Promoting Successful Weight Loss in Primary Care in Louisiana (PROPEL): Rationale, design and baseline characteristics


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A B S T R A C T

Underserved and minority populations suffer from a disproportionately high prevalence of obesity and related comorbidities. Effective obesity treatment programs delivered in primary care that produce significant weight loss are currently lacking. The purpose of this trial is to test the effectiveness of a pragmatic, high intensity lifestyle-based obesity treatment program delivered within primary care among an underserved population. We hypothesize that, relative to patients who receive usual care, patients who receive a high-intensity, literacy- and culturally-appropriate lifestyle intervention will have greater percent reductions in body weight over 24 months. Eighteen clinics (N = 803 patients) serving low income populations with a high proportion of African Americans in Louisiana were randomized to the intervention or usual care. Patients in the intervention participate in a high-intensity lifestyle program delivered by health coaches employed by an academic health center and embedded in the primary care clinics. The program consists of weekly (16 in-person/6 telephone) sessions in the first six months, followed by sessions held at least monthly for the remaining 18 months. Primary care practitioners in usual care receive information on weight management and the current Centers for Medicare and Medicaid Services reimbursement for obesity treatment. The primary outcome is percent weight loss at 24 months. Secondary outcomes include absolute 24-month changes in body weight, waist circumference, blood pressure, fasting glucose and lipids, health-related quality of life, and weight-related quality of life. The results will provide evidence on the effectiveness of implementing high-intensity lifestyle and obesity counseling in primary care settings among underserved populations.

Trial Registration: ClinicalTrials.gov Identifier NCT02561221

1. Introduction

Obesity is a highly prevalent and serious medical condition in the United States (US), and Louisiana ranks highest among the states in the prevalence of obesity [1]. Obesity increases the risk of type 2 diabetes, heart disease, stroke, gallbladder disease, respiratory problems, poor health-related quality of life, and several cancers [2]. Indeed, Louisiana sits firmly in the “Chronic Disease Belt”, characterized by high

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https://doi.org/10.1016/j.cct.2018.02.002
Received 27 October 2017; Received in revised form 22 January 2018; Accepted 1 February 2018
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prevalence of cancer [3], cardiovascular disease [4,5], diabetes [6], and obesity [7]. Given that minorities and other underserved populations have a disproportionately high obesity prevalence [8,9], identifying strategies to reduce obesity in these populations is imperative for achieving national public health goals to reduce health inequities [10].

While the high rates of obesity are of great concern, it is equally concerning that health care systems have not delivered medical interventions capable of producing even modest weight loss [11]. With primary care practitioners (PCPs) being the cornerstone of medical care in the US, the US Preventive Services Task Force recommends that physicians offer intensive multi-component behavioral interventions to individuals with obesity [12]. Further, the Centers for Medicare and Medicaid Services (CMS) covers intensive behavioral therapy for obesity by a PCP [13]. However, the sole reliance on PCPs to deliver intensive behavioral therapy for obesity has limitations, in part due to time constraints during a typical primary care visit, and lack of training among PCPs in nutrition education, as well as in the delivery of behavioral therapy [11,14]. A narrative review of obesity management in primary care indicated that obesity treatment options delivered in primary care have resulted in limited success, demonstrating only 1–3 kg weight loss over 6–24 months [11]. As most studies typically only employed monthly or quarterly visits of 10–15 min duration, this low weight loss is likely due to the low intensity of the interventions [11]. Indeed, there is evidence that higher-intensity interventions delivered by trained interventionists in primary care can produce greater weight loss [15].

The 2013 American Heart Association (AHA)/American College of Cardiology (ACC)/The Obesity Society (TOS) Guidelines for the Management of Overweight and Obesity in Adults [16,17] assert that an intensive comprehensive lifestyle intervention is the centerpiece to effectively promote weight loss and improve health. These guidelines, based on an exhaustive systematic review [18], emphasize the gold standard of on-site, high-intensity (i.e., ≥14 sessions in 6 months) comprehensive intervention delivered in group or individual sessions by a trained interventionist. Treatment models based on the AHA/ACC/TOS Guidelines which are adaptable to real-life settings and which add effective and cost-conscious delivery methods for obesity treatment in the primary care setting are needed. The purpose of the PROmoting Successful Weight Loss in Primary Care in Louisiana (PROPEL) trial is to test the effectiveness of a pragmatic, high-intensity lifestyle-based obesity treatment program delivered within the primary care setting.

2. Methods

2.1. Overview of study design

This study is a cluster-randomized, two-arm controlled trial conducted in primary care clinics. A total of 18 primary care clinics inclusive of low income populations with a high percentage of African Americans from urban and rural areas across Louisiana were randomized to either a 1) high-intensity lifestyle intervention group or 2) usual care group. Outcomes are assessed at baseline and 6, 12, 18 and 24-month visits.

2.2. Aims

The primary aim of the PROPEL trial is to develop and test the effectiveness of a 24-month, patient-centered, pragmatic and scalable obesity treatment program delivered within primary care in an underserved population. We hypothesize that:

1) Relative to patients who receive usual care, patients who receive a high-intensity, health literacy-appropriate and culturally appropriate lifestyle intervention delivered by trained health coaches embedded in a primary care setting will have greater percent reductions in body weight; and

2) Relative to patients in usual care, patients who receive the high intensity lifestyle intervention will have significant improvements in health-related quality of life, functional capacity, satisfaction with medical care, and improved obesity co-morbidities (hypertension, dyslipidemia, insulin resistance, etc.).

The three secondary aims of the PROPEL trial are 1) to evaluate relationships between adherence to intervention components (physical activity, diet, sessions, etc.) and corresponding changes in body weight and secondary outcomes (post-hoc analyses); 2) to examine the effects of the intervention on system-level practices and patient satisfaction with care, and 3) to test the heterogeneity of effects across clinics and across subgroups of patients (men versus women, white versus African American, older versus younger adults).

2.3. Stakeholder and patient engagement

The design of the trial and all intervention materials was guided by extensive stakeholder and patient engagement. Stakeholders include Chief Executive Officers and medical directors of Federally Qualified Health Centers (FQHCs) in underserved areas of the state, in addition to PCPs and community leaders. The continuous engagement of stakeholders was initiated prior to the inception of the trial, and they continue to provide input to the investigative team through regular communication via email, phone, and in-person meetings. Patient engagement occurs largely through quarterly meetings with our three Patient Advisory Boards (PABs; located in North, South, and New Orleans Louisiana) who were instrumental in designing and adapting the intervention sessions and materials for the trial. The PABs are comprised of individuals representative of the PROPEL patient population or individuals who work with the patient population living in each of the three PROPEL study areas. The PABs provide significant input on patient recruitment and retention strategies, and also review our educational webinars for the PCPs. In addition to the PABs, a series of focus groups was conducted early in the trial design phase to gather feedback about perceptions of obesity treatment options among healthcare providers and low-income patients [19]. A Community Monitoring Board (CMB), comprised of individuals representing community organizations, meets yearly to provide feedback on the overall direction of the trial and will also help disseminate the results to relevant partner organizations at the conclusion of the trial. Finally, two patient representatives attend monthly study project management committee meetings along with the study investigators and research staff.

2.4. Cluster randomization

All enrolled patients receive the intervention to which their clinic was assigned. Eighteen primary care clinics from across the state were randomized by the study statistician to either 1) a high-intensity lifestyle intervention group, or 2) a usual care group, after stratification by health system. The 18 clinics are from five health systems (one, three, four, and six clinics from each of four systems of FQHCs, respectively, and 4 clinics from one large, nonprofit academic multispecialty healthcare delivery system), and stratified randomization by health system was performed to ensure adequate local staffing of clinics assigned to the intervention arm and representation from all regions of the state and types of health systems in both arms of the trial. According to Federal Office of Rural Health Policy classification [20], 14 clinics are in urban areas, while four are in rural areas. The size of the clinics (patients served) ranges from 1100 to 35,000.

2.5. Patient recruitment and screening

Patients are recruited in the primary care clinics using a variety of approaches. Depending on the clinic, potentially eligible patients are
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