the participants nor interventionists were masked to treatment assignment, the primary outcome, fasting blood glucose, was chosen to be highly objective.

3.6. Measures

Assessments are performed at 6 month intervals (baseline, 6-, 12-, 18- and 24-months post-randomization) at the GCRC. Psychosocial measures are self-administered and remaining measures are completed by trained study staff or clinic staff.

3.6.1. Fasting Blood Glucose, Insulin, Lipids—All biochemical measurements, including glucose, are performed in a central laboratory by technicians masked to participants' intervention assignment. Phlebotomy is performed by trained, certified phlebotomists following at least an 8 hour fast (typically over night) in accordance with American Diabetes Association (ADA) guidelines (2005). Blood samples for plasma glucose are collected in tubes containing sodium fluoride in order to minimize post collection changes in glucose due to glycolysis. Cells are separated from the plasma immediately following collection and the plasma stored frozen until analyzed. Glucose is measured using a timed endpoint method supplied by Beckman Coulter for the Synchron LX Analyzer. This method, developed by the Centers for Disease Control, has been accepted as a reference method for glucose determination. Within-run coefficients of variation (CV) for this method are less than or equal to 3.9% and total CVs are less than or equal to 6.45%. The insulin assay used is the paramagnetic particle, chemiluminescent immunoassay for the Access Immunoassay Systems from Beckman Coulter. There is less than 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 are run during each 24-hour time period. The overall within assay variability is 3.9% and the between assay variability is 5.5%. The assay mean for this laboratory is 44.7 with a CV of 2.56 and 152.7 with a CV of 5.77.

3.6.2. Health-related Quality of Life (SF-36) [16]—The SF-36 is the most widely used self-reported general health status measure with extensive validation and population norms available. It allows comparison of the HELP PD study population with those of other studies and other chronic diseases. Eight scale scores are generated in the following domains: general health, physical function, role-physical, role-emotional, vitality, social function, mental health, and pain. It can also generate composite scales representing physical health and mental health. The norm based composite scales have a mean of 50 and a standard deviation of 10, whereas the subscales are typically reported as scores that range from 0-100. Higher scores on all SF-36 scores indicate more favorable levels of function.

3.6.3. Health Utilities Index—The Health Utilities Index Mark 3 (HUI3) system is a generic HRQL instrument which was developed not only for measuring health status but also for economic evaluation. HUI3 includes a health-status classification system and a preference-based scoring formula. The HUI3 has eight attributes (vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain) with five to six levels per attribute. The multiplicative multi-attribute utility function for the HUI3 system can be used to generate utility scores for use in economic analysis.

3.6.4. Medical History/Resource Utilization/Cost—The cost of HELP PD will be separated into research and intervention costs. Research costs will be excluded from the economic evaluation. The intervention costs will be classified into direct medical, direct

nonmedical, and indirect costs. The identification and measurement of the cost of a health prevention program can be determined from different perspectives: for instance, that of the individual, health care provider, third party payer (including large health care systems, insurers, government, etc.), and society. We will adopt two perspectives in our reporting of cost results. First, we will report the incremental cost of the intervention over the "usual care" group from the perspectives of a large health care system. Second we will measure the same incremental cost from the standpoint of society as a whole. Each of these perspectives will influence successful dissemination.

3.6.5. Social Cognitive process measures—We utilize a series of four brief process measures based on social cognitive theory that address 1) barriers efficacy for physical activity [17] and weight loss [18], 2) task efficacy related to specific physical capacities and weight loss [19], 3) satisfaction with physical function and body appearance [20] and 4) the desire to be physically competent and to lose varying percentages of weight (converted to pounds on an individual basis).

3.6.6. International Physical Activity Questionnaire [21]—Physical activity is assessed using a modified version of the International Physical Activity Questionnaire (IPAQ) short form, an internationally reliable and valid instrument for assessing physical activity (1). The IPAQ short form is a 7-item index that asks respondents the number of days per week and the amount of time per day spent in vigorous- and moderate-intensity activities and walking, during the seven days prior to the interview.

3.6.7. Block Dietary Measures—Usual dietary intake is assessed using a widely-used, self-administered food frequency questionnaire (FFQ) [22]. The FFQ provides estimates of macronutrients, micronutrients, and servings of particular foods of interest, and have been validated against food records. The FFQ is not assessed at the 18-month follow-up visit to reduce participant burden.

3.7. Community-based Implementation

A major translational component of HELP PD is the community-based implementation of the intervention. That is, our goal is to develop and test a translation of the DPP model that can be implemented in community settings by community organizations and community members. As such, we strive to minimize the impact of specialized research personnel (e.g., study investigators) in the implementation of the intervention to enhance the translatability of the program. To achieve this goal, the intervention is conducted in community-based sites (e.g., Parks & Recreation Centers), implemented and monitored via a local Diabetes Care Center (DCC), and led by Community Health Workers (CHWs). Study administration (e.g., recruitment, data management) is conducted by study investigators and staff, but the day to day operations of the intervention are conducted by the registered dieticians (RDs) employed by the DCC. The RDs meet with an Intervention Committee consisting of study staff and investigators regularly to provide updates of intervention implementation and progress (e.g., participant staffing).

3.7.1. Registered Dietitian Training—To ensure the community-based translation of the intervention and minimize the influence of the study staff and investigators, we adopted a "train the trainer to train the trainer" model. That is, we trained the RDs to train the CHWs. The CHWs then lead the Lifestyle Intervention group sessions. Additionally, the RDs are responsible for the implementation and monitoring of the intervention. The training program was designed with the understanding that RDs employed by a DCC have extensive training in diabetes (etiology and treatment), patient provider interaction, and nutrition. Therefore, the RD training program was focused on study specific material and consisted of a) study protocol; b)

intervention philosophy, goals, and procedures; c) weight loss (energy balance); d) physical activity basics; e) group facilitation; f) cognitive-behavioral principles; g) participant monitoring and tool box methods; h) role playing; and i) data entry. The RD training program consisted of 16 hours of instruction, interaction, and role playing and is manualized.

3.7.2. Community Health Workers—Community Health Workers (CHWs) as empowered community partners, represent an effective mechanism for the dissemination of health education [23-27]. These programs have been modeled after indigenous practices in Latin America whereby health information is shared informally through oral tradition and adopted from trusted community sources [28]. CHWs models are advantageous because of their lower costs associated with disseminating information through community volunteers with extant social networks. Moreover, CHWs are thought to be effective in delivering their message because they share common demographic and cultural traits with the intended audience [28]. Qualitative research suggests this health promotion model works because CHWs are able to influence the attitudes and behaviors of their targets. The established relationships CHWs have with their advisees, their ability to make advisees feel comfortable talking about private issues, their reputation as credible sources of information, and the support for behavior that they provide, made them effective in the perspective of the women participants in a lay health education program [29]. In addition, success in some CHW interventions is attributed to the "identification of natural helpers…and their subsequent training in interventions based on social learning theory [and] using culturally appropriate educational materials" [23].

The success of the trial is in part predicated on the successful recruitment and training of CHWs. Based on the experience of the investigative team, we felt that to be effective, CHWs would need to have experience with the behaviors that they would be asked to lead in the lifestyle intervention. Therefore, we recruited patients with Type 2 diabetes with experience in group leadership, well-controlled HbA1c, and a history of healthy eating, physical activity, and weight loss to be CHWs. CHWs were identified and recruited through local Diabetes Care Centers and clinics through direct contact by study investigators and staff.

The CHWs are responsible for conducting the intervention group sessions, managing their group participants, and data entry of participant body weights obtained at each group session. Each CHW is responsible for 1 group during the intensive phase (1 meeting/wk) of the intervention. Interested CHWs were then assigned a new group when his/her group transitions to the maintenance phase (1 meeting/mo). Therefore, each CHW is ultimately responsible for 1 group in the intensive phase and 1 group in the maintenance phase. CHWs are compensated $100/wk for their participation in the intensive phase and $200/mo in the maintenance phase.

The CHW training program consisted of a 36 hour program over the course of 6-9 weeks of experiential learning, didactic instruction, peer mentoring, and observation. Ten CHW's were trained in two groups of 5; one group prior to the start of the study and another group 4 months into participant recruitment. We felt that experiential learning would be the most efficient and powerful method for training CHWs. Therefore, CHWs participated in an accelerated and abridged form of the intensive phase of the group lifestyle intervention in which they self-monitored calories and physical activity, tracked weight, and participated in group sessions. Since the intensive phase of the Lifestyle Intervention actually consists of 24 sessions (see below), 2-3 intervention sessions were presented at each training session (2 training sessions/ week). The first session was conducted as an actual intervention session and the second and third sessions of the training session were presented in didactic format. Therefore, the CHWs experienced all of the lifestyle intervention group sessions. Additionally, willing CHWs also participated in baseline and close-out data collection similar to what study participants experience. This provided valuable firsthand knowledge of study participation as well as provided data on changes experienced during CHW participation. These visits were not

considered mandatory for participation in the CHW program and were done strictly on a voluntary basis.

The CHW training program also consisted of didactic instruction on a) study protocol; b) intervention philosophy, goals, and procedures; c) weight loss (energy balance); d) physical activity basics; e) nutrition basics; f) group facilitation; g) cognitive-behavioral principles; h) participant monitoring and tool box methods; and i) data entry. The training program concluded with the study investigators observing each CHW conduct a mock group as part of a formal certification process, with the other CHWs and RDs serving as group members. The CHW Monitoring Board Chair and the RDs rated the CHWs' performance on a criterion-based assessment of (a) group facilitation skills, (b) knowledge regarding the intervention protocol and use of the treatment manual, and (c) competence in completing requisite forms. CHWs were also provided feedback and coaching based on their performance.

In light of the group-based nature of the intervention and recruitment rates, we were able to start approximately one group per month during recruitment. Therefore, CHWs experienced a gap of 1-5 months between training and the start of an intervention group. This time lag allowed us to utilize a peer mentoring model in preparing CHWs. Upon completion of the training program, CHWs were paired and assigned to a group of study participants. One CHW served as the group facilitator and the other served as an observer. The second CHW assisted with the facilitation of the group until a sufficient number of randomized participants had been accumulated and was then assigned as the facilitator of that group. Additionally, the second group of CHWs was paired with an existing intervention group until a group was ready to begin the intervention. The RDs observed each CHW conduct their first 4 sessions and provided feedback and coaching.

3.8. Lifestyle Intervention

The lifestyle intervention in HELP PD is designed to translate the DPP Lifestyle Intervention for use in the community and it's theoretical basis has evolved from research on social cognitive theory (SCT), group dynamics, and problem-solving. Weight loss and fitness improvement achieved through a combination of changing eating and physical activity behaviors is determined by the interaction of personal factors (e.g., beliefs and values), social influences (e.g., support and strain), and the physical environment (e.g., structure and access to resources). Social cognitive constructs explicitly targeted in HELP PD include self-efficacy, outcome expectations, and incentives. The intervention involves a dietary weight loss program (1200-1800 kcal/day) and an increase in caloric expenditure through moderate physical activity (≥180 min/wk). The primary treatment objectives for the weight loss component of the intervention is to decrease caloric intake in a nutritionally sound manner so as to produce a weight loss of approximately 0.3 kg per week for the first 6-months of treatment (Phase 1) for a total weight loss of 5-7%. During Phase 2 (months 7-24) participants will be encouraged to continue to meet their weight loss goals as long as their BMI does not fall below 20 kg/m^2, but the primary focus will be on weight maintenance. Our approach is consistent with the recent recommendations of the American Diabetes Association, the North American Association for the Study of Obesity and the American Society for Clinical Nutrition [30].

3.8.1. Contact Schedule—During Phase 1 (months 1-6) participants will meet weekly for group sessions. All sessions will be coordinated and facilitated by the CHW. In addition, all participants receive three personalized consultations with an RD (during months 1, 3, and 6). The group sessions consist of 8-12 participants and are conducted at community sites (e.g., recreation centers, libraries, schools or churches) with arrangements facilitated by the HELP PD investigative team. During Phase 2 (months 7-24), participants have 2 scheduled contacts

with the CHW each month, one group session and one phone contact. The contact schedule and objectives for Phases 1 and 2 are summarized in Table 2.

3.8.2. Content—A treatment manual developed by the HELP PD Intervention Committee using the basic principles of DPP contain a session-by-session intervention plan including: specific objectives for each meeting; particular methods to accomplish the objectives; and illustrative handouts for the participants. All participant materials were designed to read at the sixth grade level. Additionally, to minimize the burden of specialized scientific knowledge in each of the core content areas on the CHWs, we include presentations from local community experts (e.g., representatives from the YMCA, local grocery store) and a DVD series, developed by the research team, to deliver core content. We developed a 13 DVD series covering core content such as a) nutrition and physical activity basics, b) energy balance, c) healthy eating, d) goal setting, and e) problem solving (see Table 3 for session content and schedule). CHWs were also provided with a "toolkit" of relevant handouts and resources (e.g., examples of household items to represent portion size, samples of meal replacement products, coupons for local athletic stores) to be used during group sessions.

The continuous care problem-solving model is a cornerstone of this intervention. The assumption underlying this approach is that problems are a normal part of weight loss and that solutions must be tailored to each individual. This procedure involves 5 steps: (1) problem orientation, (2) problem definition and formulation, (3) generation of alternatives, (4) systematic decision making, and (5) implementation and verification. Continuous care in the maintenance phase occurs through both group sessions and CHW telephone contacts. The purpose of the telephone contact is threefold: first to prompt or cue the participant to continue active use of key diet- and activity-management strategies; second to use problem-solving counseling to identify barriers to successful diet and activity behaviors and to generate a plan to overcome problems encountered by the participant; and third, to provide support and reinforcement for continued efforts at behavioral management. The CHWs were trained in a specific protocol for conducting telephone contacts.

3.8.3. Tracking progress—The success of this intervention is dependent, in part, on our ability to monitor the fidelity of intervention delivery. We monitor and track the following: a) adherence to CHW-led group meetings and make-up sessions, b) weight at all sessions, c) self-monitoring data from the participants concerning dietary intake and physical activity behaviors, and d) completion of phone contacts during the maintenance phase of the study. The two RDs supervise the CHWs and provide graphical and verbal feedback that can be shared with participants in HELP PD. In addition, the CHW Monitoring Board functions as a working group of the Intervention Committee to provide ongoing support and to monitor the activities of the CHWs, thereby providing additional access to expertise in the exercise, nutrition and behavioral sciences on an ongoing basis. Furthermore, we have monthly meetings with the CHWs to discuss intervention implementation and participant progress in order to maintain consistency across CHWs. Our real-time web-based data reporting system enables us to monitor intervention delivery by the CHWs, as reflected by participant attendance, adherence measures, and, eventually, outcomes.

3.9. Usual care

A comparison group is essential for a study translating from efficacy to effectiveness. Our comparison intervention condition is designed to exceed the usual care provided to similar community members and to enhance retention. Our comparison intervention is an individual education program that builds on an increased awareness of existing community resources. Comparison participants receive two individual sessions with a nutritionist during the first 3 months. In these sessions, the nutritionist covers basic aspects of healthy eating and activity

to support weight loss, and discuss existing community resources that may fit the individual needs of comparison participants as they pursue dietary change, increased physical activity and weight loss. In addition, comparison participants receive a quarterly newsletter with topics related to healthy lifestyle.

3.10. Data Analysis

Aim 1: Glucose and Insulin Metabolism – Primary, Secondary and Tertiary Outcomes—The primary hypothesis for the trial involves evaluating the mean difference in changes in fasting glucose levels from baseline among participants who have been assigned to the intensive lifestyle intervention versus the educational intervention. We will use general linear models to compare changes (collected across the planned visits at 6, 12, 18, and 24 months) that address intra-individual correlations. This approach, rather than examining differences at a pre-selected time point (e.g. 2 years), accommodates interim testing and allows participants with incomplete patterns of follow-up exams to contribute to the analysis and evaluation. We will include all participants, regardless of adherence, in the primary comparison (adopting the intention-to-treat approach); inference for this primary comparison will be two-sided, with significance level alpha = 0.05. Indicators for visit will be included in models to control for systematic temporal differences that may occur that are common to both intervention conditions. Random effects terms will be used to model differences among individuals nested within intervention conditions because these have been shown to yield inferences of more appropriate size than fixed effect models.[31]. Compound symmetry models will be used for intra-subject longitudinal covariances (although we will explore, through likelihood ratio tests, the fit of other models); models will be fitted via maximum likelihood.[32] The primary comparison will be based on a Wald statistic. We will not include additional covariates or stratification in the primary comparison (as this is not recommended for trials of this size);[33] however, we will describe any chance differences between cohorts and, in supporting analyses, covary comparisons on any baseline factors that appear to be unbalanced.

Secondary and Tertiary Analyses—HELP Prevent Diabetes includes secondary outcomes related to establishing whether assignment to its lifestyle intervention compared with the educational intervention influences: physical activity, dietary intake, weight, and waist circumference. Tertiary outcomes will include measures of insulin, the homeostasis model of insulin resistance, triglycerides, HDL-C, blood pressure, the metabolic syndrome, health related quality of life and behavioral constructs. We will also monitor for safety by tracking incidence of DM and serious adverse events. Results from these analyses will be clearly described as secondary and tertiary objectives: the over-riding evaluation of the effectiveness of the lifestyle intervention will be based on fasting glucose.

Diabetes will be defined using ADA criteria (i.e., fasting glucose ≥ 126 mg/dl).[34] Incident metabolic syndrome will be defined according to the NCEP criteria [35], modified to use FBG 100-125 to define IFG, among those without the syndrome at baseline. The distribution of times until the development of DM and the metabolic syndrome (measured from the date of randomization to the date of the clinical visit or report triggering the diagnosis) will be described using Kaplan-Meier plots [36], with censoring taken to occur at the time of the last contact with participants. Logrank tests will serve as the primary comparisons between intervention groups. Proportional hazards regression will be used to compute hazard ratios and 95% confidence intervals for participant subgroups and to identify predictors of endpoints.[37] The assumption of proportionality for the hazards will be assessed using residual plots; stratification will be used if this assumption is not met.

Aim 2: Costs and Cost-Effectiveness—To address Aim 2, we will perform cost analysis, cost-effectiveness analysis (CEA) and cost utility analysis (CUA) over the study period from

two separate perspectives: the perspective of a third party payer and that of society. In cost analysis we will estimate total cost, average cost, and incremental cost. Total cost will be calculated by multiplying the unit cost by the number of units for each resource in the study period. Average cost will be calculated by dividing the total cost by the number of participants in each group. Incremental cost will be calculated as the difference in average cost per participant between the intensive lifestyle intervention group and the comparison group. All costs will be adjusted to constant US dollars by the Consumer Price Index (CPI). In CEA, we will calculate incremental cost effectiveness ratios as the cost per net participant whose fasting glucose measure improved. In CUA, we will use the HUI instrument and calculate incremental cost utility ratios as the cost per net health related quality-adjusted life year (QALY) gained. The incremental CEA and CUA ratios are point estimates. A bootstrap method will be used to estimate confidence intervals for incremental cost-effectiveness ratios [38;39]. We will also calculate the cost-effectiveness (utility) acceptability curve to determine the probability of the observed incremental CEA and CUA ratios below all possible thresholds [40]. The cost-effectiveness curve informs the policy maker, for a given threshold, the probability that the alternative intervention is cost-effective. In addition, sensitivity analyses will be performed in order to examine effects of key parameters on the incremental cost-effectiveness ratios.

Aim 3: Examination of Moderating and Mediating Factors—The final aim is designed to explore whether the intervention works equally well for all participants and whether there are changes in theoretically meaningful constructs from behavior change theory that explain why the intervention was effective in improving participants' status on the primary outcome. In other words, we will address the following questions: 1) for whom was the intervention effective and 2) do the cognitive behavioral constructs mediate the behavior change. We will use regression models with potential moderators as covariates to examine their role by incorporating interaction terms in models. Specifically, we will examine the role of ethnicity, age, gender, and comorbidities as potential moderators of the intervention effects on outcomes of interest to determine whether the intervention appears to work equally well across these subgroups. As described by Kraemer, et al. [41;42] the general analytical approach to mediators will be to use regression models to examine relationships between the proximal variable and the potential mediator, and between the potential mediator and the distal variable. Ultimately, models are used to estimate the proportion of the association between the proximal and distal variables that can be attributed to the potential mediator. First, we will test the effects of the intervention on the outcomes of interest (e.g., fasting glucose). Step 2 will be to examine whether effects on outcomes are mediated by our proposed biological impact measures (weight, waist circumference and fasting glucose). Step 3 will involve examining whether effects on biologic impact measures are mediated by changes in behaviors (diet and activity), and step 4 will involve examining whether effects on behaviors are mediated by changes in social cognitive variables.

3.11. Sample size and power

HELP PD targeted the recruitment and follow-up of 300 participants. Based on a longitudinal correlation of r = 0.20, this sample was projected to provide 94% power to detect a net intervention effect of 3.5 mg/dL (two-sided alpha of 0.05) and 86% power to detect an effect size of 3 mg/dL. These estimates include allowance for a 5% loss to follow-up rate every 6 months.

3.12. Data Quality

A study data management team consisting of computer programmers and biostatisticians are responsible for data quality. All data is recorded on paper forms and entered into a web-based database. The study interventionists and clinic coordinators review completed forms for accuracy and completeness. During data entry, key variables are checked for accuracy with

the assigned range checks. Within our interactive data edit system, a review is required for any data entered outside of preset ranges.

3.13. Participant Safety

The risk to participants is modest, consisting primarily of the risk of increased moderate physical activity. Adoption of a vigorous activity regimen can increase the risk of cardiovascular events in previously sedentary individuals; hence, we focus on adoption of moderate physical activity, a much less risky behavior change. We encourage participants to adopt brisk walking as the foundation of their activity program and we educate participants about the potential risks of increased activity, including the signs and symptoms of angina and heart attack. We inform participants that some healthcare providers might recommend a cardiac evaluation (e.g., treadmill testing) prior to adopting a physical activity regimen, and we encourage potential participants to discuss this issue with their healthcare provider. However, we do not conduct treadmill testing as part of the eligibility process. Potential participants are screened using the PAR-Q and positive screens are evaluated by the study Medical Director prior to randomization. Additionally, potential participants are asked to discuss participation with their usual care physician. We have developed an informational brochure about HELP PD so that potential participants can review and obtain medical clearance from their usual care physician. If the potential participant does not have a physician, we refer him/her to a source of care in the community.

The other minor risks include risks associated with phlebotomy and confidentiality concerns. Phlebotomy carries a small risk of vasovagal syncope (fainting), hematoma formation and phlebotomy site infection. Great care will be taken to minimize the likelihood of these risks through the use of trained professional phlebotomists. The blood volume obtained at any phlebotomy visit is minimal, consisting of approximately 20 ml (5 ml for glucose and insulin, 5 ml for lipids and 10 ml for long term storage).

As this study has been classified as research that involves a minor increase over minimal risk, an independent study safety officer and the General Clinical Research Center (GCRC) Research Subject Advocate Office (as part of the GCRC Human Subjects Protection Committee) are being used to monitor trial progress and participant safety. Additionally, the principal investigator reviews the safety and progress of this study on an ongoing basis. Progress reports, including patient recruitment, retention, and adverse events are provided to the safety officer and GCRC on a monthly basis. The purpose of these reports is for the safety officer and the GCRC Research Subject Advocate Office to assess the trial progress with respect to intervention efficacy for possible decisions regarding early termination of the study. Information regarding adverse events and copies of these reports are also provided to the Wake Forest School of Medicine (WFUSM) IRB. All hospitalizations are monitored, as well as potential adverse effects of the intervention specific to physical exercise, primarily injuries and orthopedic conditions. All adverse events are recorded on standardized adverse event reporting forms, including action taken. All events are reviewed by the study safety officer and classified according to severity and possible association with the study intervention. Serious adverse events (SAEs) that are unanticipated or possibly related to the study intervention are reported to the safety officer, IRB, GCRC, and NIDDK within fifteen calendar days. Anticipated SAEs or those unrelated to the study intervention are reported to the same individuals/entities on a monthly basis.

4. Study Management

The Help PD Trial is conducted by a unique and multi-disciplinary team, including trialists, epidemiologists, internists, nutritionists, exercise physiologists, behavioral scientists, biostatisticians and economists to develop the protocol and interventional components of this

study. A companion Manual of Operations and Intervention Manual provides specific operational details of the project for all study personnel. The study is managed through several committees with distinct roles and responsibilities: Steering, Intervention, CHW Monitoring Working Group, Recruitment and Retention, Design and Analysis, and Operations

5. Discussion

Although diabetes-related mortality has declined in recent years, the continued rise in prevalence and incidence has resulted in increases in the overall public health burden and highlights the need for effective diabetes prevention interventions [4;7;8;43]. While the DPP provided compelling evidence that weight loss achieved through lifestyle behavioral interventions can decrease the risk of diabetes incidence in individuals at high risk for diabetes, additional research is needed to determine whether this approach can be effectively translated into a community-based, cost-effective, and sustainable model.

Several efforts to translate the DPP have recently been published. The DEPLOY study [10; 44] partnered with local YMCAs to translate the DPP for use in the community. Similar to the present study, this study used a group-based modification of the DPP program; however, trained YMCA wellness staff, as opposed to community health workers, delivered the intervention. Boltri and colleagues [12] translated the DPP program through an African-American church and used volunteer medical personnel to deliver the intervention. McTigue and colleagues delivered a group-based DPP via a large academic hospital [13]. The Montana Cardiovascular Disease and Diabetes Prevention Program [14] utilized a variety of community-health care facility partnerships (e.g., hospital, YMCA) across diverse urban and frontier communities to deliver a group-based modification of the 16-week core DPP intervention. Additionally, the intervention staff were dietitians and health professionals. Estabrooks and colleagues attempted to deliver the DPP via an automated telephone system [11]. Comparisons across studies are difficult due to a) the diverse methods and translational approaches; b) limited available outcome data; and c) relatively short-term follow up. In general, these approaches have shown to be successful in producing short-term, clinically significant weight loss, but it is unknown at this time whether they are effective at preventing diabetes, the effects are sustainable, or whether they are more cost-effective as compared to the DPP.

Although not a translation of the DPP, the PATHWAYS study should also be noted [45]. This study delivered a group-based, 14-week weight loss program aimed at diabetes prevention for African-American women at risk for diabetes (n = 39) delivered through churches and led by lay health facilitators. Participants in the weight loss group (n = 15) lost an average of 5% of their baseline weight following treatment. Information on changes in other metabolic and cardiovascular changes was not provided. Although this study demonstrates the efficacy of lay health facilitators in delivering a weight loss intervention, the small sample size and short term follow-up precludes meaningful conclusions regarding large-scale effectiveness.

We believe we have made several unique and important modifications to the DPP to enhance translation and dissemination. First, the overarching goal of the present study is to test a translation of the DPP that is completely administered, implemented, and delivered via existing community resources. The program is administered by an existing DCC and delivered by CHWs. Furthermore, the DCC staff was responsible for CHW training, the on-going supervision of the CHWs, and continuous participant management. Study-specific staff focus on research-specific activities (e.g., recruiting, outcome assessments) and contact with the intervention occurs via DCC staff. Thus, to maximize translation, we are seeking to minimize the contributions of research resources (e.g., research staff, investigators) and maximize the responsibilities of community-based staff (i.e., DCC, CHWs). We seek to create a translational

model that can be generalized and implemented in any community with a DCC with minimal influence of the research-specific resources, staff, and investigators.

Second, placing community-based diabetes prevention programs in existing Diabetes Education Programs (DEPs) provides a rapid dissemination channel. DCCs and DEPs already exist in many communities and include staff with most of the skills needed to implement the proposed DPP model. Furthermore, DEPs have access to patients with diabetes mellitus (DM) who have made successful lifestyle changes, and who could be effective CHWs.

It should be noted, however, that our intervention is in some ways more intensive than the original DPP and the aforementioned translational studies. That is, whereas the DPP involved a 16-week core curriculum and monthly maintenance contacts (either in-person or via telephone), we use a 24-week intensive phase and monthly group and telephone contacts for an additional 18 months. However, the DPP also involved supervised, center-based physical activity sessions (2 times per week). The present study does not include supervised physical activity sessions. Although the physical activity sessions provided in the DPP were voluntary, they certainly added to overall consumption of resources and additional participants contacts. We hope to determine whether these differences influence our program effectiveness and costs.

Our partnership with an established diabetes care organization also provides us with widespread potential for dissemination via diabetes professional organizations. The CHW identification and training modules we have developed can be disseminated through the American Association of Diabetes Educators (AADE) to address gaps in the knowledge and skills of diabetes educators, especially the process of identifying, recruiting, training, supporting and monitoring CHWs. The AADE can also disseminate our CHW support materials, including the videos. The use of a group-based, rather than an individual-based, intervention reduces the cost of intervention delivery. If this modified approach is successful, the lower cost will enhance dissemination as well. Use of fasting glucose and body mass index, rather than results from an oral glucose tolerance test, to identify persons eligible for the community-based DPP represents another translation- and dissemination-friendly modification. All of our materials can be disseminated easily through web-based methods and other strategies in partnership with the AADE, the National Diabetes Education Program, and other partners. Successful dissemination will be dependent on changes in reimbursement policies for the services provided. Reimbursement for diabetes education provides a useful model for application to the proposed community-based diabetes prevention education program, as this reimbursement covers a limited number of individual sessions and a greater number of group sessions.

This project will provide critical information regarding the effectiveness of a community-based, intensive behavioral intervention for the prevention of type 2 DM, including metabolic and behavioral outcomes, and cost. If the proposed approach is cost-effective, this information would support the development of health care policies to provide for the reimbursement of community-based diabetes prevention program services, thereby enabling the rapid dissemination of this model to the thousands of communities with DEPs in the US. Because many chronic diseases are influenced by activity and diet, this approach should translate into public health benefits in areas other than type 2 DM, such as obesity, hypertension, cardiovascular health and cancer prevention, thus greatly multiplying the potential benefits for society and serving as a model for community-based health promotion programs.

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Table 1

Eligibility Criteria

Inclusion Criteria	
Demographics	Adults 21 years of age and older who reside or work in Forsyth County, NC.
English Proficiency	Able to read/understand English at or above a level sufficient to comprehend recruitment and intervention materials
BMI	25 kg/m^2 ≤ BMI < 40 kg/m^2
Fasting Blood Glucose	95 mg/dL ≤ FBG ≤ 125 mg/dL following at least an 8-hour fast
Exclusion Criteria	
Weight Loss	Currently involved in a supervised program for weight loss
Diabetes	Clinical history of DM, or newly diagnosed DM at screening
Recent History of CVD	Clinical history of cardiovascular disease (CVD) occurring within the past 6 months, including myocardial infarction, angina, coronary revascularization, stroke, TIA, carotid revascularization, peripheral arterial disease, and congestive heart failure.
Hypertension	Uncontrolled high blood pressure: BP ≥ 160/100
Pregnancy	Pregnancy, breast feeding, or planning pregnancy within 2 years
Medication	Chronic use of medicine known to significantly affect glucose metabolism, e.g., corticosteroids
Other Chronic Conditions	Other chronic disease likely to limit lifespan to less than 2-3 years, including any cancer requiring treatment in past 5 years except non-melanoma skin cancer
Other	Criteria likely to interfere with participation and acceptance of randomized assignment, including the following an inability or unwillingness to give informed consent or accept randomization assignment, another household member already randomized to HELP PD, major psychiatric or cognitive problems, and participation in another research study that would interfere with HELP PD

Note: BMI = body mass index; FBG = fasting blood glucose; BP = blood pressure; DM = diabetes mellitus; TIA = transient ischemic attack

Table 2

Contact Schedule for the Lifestyle Intervention

Phase	Contact Schedule	Objectives
PHASE 1 Initial Lifestyle Intervention (Months 1-6)	Weekly CHW-led group meetings, with content delivered via DVD series or by community experts Individual RD sessions in months 1, 3, and 6; Session 1 to occur prior to 1st CHW lead group meeting	Knowledge: relation of body weight and fitness to disease and health; benefits of weight loss; basics of energy balance and nutrition; appropriate methods for weight loss methods and increasing physical activity; exercise precautions Diet: reduction of intake by 500-1000 kcal per day; reduction in total fats to 25-30%, saturated fats to 7%, and protein to 15% of intake; increase in fruit and vegetable consumption to 5 servings per day; intake of ≥ 3 whole grain servings per day Physical activity: gradual progression to 180 minutes of moderate intensity exercise per week (e.g., 30 min/day of walking, 6 days/week) Behavioral skills: self-monitoring, goal-setting, self-reinforcement, stimulus control, social support, cognitive restructuring Material: core content delivered through DVD videos and community experts
PHASE 2 Extended Care Intervention (Month 7-24)	2 contacts per month (one with the CHW-led group and one by telephone with the CHW)	Knowledge: proper methods for weight maintenance; appropriate levels of activity, caloric intake and sound nutrition for maintenance of stable weight Diet: isocaloric intake tailored to maintenance of lost weight; maintenance of 25-30% energy intake from total fats, 7% from saturated fat, and 15% from protein; continued daily intake of 5 fruits and vegetables and ≥ 3 whole grain servings Physical activity: maintenance of 180 min of moderate intensity exercise per week; coping with injuries and other barriers to the maintenance of exercise Behavioral skills: ongoing or intermittent self-monitoring of weight and habit changes; anticipating/avoiding obstacles to maintenance; coping with setbacks/lapses; building social support for maintenance; developing self reliance skills for long-term weight management

Table 3

Phase 1 Lifestyle Intervention Session Schedule

Session #	Session Title	Content Delivery[1]
1	Welcome to HELP PD*	CHW & Study team
2	Nutrition 101*	CHW & DVD-Nutrition 101
3	Physical Activity 101*	CHW & DVD-Physical Activity 101
4	Footwear*	CHW & Community expert
5	Troubleshooting/Q&A*	CHW & TRIP RD
6	Calorie Balance	CHW & DVD-Tipping the Calorie Balance
7	Mindfulness	CHW & DVD-Mindfulness
8	Portion Sizes	CHW & DVD-Tips for controlling portion size
9	Troubleshooting/Q&A	CHW & RD
10	Community Exercise/Nutrition Resources	CHW & Community expert
11	Problem Solving	CHW & DVD- Healthy approaches to solve problems
12	Physical Activity Hands On	CHW & DVD-Physical activity and Weight Loss
13	Troubleshooting/Q&A	CHW & RD
14	Emotions and You	CHW & DVD-The ABCs of Emotions and Weight Loss
15	Healthy Eating	CHW & DVD-Healthy Eating
16	Stretching/Injury Prevention/Strength Training	CHW & Community expert
17	Troubleshooting/Q&A	CHW & RD
18	More about Healthy Eating	CHW & DVD-More about Healthy Eating
19	Food shopping/eating out	CHW & Community expert
20	Creating an Environment for Success	CHW & DVD-Creating an Environment for Success
21	Troubleshooting/Q&A	CHW & RD
22	Wt. loss maintenance	CHW
23	Q&A/Preparation for Independence	CHW & RD
24	Transition*	CHW & Study team

Note:

* = Study team member(s) attend sessions;

1 = All sessions are led by a Community Health Worker (CHW) and content will be delivered via the mechanism indicated; Q&A = Questions and Answers