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Healthy Living Partnerships to Prevent Diabetes: Recruitment and Baseline Characteristics

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Abstract

Healthy Living Partnerships to Prevent Diabetes (HELP PD) is a randomized controlled trial designed to translate the Diabetes Prevention Program (DPP) lifestyle intervention into a community setting using community health workers engaged through an existing Diabetes Care Center (DCC). Overweight and obese (BMI 25-40 kg/m²) individuals with pre-diabetes (fasting blood glucose 95-125 mg/dl) with no medical contraindications to participate in a lifestyle intervention were recruited for participation in this study. Standard recruitment strategies were employed, including mass mailing, direct provider referral, and community events. Participant recruitment and randomization for this trial began in 2007 and was concluded in 2009. 1818 screenings were conducted; of these, 326 (17.9%) qualified and 301 (16.6%) participants were randomized over a 21 month period. 23.8% of potential participants were excluded during the initial telephone screening, primarily for BMI and recent history of CVD. The majority of participants (220, 73.1%) reported mass mailing as their primary source of information about the study. Mass mailing was more effective with participants who identified themselves as white when compared to African Americans. The cost of recruitment per randomized participant was \$816, which includes direct costs and staff effort. 41% of the randomized participants were male and approximately 27% reported a race or ethnicity other than white. In comparison to the DPP study cohort, the HELP PD population is older, more educated and predominately white. These differences, reflecting in part the community in which HELP PD was conducted, may have implications for retention and adherence in the lifestyle intervention group.

Keywords

Translational research; randomized controlled trial; recruitment; screening; lifestyle

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INTRODUCTION

Type 2 diabetes mellitus is a major health concern in the United States, accounting for 90 to 95% of the more than 23 million diagnosed cases of diabetes in 2007 [1]. Estimated healthcare expenditure in the United States for persons with diabetes could rise above 197 billion dollars in 2010 [2], making it one of the costliest chronic diseases. Large-scale clinical trials have demonstrated that lifestyle interventions focused on weight loss, physical activity and nutrition can prevent or delay the onset of diabetes mellitus [3,4]. The Diabetes Prevention Program (DPP), using a behavioral lifestyle intervention implemented by professional case managers with training in nutrition, exercise, or behavioral modification in an individual setting, demonstrated a reduction in the incidence of diabetes in the lifestyle treatment group of 58% compared to the control group [3,5]. The Finnish Diabetes Prevention Study (FDPS) also reported a 58% reduction in the relative risk of diabetes using an individual behavioral intervention focused on weight loss, reduction in fat intake, and increased fiber intake and physical activity implemented by dietitians, physicians, and nurses [4,6]. Although these studies have achieved promising results, there is a need to enhance the logistical and fiscal feasibility and long term potential for dissemination of these interventions. The Healthy Living Partnerships to Prevent Diabetes (HELP PD) study was designed to translate the results of the DPP into a community-based model, implementing a group-based lifestyle intervention led by trained community health workers (CHWs) implemented at an existing Diabetes Care Center (DCC).

The few previous studies designed to translate the DPP and FDPS into community settings have enrolled participants through existing primary care networks, cardiac rehabilitation programs, and workplace programs; hence, there is limited evidence on the recruitment of adults at risk for type 2 diabetes into a community-based prevention program [7-14]. The DPP was able to enroll 3819 participants in 35 months using a mixture of recruitment strategies including direct mail, print, television and radio advertising, provider and participant referral, and worksite and community screenings. However, the total cost of recruitment exceeded four million dollars, well over \$1000 per participants, excluding staff and coordinating center costs [15]. The need exists to identify cost-effective strategies to recruit participants for community-based disseminations of the DPP.

This paper describes 1) the development and implementation of a recruitment plan appropriate for a translational study of diabetes prevention, 2) the cost and relative effectiveness of specific recruitment strategies, 3) the distribution of excluded potential participants, and 4) the baseline characteristics of the HELP PD cohort compared to the DPP participants and a representative sample of persons with pre-diabetes from the National Health and Nutrition Examination Survey (NHANES). These results should aid interpretation of the results of HELP PD and assist in planning for dissemination, if successful.

METHODS

Design of the HELP Prevent Diabetes Study

The design and rationale of HELP PD have been published elsewhere [16]. Briefly, adults at high risk for developing diabetes mellitus were randomized into two treatment groups, a lifestyle intervention and an enhanced usual care comparison condition. The HELP PD intervention was modeled after the intensive intervention used in DPP and designed to elicit modest weight loss of 5-7% through a reduction in caloric intake and an increase in moderate intensity physical activity. Participants in the intervention group were placed in groups of 8-12 led by trained community health workers who were supervised by two dietitians. These supervising dietitians were Certified Diabetes Educators and had access to

exercise and behavioral experts. The intervention groups met weekly during a 6-month intensive phase and monthly during the ensuing 18-month maintenance phase. Participants randomized to the comparison condition received monthly newsletters and two individual sessions with a nutritionist during the first six months of the study. Participants in both treatment groups were seen at six-month intervals over a 24-month period to assess cardiovascular risk factors, health-related quality of life, social cognitive variables, healthcare utilization and cost. The primary outcome was change in fasting glucose; additional outcomes included physical activity, dietary intake, weight, waist circumference, metabolic syndrome status, insulin, the homeostasis model index of insulin resistance, triglycerides, high-density lipoprotein cholesterol (HDL-C), blood pressure, and health-related quality of life. Cost effectiveness of the lifestyle intervention was also examined.

The recruitment goals for HELP PD were to randomize 300 adults, aged 21 and older, who lived or worked in Forsyth County, NC over a 2-year period. This sample size was needed to provide reasonable power to detect the desired intervention effect while accounting for those participants who would likely become lost to follow-up. Other recruitment objectives were to recruit at least 50% women and a percentage of minorities equivalent to their representation in the population of the area, approximately 30%. Our recruitment goals were chosen to adhere to the policy on inclusion of women developed by the National Institutes of Health. In addition to attempting to include at least 50% women, we had a secondary goal of including at least 40% men to ensure adequate representation of both sexes.

Eligibility Criteria

The eligibility criteria for HELP PD were designed with a focus on prevention and translation; hence, inclusion and exclusion criteria were chosen to target a sample that was representative of the local community and at high risk of diabetes mellitus with no major contraindications for participation in a weight-loss/lifestyle intervention. As such, participants were required to have evidence of pre-diabetes on at least two occasions. An initial qualifying glucose value could be collected in any of the following ways: an elevated fasting glucose between 95-125 mg/dl collected during the previous 3 months at the usual source of care, a non-fasting glucose between 120-199 mg/dl collected at a study information session, or a fasting glucose between 95-125 mg/dl collected at the General Clinical Research Center (GCRC) during a study screening visit. All participants were required to have an additional confirmatory fasting blood glucose between 95-125 mg/dl collected during a screening visit at the GCRC. The glucose range was originally 100-125 mg/dl inclusive based on the definition of pre-diabetes put forth by the American Diabetes Association, but was changed in month 4 of recruitment to better reflect the criteria for fasting glucose used in DPP [17]. Participants were also required to have a Body Mass Index (BMI) of at least 25.0 kg/m² but no more than 39.9 kg/m², as current recommendations indicate that intensive weight loss management should be provided to persons with BMI greater than 40 kg/m², including consideration of bariatric surgery. A comprehensive list of all inclusion and exclusion criteria can be found in Table 1.

Identification of participants

Potential participants were identified using a variety of approaches as appropriate for this community-based translational study, including referrals from primary care clinics, community and worksite screenings organized by the study team, and community-based recruitment via mass mailing and group presentations to community and civic groups. In order for participants to begin an intervention group within one month of randomization, weekly recruitment goals were set at 20-30 participants at study information sessions and 3-5 participants qualifying for randomization to allow for the formation of one intervention

group every four to six weeks. These goals were flexible to coincide with the availability of community health workers to begin groups, holiday periods, and other time constraints.

Initial recruitment efforts were centered on strategies that offered the greatest potential yield of participants. Mass mailings to selected zip codes were distributed through the marketing division of a local newspaper on a weekly basis. The number of pieces mailed was variable (500-2000/week) depending on previous recruitment yields and progress towards goals. Throughout the recruitment period, addresses in each zip code received 2-5 mailings, depending on the size of the population for that zip code and the previous yield. The Volunteers In Touch with Aging and Life (VITAL) database of persons interested in participating in clinical studies, maintained by the Claude Pepper Older Americans Independence Center of Wake Forest University Baptist Medical Center, was also used to generate two mailings. Mailings distributed through both the local newspaper and the Pepper Center were printed, stuffed, and mailed by those organizations. Letters were also mailed to former participants from another lifestyle study who had expressed an interest in future contact, leaders of a local organization of churches, and faculty and staff at a local community college. These mailings were prepared by the study team. Similarly, study fliers were distributed to all department locations of Wake Forest University Baptist Medical Center and the Reynolda Campus of Wake Forest University for display. Team members regularly attended community health fairs and screenings and conducted worksite recruitment presentations. Additionally, fliers and posters were developed and distributed to interested local physicians and used to refer potential participants for screening. During the last four months of recruitment, a direct referral system was implemented at the Downtown Health Plaza of North Carolina Baptist Hospital, a community-based outpatient practice serving a socioeconomically disadvantaged population, wherein interested patients seen in clinic could be introduced to a study team member and screened on location. This system was developed to increase the number of African-American males screened for participation. No print, radio, or television advertisements were used in the recruitment process for this study. All brochures, posters, fliers, and recruitment letters directed interested potential participants to contact a local study phone number for screening. All recruitment materials were reviewed and approved by the Institutional Review Board of Wake Forest University Health Sciences.

Screening

A tiered screening process was developed to maximize the efficiency of screening. Interested prospective participants contacted study recruitment staff and were provided information about the study before being telephone screened. During this contact, age, self-reported body mass index, medical history including diagnosis of diabetes and other chronic diseases and history of hospitalization for psychiatric or cognitive issues, participation in other supervised weight loss programs or research trials, and use of medicine known to significantly affect glucose metabolism were assessed. On average, the telephone screening took ten to twenty minutes to complete.

Those subjects that were potentially eligible at the conclusion of the telephone screening were invited to a study information session. This session featured a professionally developed video that described all aspects of study participation and allowed for an interactive question and answer session, followed by the informed consent process. These information sessions usually had 10-15 potential participants and were approximately one hour in duration. A glucometer was used to assess a non-fasting blood sample, blood pressure was measured, and the Physical Activity Readiness Questionnaire (PAR-Q) was administered. As clinic space and staff time were limited, potential participants were triaged based on their non-fasting glucose values and scheduled for clinic visits according to likelihood of qualifying for randomization. All those whose non-fasting glucose was above 85 mg/dl and who met

the other eligibility criteria were automatically scheduled for a clinic screening visit, while those whose non-fasting glucose was below 85 mg/dl were initially deferred from clinic screening unless there was a history of impaired fasting glucose or diagnosis of pre-diabetes to increase the likelihood of subsequent qualification. These potential participants could continue the recruitment process at a later time if clinic space and recruitment flow allowed.

At each clinic screening visit in the GCRC, body mass index, blood pressure, fasting glucose, and depression score were assessed to determine final eligibility. Depression was assessed using the Beck Depression Inventory II [18]. Participants were excluded for scores corresponding to moderate and severe depression, and were required to obtain clearance prior to randomization if scores fell in the mild depression range. For those participants who needed a second glucose value to qualify for randomization, a second clinic screening visit was scheduled. Those potential participants who qualified were then scheduled for a randomization visit. No additional screening was conducted at the baseline/randomization visit.

Cost

Absolute cost for production of recruitment materials was collected and is reported here. Recruitment materials included study brochures, fliers, letters, and posters. Additional cost information was collected on the use of third-parties to mail recruitment letters, postage, use of mailing lists, and other costs for printing, supplies and materials. Mean staff effort during the recruitment period is reported in addition to mean personnel costs because several team members were involved in the effort, not all of whom were focused exclusively on recruitment. These team members include data collectors, clinic coordinators, nurses, the project manager, and other administrative personnel. The bulk of staff time spent on recruitment was devoted to answering incoming telephone calls and conducting telephone, information session, and clinic screenings. Staff effort is reported as full-time equivalents (FTEs) and is calculated based on the estimated monthly percent effort contributed by all staff members to all phases of the recruitment process from development of recruitment strategies through final determination of eligibility. As time devoted by team members to recruitment activities varied from month to month, FTE was calculated for each month of recruitment (April 2007-April 2009) and averaged to obtain a mean for each recruitment year. The means for each year of recruitment were then totaled to ascertain a total FTE expenditure for the recruitment period. A unit cost per FTE spent on recruitment was also calculated. Using the mean salary figure for the duration of the recruitment period for each team member involved in the recruitment process, a mean staff salary was calculated. Fringe and overhead charges were added using the mean rate of 40%, as fringe rates vary even within a single institution.

Analytic Plan

Chi-square tests were used to discern any differences in the exclusion of potential participants and in rates of randomization from each recruitment strategy by demographic characteristics, specifically age, ethnicity and gender.

RESULTS

Recruitment Flow

Initial recruitment efforts began in April 2007. Three hundred and one participants were randomized over a twenty-one month period, from August 2007 through April 2009. Figure 1 shows the number of participants randomized versus study goal for the randomization period. Figure 2 illustrates the flow of the screening process from initial telephone contact through randomization and contains details regarding the number of candidates excluded

through the three tiered screening process. Of the 1818 initial telephone screenings completed, 301 participants (16.6%) were eventually randomized; 150 in the usual care condition and 151 in the lifestyle intervention. Almost a quarter of the potential participants that failed to qualify for participation (433, 23.8%) were excluded during the initial telephone screening; another 379 (27.4%) declined further screening.

Distribution of Excluded Participants

Of the 950 excluded participants, almost half of these were excluded during the initial stage of the screening process, the pre-screening interview (433, 45.6%). The main criterion for which participants were excluded at this stage was BMI (31.9% of prescreening exclusions). However, the frequency of BMI exclusion varied by gender, race, and age. Women were excluded at a higher rate than men during this stage of screening for BMI (107, 17.3%). African Americans (77, 23%) and participants under the age of 40 (30, 26.1%) were also excluded at a higher rate for BMI during the prescreening interview than their counterparts. An inability to perform exercise (62, 14.3%) and recent history of CVD (80, 18.5%) were also responsible for a large number of exclusions during the pre-screening interview. African Americans (30, 9%) and participants over the age of 60 (31, 10.1%) were excluded at higher rates for an inability to perform exercise and a higher percentage of men were excluded for a recent history of CVD (45, 13.6%). All of the above differences were significant ($p < 0.05$). Very few participants were excluded during the information session stage of screening (100, 10.5%), and the only significant difference in rate of exclusion was between men and women for glucose. 4.7% of women excluded from HELP were excluded for glucose at the information session, as compared to only 1.5% of men excluded. Of the participants excluded at clinic screening, the majority were excluded for glucose (379, 90.9%). No significant differences could be detected between age and ethnic groups with regard to exclusion at either the information session or clinic screening visits. As a very small number of potential participants identified their ethnicity as Hispanic (24 of 1818 screened) no significant differences can be reported with regard to exclusion and Hispanic ethnicity.

Strategies and Yield

Individual recruitment strategies met with varying degrees of success within gender, age, and ethnic categories. Mass mailing of recruitment letters resulted in the highest number of randomized participants (220, 73.1%). However, a higher percentage of participating men (109, 85.2%) reported hearing about the study through a letter when compared to participating women (111, 64.2%). Only 60.8% of the randomized participants who identified themselves as African Americans selected the mass mailing as the main contact, while 77% of those who identified themselves as white selected the letter as the primary source of information. These differences were all significant at $p < 0.05$. The remaining randomized participants identifying themselves as African-American were recruited by a doctor/doctor's office (5.4%), other referral (6.8%), community event (4.1%) or brochure (5.4%), although these proportions were not significantly different from those observed in whites. After mass mailing, the largest sources of randomized participants were from the Pepper Center database (22, 7.3%) and by referral (23, 7.6%). No significant differences were detected between randomization rates for these strategies with regard to race-ethnicity, gender, or age. Additional recruitment strategies resulting in small numbers of randomized participants included the study brochure (4, 1.3%), community events (4, 1.3%), flier (9, 3%), and other (11, 3.7%). The other category included email communications, clinical trial websites, and a story on the local news about the study. It should be noted that 2 randomized participants reported learning about the study from a newspaper advertisement, although the HELP PD study never ran any print, television, or radio advertisements. Detailed

information on the distribution of randomized participants by recruitment strategy can be found in Table 2.

Cost

The total direct cost of recruitment for the HELP Prevent Diabetes study was \$62,745. 120,447 letters were mailed through the local newspaper from April 2007-March 2009 resulting in 220 randomized participants. The total cost of these mailings was \$57,217, or \$260 per randomized participant. Two separate mailings to the VITAL database were also completed resulting in 22 randomizations. A total of 5,519 letters were mailed to those listed in this database at a total expense of \$886, or \$40 per randomized participant. Members of the study team conducted 3 worksite presentations and attended 12 community health fairs and similar events. Posters and fliers were also distributed to several doctor's offices associated with the institution and the local Veteran's Administration clinic. Although the exact cost of these strategies cannot be determined, the total cost of printing advertising materials distributed at these events and locations includes: \$3,320 spent on brochures, \$75 on fliers, and \$1,247 on posters. Four participants reported being recruited via brochure, 9 via flier, 23 by referral, 4 at a community event, and 6 by a doctor or doctor's office. Total direct cost of recruitment per randomized participant was \$208, although this does not include staff costs. More detailed information about the direct costs of recruitment strategies can be found in Table 3. Staff effort devoted to recruitment fluctuated between 1.15 and 2.5 full-time equivalents (FTEs) per month throughout the almost 25-month period, from the outset of recruitment activities to the end of randomization, with a mean of 1.8 FTEs and a total usage of 3.7 FTEs during this time period. In order to recruit and randomize 301 participants, 0.0123 of an FTE was expended per randomized participant. The unit salary cost per FTE for staff members involved in recruitment activities on this study was \$49,500, including salary, fringe, and overhead, meaning that the staff cost per randomized participant was \$608. When combined with the direct cost previously described, total cost per randomized participant for HELP PD for all recruitment activities from April 2007-April 2009 was \$816.

Baseline Characteristics

The baseline characteristics for the randomized sample are shown in Table 4 along with the baseline characteristics of the DPP participants. We also compared our sample to the National Health and Nutrition Examination Survey (NHANES) 2007-2008 dataset, restricted to those participants 21-80 years of age with a fasting glucose in the same pre-diabetes range (95-125 mg/dl inclusive) and a BMI between 25.1 and 39.9 kg/m² inclusive, as a reference for the general population. Over 40% of the randomized participants in HELP PD were male and the mean age of the sample was 57.9 years, with more than 41% reporting an age of 60 or older. Approximately 27% of the randomized participants reported a race or ethnicity other than white, and over 70 % reported education attainment beyond a high school diploma. Of the 301 randomized participants, over 70% reported being married at baseline and over 65% were employed full or part-time. The mean body mass index of randomized participants was 32.7 kg/m² and almost 73% had a BMI of 30.0 kg/m² or greater, fitting the World Health Organization classification for obesity. The mean fasting glucose at baseline was 105.5 mg/dl, although it varied widely, as the standard deviation was 11.3 mg/dl.

In general, the HELP Prevent Diabetes study participants represent a reasonably similar population to those who participated in DPP. The most prominent differences are that the HELP sample was older and had a higher proportion of males, whereas the DPP sample had greater representation of minority groups. The HELP PD population was more highly educated than either the DPP or NHANES samples. Additionally, more of the HELP PD

participants were married than either the DPP or NHANES samples, and a lower proportion of HELP PD participants were employed compared to the DPP population. Information on employment status was not available for the 2007-2008 NHANES dataset. Fasting glucose measures were similar between the HELP (105.5 ± 11.3) and DPP (107.33 ± 7.72) populations, as would be expected in interventions requiring participants to have impaired fasting glucose. The NHANES population also had a mean glucose very similar to that of HELP PD (105.7 ± 7.9). The DPP study cohort was heavier than the HELP PD sample, as more than 15% of DPP participants had BMIs greater than or equal to 40 kg/m^2 , a level excluded in HELP PD; however, the HELP PD cohort was heavier than the NHANES pre-diabetes sample.

DISCUSSION

The recruitment goal of 300 randomized participants was very nearly met within the timeframe allotted for recruitment (24 months). As more than 55% of participants were women, the goal of female participation was also met. We initially sought to enroll at least 30% minority participants, and finished with 26.7% of randomized participants identifying themselves as a race other than Caucasian/White. 24.7% of HELP PD participants identified themselves as African-American, essentially equal to the 25.6% of the total population of Forsyth County who identify themselves as African-American.

The two-year recruitment and randomization period for this trial is consistent with other trials of this size and scope. DPP allotted three years for the enrollment of 4000 participants across 27 clinical centers, and this goal was met approximately one month ahead of schedule. Other trials to date designed to translate the DPP intervention have been operated through workplace, primary care, cardiac rehabilitation or hospital settings, allowing for screening and enrollment of participants by employers, providers, or managed care organizations to drive recruitment efforts. As HELP PD was designed to implement the DPP lifestyle intervention in a community setting, a comparison of recruitment methodology and results with these trials is complex. The Diabetes Education & Prevention with a Lifestyle Intervention Offered at the YMCA (DEPLOY) pilot study, conducted in a YMCA setting, was able to enroll 92 participants in 10 months [19]. This pilot study implemented single-stage screening events wherein BMI, non-fasting glucose, and a diabetes risk assessment questionnaire were collected to determine eligibility. Comparably, HELP PD was able to randomize 301 participants in 21 months at a rate of 14.33 participants per month. HELP PD eventually randomized 16.6% of all screenings, compared to the 2.4% of all screenings enrolled in DPP [15], although DPP employed a more intensive screening process, longer behavioral run-in, and more rigorous eligibility criteria. For both trials, the majority of exclusions occurred at the initial screening.

Mass mailing proved to be the most effective strategy to enroll participants in this trial. As in DPP and other prevention trials, a higher proportion of men reported mass mailing as the primary source of information [15,20]. While the total cost may seem expensive in comparison to other strategies, mass mailing required little staff effort and produced a large number of screenings. It also remained significantly cheaper than other promotion techniques, including television, newspaper, and radio advertisements. As the lifestyle intervention in HELP PD necessitated rapid recruitment to allow the formation of intervention groups on an almost monthly basis and reduce participant initiation time, the cost of mass mailings seemed justified. The use of the VITAL database to generate mailings also proved to be successful, costing only \$40 per randomized participant and generating 22 randomizations. However, this strategy was quickly exhausted and, given the size of the database, could not generate enough contacts to meet study recruitment goals. This finding is consistent with current literature, indicating that recruitment strategies that utilize

previous relationships, like provider referral and recruitment databases, are often successful [21,22]. Additionally, although this strategy was quickly exhausted, it is also highly translatable as it is likely that DCCs will have existing relationships with health care settings serving individuals interested with weight loss/diabetes prevention. No television, print, or radio ads were produced for this trial because past research has indicated that these techniques produce mixed recruitment results and the costs per randomized participant associated with these techniques are much higher than mass mailings [15,20].

As in the DPP, recruitment required approximately two full-time equivalents per clinic of staff effort at its peak [15]. The mean number of participants per clinic in the DPP was 141, including those recruited to the troglitazone arm which was discontinued early in the study. Given that the recruitment period for DPP lasted 35 months at a rate of 4.03 randomizations per month per clinic, fewer participants were recruited per clinic over a longer period of time when compared to HELP PD. However, the screening process for DPP included an Oral Glucose Tolerance Test (OGTT), behavioral run-in, and electrocardiogram. These steps were not included in the screening for HELP PD in order to ease translation in a community setting. The cost of recruitment for HELP PD was also substantially lower, at \$816 per randomized participant including staff costs, compared to the \$1075 per randomized participant spent by DPP, which excluded coordinating center and clinic staff costs. Other prevention studies have fared better than DPP, but still may have spent significantly more than HELP PD. Katula et al reported spending more than \$430 per randomized participant, not including personnel and indirect costs, to recruit for a mobility disability prevention trial in older adults, with the bulk of randomized participants coming from mass mailings (61.6%) [20]. As the total cost per randomized participant reported for HELP PD includes personnel costs, these results may provide a reasonable guide for those planning similar community translations of prevention programs in the future.

As a study translating the DPP into a community setting, it is important to evaluate the differences in the HELP PD and DPP populations. In comparison to the participants enrolled in DPP, the HELP PD population is older, more educated and predominately white, though to some extent, these differences reflect the regional population. These differences may have implications for overall study attrition and intervention adherence and success. Other behavioral interventions and weight loss programs have found age, education, and race to be predictors of success and attrition [23-25]; however, a 1999 review by Davis and Addis found that psychological variables like self-efficacy were more predictive of attrition in weight management programs than demographic variables [26]. Other differences between the HELP PD and DPP samples are the result of design differences between the two studies. In developing the eligibility criteria for HELP PD, the study team focused on generalizability, easy translation into a community setting and participant safety. DPP set a recruitment goal of greater than 50% minority participation and had the added benefit as a multi-center trial of selecting specific sites to recruit predominately minority populations. In contrast, HELP PD was limited to recruiting a representative sample within the confines of Forsyth County, NC. DPP also included a behavioral run-in during the screening process [15]. This step was not included in the screening process for HELP PD in order to facilitate translation into a community setting and to maintain high generalizability. As such, participants were not screened for their ability to meet the requirements of the intervention. This difference may also influence adherence to the lifestyle intervention.

The successful implementation of this intervention depended on rapid enrollment, and this consideration caused development of a fully translated and sustainable process for participant identification to be a secondary consideration. Nevertheless, these recruitment results do have implications for community-based translations of the DPP. First, we were able to determine that referral from primary care settings is a feasible source of participants.

As the HELP PD intervention is designed to operate in Diabetes Care Centers and educational programs already in the community, existing referral mechanisms in place for patients with diabetes could be adapted for referral of patients for diabetes prevention. These efforts could be supplemented by mass mailings and community advertising if needed, as they are accepted marketing techniques for clinical services. The screening process implemented in HELP PD was simplified from that of DPP, but had some attributes related to research purposes. The process could be further simplified to be conducted within primary care settings to document patient eligibility for reimbursement as routinely done for other healthcare services.

In conclusion, HELP PD has developed a successful model of enrollment for a community-based translation of DPP. Similar large-scale endeavors in the future should consider dedicating resources to high-yield strategies like mass mailing to supplement clinic referrals, as mailings have proven to be effective to meet the demands of a group-based lifestyle intervention and may cost less in the long run than other traditional recruitment strategies. Additionally, the use of a tiered screening process with an initial telephone interview to determine eligibility may enhance enrollment for similar interventions and reduce the staff effort needed to conduct in-person screenings. Comparable community-based translations in the future may also be able to further simplify the screening process by using direct provider referral.

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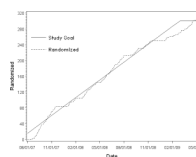


Figure 1. Cumulative number randomized versus study goal for randomization period (August 2007-August 2009) in the HELP PD study.



Figure 2. Screening flow through randomization, including exclusion criteria for HELP PD.

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	$25 \text{ kg/m}^2 \leq \text{BMI} < 40 \text{ kg/m}^2$
Fasting Blood Glucose	$95 \text{ mg/dL} \leq \text{FBG} \leq 125 \text{ mg/dL}$ 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: $\text{BP} \geq 160/100$
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

Distribution of randomized HELP PD participants by recruitment strategy (percentage).

Strategy	Number N=301	Gender		Age			Race				Ethnicity		
		Men (n=128)	Women (n=173)	21-39 (n=8)	40-60 (n=170)	60+ (n=123)	AA/Black (n=74)	White (n=222)	Native A (n=1)	Other/Refused (n=4)	Hispanic (n=4)	Non-Hispanic (n=295)	Refused/Missing (n=2)
Letter	220 (73.1)	109 (85.2)*	111 (64.2)*	3 (37.5)	129 (75.9)	88 (71.5)	45 (60.8)*	171 (77)*	1 (100)	3 (75)	2 (50)	217 (73.6)	1 (50)
Brochure or Flier	13 (4.3)	3 (2.3)	10 (5.8)	1 (12.5)	3 (1.8)	2 (1.6)	5 (6.8)	1 (0.5)	0 (0)	0 (0)	0 (0)	6 (2.0)	0 (0)
Doctor/Doctor Office	6 (2)	2 (1.6)	4 (2.3)	0 (0)	4 (2.4)	2 (1.6)	4 (5.4)	2 (0.9)	0 (0)	0 (0)	0 (0)	6 (2)	0 (0)
Community Event	4 (1.3)	0 (0)	4 (2.3)	1 (12.5)	3 (1.8)	0 (0)	3 (4.1)	1 (0.5)	0 (0)	0 (0)	0 (0)	4 (1.4)	0 (0)
Previous Relationship	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Referral	23 (7.6)	6 (4.7)	17 (9.8)	2 (25)	12 (7.1)	9 (7.3)	5 (6.8)	18 (8.1)	0 (0)	0 (0)	1 (25)	21 (7.1)	1 (50)
Pepper Center	22 (7.3)	6 (4.7)	16 (9.2)	0 (0)	4 (2.4)	18 (14.6)	5 (6.8)	17 (7.7)	0 (0)	0 (0)	0 (0)	22 (7.5)	0 (0)
Don't Know/Refused	1 (0.3)	0 (0)	1 (0.6)	0 (0)	1 (0.6)	0 (0)	0 (0)	0 (0)	0 (0)	1 (25)	1 (25)	0 (0)	0 (0)
Don't Know/Refused/Other	14 (4.7)	3 (2.3)	11 (6.4)	0 (0)	10 (5.9)	4 (3.3)	4 (5.4)	8 (3.6)	0 (0)	1 (25)	1 (25)	13 (4.4)	0 (0)

* p<0.05

Table 3

Direct cost per recruitment strategy in the HELP PD study.

Recruitment Source	Total Cost (\$)	Units	Participants Randomized	Cost per Participant Randomized (\$)
Direct Mail	57218	120,447	220	260
Printed Materials	4642	7295	46	101
Brochure	3320	6620		
Flier	75	600		
Poster	1247	75		
Pepper Center Mailing	886	5519	22	40
Other			13	
Total	62745	12814	301	208

Table 4

Baseline characteristics of HELP PD study sample.

Characteristic	HELP PD N=301	Diabetes Prevention Program N=3665	NHANES 2007-2008 N=1055
Age, mean \pm SD	57.9 \pm 9.5	^a 50.6 \pm 10.4	52.6 \pm 16.4
Less than 40	6 (2.0)	529 (14.4)	270 (25.6)
40-59	171 (56.8)	2387 (65.1)	388 (36.8)
60 and older	124 (41.2)	749 (20.4)	397 (37.6)
Sex, n (%)			
Male	128 (42.5)	1228 (33.5)	562 (53.3)
Female	173 (57.5)	2437 (66.5)	493 (46.7)
Race/Ethnicity, n(%)			
Caucasian/White	220 (73.3)	2117 (57.8)	5112 (48.5)
African American/Black	74 (24.7)	751 (20.5)	154 (14.6)
Hispanic (of any race)	4 (1.3)	609 (16.6)	358 (33.9)
Mixed/Other/Unknown	2 (0.7)	188 (5.1)	31 (2.9)
Education, n (%)			
< High School	8 (2.7)	1902 (51.9)	320 (30.3)
High School or Equivalent	53 (17.6)	760 (20.7)	251 (23.8)
> High School	217 (72.1)	1003 (27.4)	483 (45.8)
Other	23 (7.6)	0	1 (0.1)
Marital Status, n(%)			
Never married	17 (5.7)	478 (13.0)	124 (11.8)
Living together	1 (0.3)	130 (3.6)	72 (6.8)
Married	211 (70.1)	2267 (61.9)	607 (57.5)
Separated	10 (3.3)	98 (2.7)	36 (3.4)
Divorced	49 (16.3)	527 (14.4)	121 (11.5)
Widowed	13 (4.3)	165 (4.5)	95 (9.0)
Employment Status, n(%)			
Employed (Full or Part Time)	198 (65.8)	2729 (74.5)	
Not Employed/Other	103 (34.2)	936 (25.5)	
Fasting Glucose (mg/dL), mean \pm SD	105.5 \pm 11.3	107.33 \pm 7.72	105.7 \pm 7.9
Fasting Insulin (uU/mL), mean \pm SD	16.7 \pm 9.8	26.4 \pm 14.8 (n=2662)	14.2 \pm 9.9 (n=1046)
Lipids (mg/dL), mean \pm SD			
Total cholesterol	185.3 \pm 38.8	203.8 \pm 36.0 (n=2660)	200.2 \pm 41.7 (n=1052)
HDL cholesterol	46.4 \pm 12.1	45.6 \pm 11.8 (n=2660)	51.1 \pm 14.2 (n=1052)
LDL cholesterol	113.2 \pm 33.2 (n=297)	125.4 \pm 32.6 (n=2660)	119.8 \pm 34.9 (n=1028)
Triglycerides	135.7 \pm 85.2	163.5 \pm 97.0 (n=2660)	151.5 \pm 131.2 (n=1051)
BMI (kg/m ²), mean \pm SD	32.7 \pm 4.0	^b 33.5 \pm 5.8	30.3 \pm 3.6
Less than 26	10 (3.3)	254 (6.9)	100 (9.5)

Characteristic	HELP PD N=301	Diabetes Prevention Program N=3665	NHANES 2007-2008 N=1055
26-30	72 (23.9)	945 (25.8)	471 (44.6)
30-34	99 (32.9)	915 (25.0)	300 (28.4)
34-38	86 (28.6)	725 (19.8)	148 (14.0)
38 or greater	34 (11.3)	826 (22.5)	36 (3.4)
Blood Pressure (mmHg), mean \pm SD			
Systolic	127.2 \pm 14.1	124.2 \pm 14.6	125.7 \pm 18.7 (n=1016)
Diastolic	73.2 \pm 9.4	78.6 \pm 9.3	70.28 \pm 13.3 (n=1016)
Waist Circumference (cm), mean + SD	104.7 \pm 10.0	104.9 \pm 14.5 (n=2662)	103.2 \pm 10.1 (n=1024)

^aDPP data coded only as a categorical variable: \pm 40, 40-44, 45-49, 50-54, 55-59, 60-64, \geq 65. To estimate mean age \pm SD, the midpoint values for each range and the values of 35 and 70 for the endpoints were substituted in the calculations.

^bDPP data coded only as a categorical variable \pm 26, 26-28, 28-30, 30-32, 32-34, 34-36, 36-38, 38-40, 40-42, \geq 42. To estimate mean age \pm SD, the midpoint values for each range and the values of 24 and 44 for the endpoints were substituted in the calculations.