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Planned care for obesity and cardiovascular risk reduction using a stepped-down approach: A randomized-controlled trial

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ABSTRACT

Primary care-based approaches to address concurrent obesity and cardiovascular disease risk factors (CVDRFs) that begin with a high intensity intervention that is subsequently decreased (i.e., stepped-down) if weight loss is achieved have not been rigorously examined. Our study is a 20-month, single-blind randomized controlled trial at five primary care clinics in San Diego, CA, in 2013, where 262 obese adults (aged 25–70 years; 32.1% male; 59.2% white) with at least one CVDRF were enrolled into planned care for obesity and risk reduction (PCORR) using a stepped-down approach or enhanced usual care (EUC). All patients received physician recommendations for weight loss and CVDRFs. EUC patients (n = 132) received an individual session with a health educator every 4 months. PCORR patients (n = 130) received individual and group sessions (in-person, mail, telephone, and email) in three steps, characterized by less contact if success was achieved. At 20 months, 40.7%, 23.8%, and 15.4% of PCORR patients were in steps 1, 2, and 3, respectively (25.2% were lost to follow-up). PCORR resulted in a between-group difference in reduction in body weight of 6.1% [95% CI, 5.3 to 6.9] compared to EUC 2.8% [95% CI, 2.0 to 3.6] p = 0.007, with a greater reduction in BMI (35.2 [95% CI, 34.4 to 35.9] to 33.7 [95% CI, 32.9 to 34.5] kg/m^2) than EUC (36.0 [95% CI, 35.3 to 36.8] to 35.1 [95% CI, 34.3 to 35.9] kg/m^2), as indicated by a significant treatment by time interaction (p = 0.009). PCORR resulted in greater weight loss over 20 months than EUC.

Trial Registration: ClinicalTrials.gov, NCT01134029

1. Introduction

By 2030, 50% of the US population is projected to be obese (body mass index (BMI) ≥ 30 kg/m^2) (Wang et al., 2011). Obesity is associated with substantial increases in the risk of morbidity (e.g., hypertension, dyslipidemia, type 2 diabetes, and cardiovascular disease) and mortality (Kramer et al., 2013; Lavie et al., 2009). Previous research has demonstrated that modest reductions in weight (5% to 10% of body weight) through healthy changes in diet and physical activity can result in significant improvements in cardiovascular disease risk factors (CVDRFs) (Lavie et al., 2009; Wing, 2010). Given the increasing burden of obesity and the health benefits of weight-loss, there is a great need for clinically effective and resource-efficient weight-loss interventions.

Intensive multicomponent weight loss interventions are recommended for all obese adults (Moyer, 2012; National Institutes of Health, 2000). Stepped-care approaches that vary treatment intensity depending upon individual treatment response enable more efficient allocation of resources (Von Korff and Tiemens, 2000). The typical stepped-care approach uses a stepped-up process in which patients receive a low-intensity intervention to start, and if treatment goals are not met at designated time points, patients are given a more intensive intervention (Carels et al., 2012, 2009, 2007, 2005; Jakicic et al., 2012). Weight-loss studies that have utilized this approach report modest intervention effects and the need for a substantial number of participants to be stepped-up to a higher intensity intervention (Carels et al., 2012,

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2009, 2007, 2005; Jakicic et al., 2012).

Stepped-down interventions that begin with high intensity treatment that is subsequently decreased if goals are achieved have not been rigorously examined in randomized controlled trials with adequate sample sizes. The most effective intensive multicomponent behavioral interventions include 12 to 26 behavioral management sessions in the first year (Moyer, 2012; National Institutes of Health, 2000; Wadden et al., 2014). These typically include individual and group sessions that focus on weight-loss goal setting and self-monitoring, ways to improve diet and physical activity, and reducing barriers to adopting or maintaining healthy changes in behavior (Moyer, 2012; National Institutes of Health, 2000; Wadden et al., 2014). The amount of weight-loss early in treatment predicts success in achieving long-term weight-loss goals (Waring et al., 2014; Wing et al., 2004), suggesting that stepped-down approaches may be well suited for the treatment of obesity. However, to our knowledge, there has been only one pilot weight-loss study that has compared a stepped-down intervention to usual care among overweight or obese adults (Carels et al., 2013). The findings did not support efficacy of the stepped-down method but were limited by a small sample size and short follow-up (Carels et al., 2013). Another study conducted by our group did find some evidence supporting the efficacy of a stepped-down approach to generate weight-loss in adolescent boys (Norman et al., 2016).

In the present study, we utilized a stepped-down approach to deliver planned care for obesity and risk reduction (PCORR) that integrated behavior change theory with a delivery strategy based on the principles of the Chronic Care Model (CCM, also called the "Planned Care Model") (Bodenheimer et al., 2002; Coleman et al., 2009; Group Health Research Institute, n.d.). We are aware of no studies that explicitly incorporated these two approaches—a stepped-down behavioral intervention anchored in the CCM—to treat obese patients with increasingly common comorbidities. We hypothesized that PCORR would result in greater weight loss and improvement in CVDRFs than enhanced usual care (EUC) over the study period.

2. Methods

2.1. Study design

We conducted a single-blind randomized controlled trial among obese adults with additional CVDRFs in five primary care clinics in San Diego, California. Participants were followed for 20 months. The University of California, San Diego (UCSD) Institutional Review Board (#071942, 12/11/2007 to 5/20/2016) approved all study procedures and the trial was registered with ClinicalTrials.gov (NCT01134029). The funding source had no involvement in the design, data collection, analysis or interpretation of the data.

2.2. Setting and patients

From January 2010 to January 2012, physicians identified potential study participants during routine patient visits. Additionally, community-based advertisements, media, newsletters, and electronic mailing lists were used to elicit external providers to refer potential study participants. Patients who were referred by their physicians or who responded to advertisements were screened for eligibility by study staff via telephone interview.

Patients were English or Spanish-speaking adults aged 25 to 70 years living in San Diego County, CA with a BMI of 30 to 45.0 kg/m^2 and at least one additional CVDRF. CVDRFs included 1) hypertension defined as taking prescription of blood pressure-lowering medication or blood pressure > 140/90 mmHg; 2) metabolic syndrome defined as the presence of at least 3 of the following 5 factors: i) elevated waist circumference (≥ 40 in. (102 cm) for men and ≥35 in. (88 cm) for women), ii) elevated triglycerides (≥ 150 mg/dL), iii) reduced high density lipoprotein (HDL) cholesterol (< 40 mg/dL for men and < 50 mg/dL for women), iv) elevated blood pressure (≥130/85 mmHg), and v) elevated fasting blood glucose (100 to 125 mg/dL); 3) controlled type 2 diabetes defined as an hemoglobin A_{1c} (HbA_{1c}) < 8.5%; or 4) current smoker defined as the use of tobacco in cigarettes, cigars, or pipes at least once in the last 30 days. Exclusion criteria included having any type of bariatric surgery, the use of medications that alter weight, or enrollment in another weight loss program. Patients were also excluded if they had a diagnosis of type 2 diabetes within the previous 6 months or an HbA_{1c} level ≥ 8.5%, were unable to engage in moderate-intensity physical activity (e.g., walking) due to any pulmonary, cardiovascular, or musculoskeletal problem, were pregnant or planning to become pregnant during the study period, or had a history of substance abuse or other psychiatric disorder that would impair compliance with the study protocol.

Eligible patients provided written informed consent to participate in a 2-week run-in period that included activities similar to those that occurred throughout the 20-month study. The goal of this was to provide patients with a better understanding of the expected level of engagement in weight-loss related activities. Patients who satisfactorily completed the run-in period were enrolled in the study and provided written informed consent at their baseline visit. The study was originally planned for 24 months; however, unforeseen staffing circumstances, delays, as well as resource constraints necessitated a cutback to 20 months.

2.3. Randomization and blinding

After completing their baseline visit, participants were allocated to the study groups using computer-based permuted-block randomization with varying block sizes. Allocation was concealed from the participants, physicians, study staff, and investigators until the interventions were assigned. It was not possible to blind participants or the physicians and study staff who delivered the interventions. However, investigators who analyzed the data remained blinded to allocation throughout the study.

2.4. Interventions

All participants received physician recommendations for weight loss. Participants allocated to PCORR received: 1) primary care physician visits; 2) health educator visits; 3) health educator phone calls; 4) group sessions; and 5) mailed or emailed materials (see Table 1 for an outline of the intervention). These were delivered based on the CCM, where clinical information systems, decision support, delivery system design, self-management support, healthcare policy and community resources are integrated to provide obesity management within the primary care setting (Bodenheimer et al., 2002; Wagner et al., 1996). Within the framework of the CCM, non-physician health educators were utilized in PCORR as case-managers to improve clinical outcomes. PCORR applied a behavioral determinants model (Sallis et al., 1992). The behavioral determinants model, based on Social Cognitive Theory, specifies that there are personal, social, and environmental antecedents, or mediators, to changes in diet and physical activity behaviors (Bandura, 1986; Baranowski et al., 1997). This combined framework offered guidance for selecting the most appropriate mediators for behavior change for individual participants while providing support to promote success with long-term disease management.

The intensity and frequency of PCORR content was adapted to the needs of participants based upon their success in achieving weight loss during 4-month periods (i.e., steps). All participants began with Step 1, the most intensive step. Those who achieved 5% weight loss after 4 months were stepped-down to a less intense intervention, Step 2. Participants who failed to graduate to Step 2 continued the intervention activities of Step 1. If participants achieved 5% weight loss by month 8, they then progressed to Step 2. Participants who graduated to Step 2 after 4 months had the goal of continued weight loss to achieve an