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Original article

The 24-month metabolic benefits of the healthy living partnerships to prevent diabetes: A community-based translational study

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ABSTRACT

Aims: Large-scale clinical trials and translational studies have demonstrated that weight loss achieved through diet and physical activity reduced the development of diabetes in overweight individuals with prediabetes. These interventions also reduced the occurrence of metabolic syndrome and risk factors linked to other chronic conditions including obesity-driven cancers and cardiovascular disease. The Healthy Living Partnerships to Prevent Diabetes (HELP PD) was a clinical trial in which participants were randomized to receive a community-based lifestyle intervention translated from the Diabetes Prevention Program (DPP) or an enhanced usual care condition. The objective of this study is to compare the 12 and 24 month prevalence of metabolic syndrome in the two treatment arms of HELP PD.
Materials and methods: The intervention involved a group-based, behavioral weight-loss program led by community health workers monitored by personnel from a local diabetes education program. The enhanced usual care condition included dietary counseling and written materials.
Results: HELP PD included 301 overweight or obese participants (BMI 25–39.9 kg/m^2) with elevated fasting glucose levels (95–125 mg/dl). At 12 and 24 months of follow-up there were significant improvements in individual components of the metabolic syndrome: fasting blood glucose, waist circumference, HDL, triglycerides and blood pressure and the occurrence of the metabolic syndrome in the intervention group compared to the usual care group.
Conclusions: This study demonstrates that a community diabetes prevention program in participants with prediabetes results in metabolic benefits and a reduction in the occurrence of the metabolic syndrome in the intervention group compared to the enhanced usual care group.

1. Introduction

The metabolic syndrome is a constellation of clinical features [1] which in combination identify individuals who are at increased risk for developing diabetes, some cancers, and cardiovascular disease including stroke [2–4]. Diseases related to metabolic syndrome represent the leading causes of death in the United States, making interventions to improve the components of metabolic syndrome especially needed. Programs specifically designed to promote weight loss have been successful in improving these parameters but have been criticized as being too expensive for dissemination to the general population.

The Diabetes Prevention Program (DPP) and the Finnish Diabetes Prevention Study (FDPS) were successful in altering the metabolic profiles of participants and such benefits were found to be long lasting. The DPP [5,6] reported that the prevalence of metabolic syndrome at 3 years among those who had metabolic syndrome at baseline was significantly lower in the lifestyle intervention group compared to the placebo group [7]. Similarly in the FDPS [8], with a mean follow-up of 3–9 years, the prevalence of metabolic syndrome decreased significantly in the intervention group compared to the control group [9]. The Healthy Partnerships

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to Prevent Diabetes (HELP PD) trial was a single center randomized controlled trial (RCT) targeting overweight individuals with elevated fasting glucose levels (95–125 mg/dL) [10] and was successful in reducing fasting glucose in the intervention arm compared to the enhanced usual care arm at one and two years [11,12]. The cost of the intervention program was approximately one-third that of DPP as HELP PD employed community health workers to facilitate the intervention groups [13]. The intervention resulted in weight loss in most participants in the first 6 months comparable to DPP [14] and the weight loss was maintained in a significant number of participants for a 24 month period. [11,12] This paper summarizes the impact of the intervention on 12 and 24 month changes in the metabolic syndrome and its individual components in these individuals.

2. Methods

The design and methods, recruitment details, and primary outcome measures of this study have previously been reported [10–16]. Briefly, this single center RCT of overweight and obese participants (BMI 25–39.9 kg/m^2) with elevated fasting blood glucose between 95 and 125 mg/dl were randomly assigned to either the group-based lifestyle weight loss (LWL) intervention or enhanced usual care (EUC) [10]. Exclusion criteria were diabetes, cardiovascular disease in the past 6 months, uncontrolled hypertension, medications affecting glucose metabolism, and major chronic illnesses that would affect participation and/or limit lifespan [15]. Overall the goal of recruitment was to be representative of the community so that the intervention could be translated to the general population; 301 individuals were enrolled in the trial and data was collected during 2007–2011 [15]. There was no racial or gender bias in the selection of participants. Outcomes were assessed every 6 months and included fasting blood glucose, weight, waist circumference, triglycerides, blood pressure, LDL and HDL cholesterol [10]. All participants provided written informed consent and the study was approved by the Wake Forest School of Medicine Institutional Review Board. The analyses described in this report were performed in 2015–2016.

2.1. Interventions

The LWL intervention was adapted from the DPP curriculum [5] to be delivered by community health workers (CHWs) in group settings [10]. The objective was to achieve weight loss through reductions in caloric intake of approximately 500 kcal/day and moderate intensity exercise of 180 min/week to achieve weight loss of 0.3 kg per week for the first 6 months (Phase 1) for 5%–7% total weight loss. Months 7–24 (Phase 2) were focused on weight maintenance but weight loss goals were encouraged as long as BMI did not fall below 20 kg/m^2. Participants met in groups of 8–12 in community sites such as recreation centers, and sessions were led by the CHWs who were trained, monitored, and supervised by registered dietitian nutritionists (RDN) affiliated with the local diabetes education program [16]. In addition, participants met in individual sessions with an RDN during months 1, 3 and 6. Group sessions were weekly during Phase 1 and then monthly in Phase 2. The CHWs also contacted the participants by phone once a month in Phase 2.

The EUC comparison arm was designed to offer more than what was usual care for participants to enhance continued participation in the trial. EUC consisted of two individual sessions focusing on healthy lifestyle with an RDN during the first three months of the trial and a monthly newsletter which addressed healthy lifestyle behaviors and community resources.

2.2. Outcome measures

Metabolic Syndrome was determined using current ATP (Adult Treatment Panel III)/NCEP (National Cholesterol Education Program) guidelines [1,17–19] as the combination of any three of the following five conditions: waist circumference male $\geq$102 cm (40in) female $\geq$88 cm (35in); fasting triglycerides $\geq$150 mg/dl or drug treatment for elevated triglycerides; HDL cholesterol male ($<$40 mg/dl) and female ($<$50 mg/dl) or drug treatment for low HDL cholesterol; blood pressure $\geq$130 systolic or $\geq$85 diastolic or drug treatment for elevated blood pressure and fasting plasma glucose (FPG) $\geq$100 mg/dl or drug treatment for elevated blood glucose [17]. All parameters were reported at baseline, 12 months and 24 months for both the LWL and EUC groups. Waist circumference was also assessed at 6 months while blood pressure and fasting plasma glucose were also assessed at 6 and 18 months. All blood tests were performed after an 8 h fast and samples were processed by a central lab masked to the participants' intervention assignment. Glucose was measured using a timed endpoint method supplied by Beckman Coulter for the Synchron LX analyzer. Waist circumference was measured using a Gulick II 150 cm anthropometric tape with the subject in a recumbent position without clothing touching the skin midpoint between the inferior margin of the last rib and the iliac crest [20].

2.3. Statistical analysis

Constrained longitudinal data analysis (repeated measures analysis of variance with the baseline treated as a response and baseline means constrained to be equal in the two groups) [21] was used to assess the effect of the HELP intervention on the components of the metabolic syndrome (waist circumference, SBP, DBP, fasting blood glucose, triglycerides, and HDL) over time. Note that some outcomes (e.g., SBP, DBP, and glucose) were measured every six months while others (e.g., triglycerides, HDL) were measured every year. All available data were used in the analyses; results are reported at baseline, 12, and 24 months for all outcomes. An unstructured covariance matrix was used to model the within patient correlations over time. Linear contrasts were used to assess the intervention effect at 12 and 24 months. Chi-square tests were used to assess treatment differences in the proportion of individual metabolic components and the metabolic syndrome. Hochberg's modified Bonferroni step-up multiple test procedure was used to adjust p-values for multiple contrasts for each outcome [22]. Chi-square tests and t-tests were used to assess differences in participant characteristics between those who did and did not drop out of the study. SAS version 9.4 was used to perform the analyses.

3. Results

A total of 301 participants were randomized between 8/2007 and 4/2009, 151 to LWL and 150 to the EUC condition. Fig. 1 illustrates the recruitment, screening, randomization, and retention process. Baseline characteristics for randomized participants are summarized in Table 1. Ages ranged from 34 to 81 with a median of 58 years; 57% were female and 27% were minority. Most participants were married (70%), employed full or part-time (66%), and lived with other people (81%). BMI ranged from 24.6 to 40.5 with a median of 32.8; by CDC criteria, 27% of participants were overweight and 73% were obese. Baseline characteristics were similar in the two groups.

The estimates of the prevalence of the metabolic syndrome components are also shown in Table 1 and descriptive statistics for the metabolic components of metabolic syndrome at baseline are shown in Table 2. Overall, 70% of the participants met the criteria

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