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Tailored weight loss intervention in obese adults within primary care practice: Rationale, design, and methods of Choose to Lose

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ABSTRACT

Although there are efficacious weight loss interventions that can improve health and delay onset of diabetes and hypertension, these interventions have not been translated into clinical practice. The primary objective of this study is to evaluate the effectiveness and cost effectiveness of a tailored lifestyle intervention in primary care patients. Patients were recruited by their primary care physicians and eligible participants were randomized to an enhanced intervention or standard intervention. All participants met with a lifestyle counselor to set calorie and physical activity goals and to discuss behavioral strategies at baseline, 6 and 12 months. During the first year, enhanced intervention participants receive monthly counseling phone calls to assist in attaining and maintaining their goals. Enhanced intervention participants also receive weekly mailings consisting of tailored and non-tailored print materials and videos focusing on weight loss, physical activity promotion and healthy eating. The second year focuses on maintenance with enhanced intervention participants receiving tailored and non-tailored print materials and videos regularly throughout the year. Standard intervention participants receive five informational handouts on weight loss across the two years. This enhanced intervention that consists of multiple modalities of print, telephone, and video with limited face-to-face counseling holds promise for being effective for encouraging weight loss, increasing physical activity and healthy eating, and also for being cost effective and generalizable for wide clinical use. This study will fill an important gap in our knowledge regarding the translation and dissemination of research from efficacy studies to best practices in clinical settings.

1. Introduction

Obesity is a major public health problem that has reached epidemic proportions with 65% of the adult U.S. population overweight or obese [1]. Overweight individuals are at risk for developing co-morbid medical problems including hypertension, diabetes, and dyslipidemia. Many obese people already have these co-morbid medical problems, which along with obesity places them at increased mortality risk [2–4]. Primary care physicians (PCPs) are in a unique position to motivate patients to lose weight, improve their diet, and increase physical activity because they reach most segments of the population, and their expertise is highly regarded by patients [5]. Although

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interventions can produce weight reduction to improve health, and delay onset of diabetes and hypertension, existing research has not been translated into clinical practice. Most weight loss trials have been efficacy studies conducted on highly motivated participants led by teams of experts using multiple face-to-face encounters [6–11]. The expense and resource utilization involved in these efficacy trials make such an approach impractical and cost prohibitive in clinical practice. Most weight loss trials focusing on PCP counseling have been less intensive and have not demonstrated efficacy [12–18]. However, there is growing evidence that PCP referrals to weight loss programs and use of non-face-to-face interventions can be effective for weight loss [19–22]. Additionally, a recent, highly efficacious and less costly approach to the promotion of health behavior change has been the development of tailored interventions that match patient characteristics and treatment needs often delivered using computerized expert systems. Tailored interventions can be implemented by print, telephone, video or a combination of these media with limited face-to-face counseling [23–29]. They hold promise to be not only effective for encouraging weight loss, but also cost effective and generalizable for wide clinical use. These practical, innovative interventions can be easily replicated and sustained linking primary care practices with home-based programs supported by third party payers or employers. This study tests such an intervention in overweight or obese adults in a primary care setting using a randomized controlled trial.

The primary aim is to evaluate the effectiveness of a tailored lifestyle intervention in primary care patients: the Choose to Lose Study. First, we hypothesize that the enhanced intervention group would demonstrate greater reductions in their body mass index (BMI) and better maintenance of this change at 2 years compared to the standard intervention group. Second, we hypothesize that the enhanced intervention group would engage in greater levels of physical activity and would demonstrate greater reductions in total calories and maintain these changes at the 2 year follow-up compared to the standard intervention group.

The study has two exploratory aims: 1. To evaluate the cost of the intervention for replication purposes and the cost effectiveness of the intervention per unit of BMI loss (as well as physical activity and dietary change). 2. To examine relationships among important mediating variables with changes in BMI, diet and physical activity. These variables include: self-efficacy, decision-making, processes of change, perceived barriers, perceived social support, behavioral capability, outcome expectations, and problem solving skills. We will examine whether these variables mediate the intervention's success. We anticipate that successful weight loss, physical activity and dietary change will be correlated with positive changes in many of the above variables.

2. Methods

2.1. Overview of study design

This study is testing a tailored lifestyle weight loss intervention in overweight/obese patients recruited from primary care practices. A total of 211 patients with a BMI above 25 kg/m^2 were recruited from 24 PCPs. Participants were randomized into either a tailored lifestyle intervention focused on weight loss, physical activity, and nutrition (Enhanced Intervention) or a non-tailored, less intensive weight loss intervention (Standard Intervention). The intervention lasted 24 months, with the first 12 months focused on weight loss and the second 12 months focused on maintenance. All study procedures and materials were approved by the Institutional Review Boards at Memorial Hospital of Rhode Island and Brown University.

2.2. Recruitment of primary care providers

In April 2010, 111 provider recruitment letters were sent out to Family and Internal Medicine physicians representing 86 practices in Rhode Island and southeastern Massachusetts. Of the letters sent, 41 providers showed interest in the Choose to Lose Study, 2 providers declined. Of the 41 interested providers, 17 providers were not approached due to the following reasons: only one PCP per practice eligible to participate; PCP leaving the area; the geographic location of the practice; time constraints on the practice; or their self-reported inability to recruit at least 20 overweight/obese patients into the study. In the fall of 2010, the eligible providers were contacted to schedule a visit with the Principal Investigator (CBE) to provide detailed information about the study. Between October 2010 and September 2011, 24 providers (representing 24 practices) were consented and formally enrolled.

2.3. Participant eligibility criteria

Inclusion criteria included: men and women at least 18 years of age and less than 80 years old whose BMI was $\geq$25 kg/m^2; available for the entire 24-month study period; able to read and speak English; able to provide informed consent; able to accept phone calls; able to attend study visits; and have access to a DVD player.

Exclusion criteria included: diagnosed or hospitalization for active CVD disease in the past 6 months; history of a significant orthopedic limitations or other conditions that make exercise dangerous or extremely difficult; limited physical ability to be active (e.g., unable to walk briskly); another family member in the study; unstable psychiatric co-morbidity; participant requesting surgical treatment of obesity; weighing over 400 lb; participating in another clinical trial with regard to obesity or physical activity; having poorly controlled diabetes mellitus (hospitalized for poor diabetes control in the past 6 months); limited prescribed diet (e.g. gluten free diet); present treatment for an eating disorder; taking over the counter diet aids or medications for weight loss for the previous 6 months; underwent treatment for cancer in the past 5 years; end stage renal disease requiring dialysis; chronic steroid therapy; major surgery in the past month; planning a pregnancy in the next two years or delivered a baby within the past six months; exercising $\geq$90 min/typical week of moderate intensity activity; unwilling or unable to complete study requirements.

2.4. Recruitment of participants

Patients were recruited through their PCPs. Recruitment occurred in two ways: 1) the provider obtained their patients' written authorization for them to be contacted by the research staff or 2) after discussing the study with their provider, patients initiated contact with the research staff.