Contemporary Clinical Trials Communications 9 (2018) 151–163

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

A gender- and culturally-sensitive weight loss intervention for Hispanic males: The ANIMO randomized controlled trial pilot study protocol and recruitment methods

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ARTICLE INFO

Keywords:
Hispanic
Men
Recruitment
Weight loss
mHealth

ABSTRACT

Hispanic men have the highest rates of overweight and obesity when compared to men of other racial/ethnic groups, placing them at increased risk for obesity-related disease. Yet, Hispanic men are grossly underrepresented in weight loss research. Tailored intervention strategies to improve obesity treatment programs for this vulnerable racial/ethnic subgroup are needed. This manuscript describes recruitment strategies, methodology, and participant characteristics of the ANIMO study, a 24-week randomized controlled pilot trial testing the effects of a gender- and culturally-sensitive weight loss intervention (GCSWLI) on body weight in Hispanic men compared to a wait-list control condition. The ANIMO study included two phases. The first phase was a 12-week GCSWLI. Participants attended weekly in-person individual sessions guided by a trained bilingual Hispanic male lifestyle coach, were prescribed a daily reduced calorie goal, and 225 min of moderate-intensity physical activity per week. In the second phase, GCSWLI participants received bi-weekly phone calls across a 12-week follow-up. Wait-list control (WLC) participants from phase 1 received the GCSWLI plus mobile health technology support. Recruitment strategies included face-to-face efforts at a swap meet (outdoor marketplace), family/friend referrals, printed advertisements and social media. Recruitment, screening, and participant enrollment occurred over three months. Overall, 143 men expressed interest in participation. Of these, 115 were screened and 78% (n = 90) were eligible to participate; 45% of enrolled participants (n = 52) completed baseline assessments and 43% (n = 50) were randomized (mean age of 43.3 ± 11.4 years; BMI: 34.1 ± 5.3 kg/m^2; 58% Spanish monolingual). Parameter estimates from ANIMO will support future adequately powered trials for this health disparate population.
Trial registration: ClinicalTrials.gov: NCT02783521

1. Introduction

Hispanic males have the highest prevalence of overweight and obesity among racial/ethnic groups in the U.S. [1]. Obesity is strongly linked to cardiovascular disease, metabolic syndrome, type 2 diabetes, hypertension, non-alcoholic fatty liver disease (NAFLD), and certain types of cancers such as colorectal and liver [2–4]. Consequently, Hispanic males have the highest prevalence of obesity-related comorbidities relative to other racial/ethnic subgroups. For example, estimates suggest that Hispanic men are 1.4 times more likely than non-Hispanic white (NHW) men to have been diagnosed with diabetes by a physician despite lower healthcare access [5]. Cardiometabolic abnormalities such as abdominal obesity, hypertension, high cholesterol and triglycerides, and high blood glucose levels are also significantly higher in this population subgroup overall [6,7].

Current evidence-based guidelines for the management of overweight and obesity in adults recommend weight loss treatment for individuals with a body mass index (BMI) $\geq 30\ kg/m^2$ or with a BMI $\geq 25\ kg/m^2$ coupled with weight-related comorbidities [8]. While behavioral weight loss interventions, delivered on-site in academic

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https://doi.org/10.1016/j.conctc.2018.01.010
Received 2 November 2017; Received in revised form 24 January 2018; Accepted 31 January 2018
Available online 09 February 2018

research settings, are capable of producing approximately an 8–10% weight loss over the course of 6 months [8,9], approximately 73% of study samples are comprised of women [10,11]. Further, Hispanic participants tend to lose less weight and are more likely to regain weight at follow-up compared to other racial/ethnic groups [12–18]. It has been suggested that culturally-specific gender roles may contribute to this differential effect; however, there is limited evidence of effectiveness of behavioral weight loss interventions for Hispanics long-term [17]. The Diabetes Prevention Program (DPP) is one of few randomized controlled studies with long-term weight loss data among Hispanic men. Data specific to the intensive lifestyle intervention demonstrated weight loss achieved by Hispanic men (−6.8 kg) and non-Hispanic White men (−7.1 kg) at 24 months were not significantly different [19]. While these data are promising, the DPP enrolled only 58 Hispanic men in the intensive lifestyle intervention, comprising only 6.0% of the total intervention arm population [19]. Identifying intervention strategies to engage and promote successful weight management in Hispanic males is critical to reducing morbidity and mortality among this large and growing population [20,21].

Using existing practice guidelines and evidence from our recently completed in-depth qualitative interviews in overweight/obese Hispanic males [22,23], we developed and tested a novel intervention to address this gap in knowledge. We proposed to 1) assess the feasibility, acceptability and preliminary efficacy of a gender- and culturally-sensitive weight loss intervention in 48 overweight/obese Hispanic males ages 18–64 over 12-weeks; 2) assess participant characteristics and process measures related to the uptake of mobile-health (mHealth) technology in overweight/obese Hispanic males over 12-weeks; and 3) evaluate pathologic changes in the liver in Hispanic men enrolled in a 12-week weight loss intervention using non-invasive magnetic resonance imaging (MRI) as a therapeutic response biomarker. This manuscript describes the study's recruitment strategies, methodology, and participant characteristics.

2. Methods

2.1. Experimental study design

The ANIMO (Spanish term for encouragement or motivation) pilot study was a 24-week randomized controlled trial testing the effects of a gender- and culturally-sensitive weight loss intervention (GCSWLI) on body weight in Hispanic men compared to a wait-list control condition (Fig. 1). Phase 1 of the GCSWLI consisted of 12-weeks of individual counseling, while in the second phase, GCSWLI participants received bi-weekly phone calls for another 12-weeks. Wait-list control (WLC) participants received the GCSWLI plus mobile healthmHealth technology support after 12-weeks of no intervention. Qualitative inquiry of weight loss experiences, for both groups, was conducted with participants shortly after their 24-week intervention process.

2.2. Setting of the human research

Research activities took place at the University of Arizona (UA) Collaboratory for Metabolic Disease Prevention and Treatment. The Collaboratory is located in a high need, underserved area of Tucson, Arizona whose residents suffer a disproportionate burden of chronic disease. All research activities were approved by the University of Arizona Institutional Review Board (IRB approval # 604536275).

2.3. Randomization

Participants were randomized to intervention arm using stratified block randomization with variable block sizes, where BMI category (overweight or obese) and diabetes status (yes/no) were used as strata. A computer randomization system was used to complete the randomization assignment by a statistician who had no contact with participants.

2.4. Study population

Individuals were considered eligible if they self-reported meeting all of the following criteria: 1) self-identified as Hispanic; 2) 18–64 years of age; 3) BMI between 25 and 50 kg/m^2 (we elected to cap this at 50.0 kg/m^2 to minimize potential risks and reduce the potential for obesity to limit exercise participation); 4) ability to provide informed consent and complete health risk assessment prior to participation in the pilot study; and 5) speak, read, and write English and/or Spanish.

Individuals were excluded if they self-reported meeting any of the following criteria: 1) Uncontrolled diabetes mellitus; 2) history of bariatric surgery; 3) reported medical condition or treatment for a medical condition that could affect body weight or ability to engage in structured physical activity that is consistent with the intervention for this pilot study; 4) currently treated for congestive heart failure, angina, uncontrolled arrhythmia, or other symptoms indicative of an increased acute risk for a cardiovascular event; 5) resting systolic blood pressure of ≥150 mmHg or resting diastolic blood pressure of ≥100 mmHg; 6) eating disorder that would contraindicate weight loss or physical activity; 7) alcohol or substance abuse; 8) currently treated for psychological issues (e.g., depression, bipolar disorder, etc.), taking psychotropic medications within the previous 12 months, or hospitalized for depression within the previous 5 years; 9) reported exercise on ≥3 days per week for ≥20 min per day over the past 3 months; 10) reported weight loss of ≥5% or participation in a weight reduction diet program in the past 3 months; or 11) reported plans to relocate to a location that limited their access to the study site or having employment, personal, or travel commitments that prohibit attendance to all of the scheduled assessments.

2.5. Recruitment and screening process

Face-to-face recruitment efforts primarily occurred at a swap meet (outdoor marketplace) frequented by the Hispanic community in Tucson. Family and friend referrals, printed advertisements, and social media posts comprised additional recruitment efforts. We also contacted individuals who had previously expressed interest in weight loss treatment and signed consent to be contacted for future intervention studies. Interested men were instructed to call study staff and a telephone screening was conducted to determine initial eligibility. Those

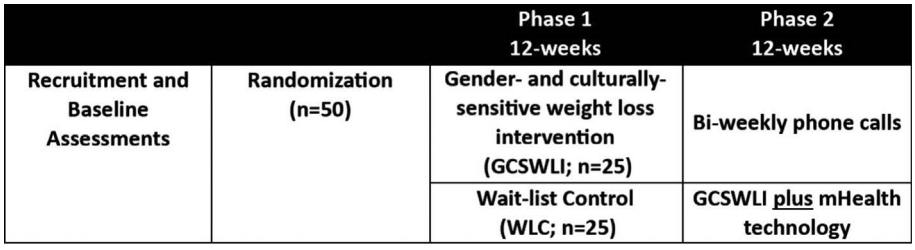

Fig. 1. Study phases and participant randomization for the ANIMO Pilot Study.