



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

Jeffrey A. Katula^{a,*}, Mara Z. Vitolins^b, Erica L. Rosenberger^b, Caroline Blackwell^b, Mark A. Espeland^c, Michael S. Lawlor^d, W. Jack Rejeski^a, David C. Goff^b

^a Wake Forest University, Department of Health & Exercise Science, PO Box 7868, Winston-Salem, NC 27109, USA

^b Wake Forest University School of Medicine, Division of Public Health Sciences, Department of Epidemiology & Prevention, Medical Center Blvd., Winston-Salem, North Carolina 27157-1063, USA

^c Wake Forest University School of Medicine, Division of Public Health Sciences, Department of Biostatistics, Medical Center Blvd., Winston-Salem, North Carolina 27157-1063, USA

^d Wake Forest University, Department of Economics, PO Box 7505, Winston-Salem, NC 27109, USA

ARTICLE INFO

Article history:

Received 7 May 2009

Accepted 9 September 2009

Keywords:

Translational research

Randomized controlled trial

Weight loss

Prevention

Type 2 diabetes

Obesity

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/m²) 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 $\geq 7\%$ 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.

© 2009 Elsevier Inc. All rights reserved.

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],

* Corresponding author. Tel.: +1 336 758 3612; fax: +1 336 758 4680.
E-mail address: katulaj@wfu.edu (J.A. Katula).

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 $\leq$ FBG $\leq$ 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

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 $\leq$ BMI < 40 kg/m ²
Fasting Blood Glucose	95 mg/dL $\leq$ FBG $\leq$ 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 $\geq$ 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.

Download English Version:

<https://daneshyari.com/en/article/3463137>

Download Persian Version:

<https://daneshyari.com/article/3463137>

[Daneshyari.com](https://daneshyari.com)