Methodology of a multispecialty outpatient Obesity Treatment Research Program

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ABSTRACT

Despite the large number of U.S. adults who overweight or obese, few providers have ready access to comprehensive lifestyle interventions, the cornerstone of medical obesity management. Our goal was to establish a research infrastructure embedded in a comprehensive lifestyle intervention treatment for obesity. The Obesity Treatment Research Program (OTRP) is a multi-specialty project at Mayo Clinic in Rochester, Minnesota designed to provide a high intensity, year-long, comprehensive lifestyle obesity treatment. The program includes a nutritional intervention designed to reduce energy intake, a physical activity program and a cognitive behavioral approach to increase the likelihood of long-term adherence. The behavioral intervention template incorporated the Diabetes Prevention Program and the Look AHEAD trial materials. The OTRP is consistent with national recommendations for the management of overweight and obesity in adults, but with embedded features designed to identify patient characteristics that might help predict outcomes, assure long-term follow up and support various research initiatives. Our goal was to develop approaches to understand whether there are patient characteristics that predict treatment outcomes.

1. Introduction

Despite how frequently patients present for adiposity-related health problems, many providers do not have access to an organized obesity treatment program that employs all of the modalities needed to implement a comprehensive lifestyle intervention. The optimal outcomes of weight loss medications, bariatric surgery and endoscopic procedures are attained in conjunction with lifestyle treatment that includes a nutritional intervention designed to reduce energy intake, a physical activity program designed to increase energy expenditure, and a cognitive behavioral approach to increase the likelihood of long-term adherence to dietary changes and greater physical activity [1]. Although there are variations in the components of any given lifestyle intervention, there are reasonable templates for the behavioral components of weight management, including the Diabetes Prevention Program and the Look AHEAD protocol [2,3].

The goal of the Obesity Treatment Research Program (OTRP) is to establish a high intensity, year-long, comprehensive lifestyle treatment program for the medical management of obesity at Mayo Clinic, Rochester, MN, that is consistent with the recommendations of the 2013 American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society Guidelines for the Management of Overweight and Obesity in Adults [4]. As part of the development process we sought to build in features that could help to improve the program outcomes by identifying patient characteristics that might predict successful weight loss or early drop out. If successful, this approach will allow future, selective enrollment of adults most likely to benefit from participating in a comprehensive lifestyle program. The nutritional, physical activity, behavioral and pharmacological approaches were developed by consensus amongst groups of primary care and specialty care providers; ancillary protocols were solicited from subspecialty providers.

We have the following 3 sub-goals: 1) To provide this intervention as a resource to Mayo Clinic investigators who wish to study the effects of non-surgical weight loss on health; 2) To provide support to Mayo Clinic investigators to allow them to gather preliminary data for funding proposals; 3) To serve as a "baseline" program to attract prospective, randomized clinical trials from other sources. This program developed an intensive lifestyle intervention to assist patients in modifying eating habits and increasing physical activity. We also developed a strategy to collect data that supports a number of investigators with an interest in adiposity-related illnesses.

1.1. Protocol

1.1.1. Study design

1.1.1.1. Overview. The goal is to enroll a group of subjects approximately every 3 months. This allows for reasonably rapid participation enrollment and utilization of a closed group format with 15–20 participants per group.

Potential participants attend a group information session and are interviewed by the study coordinator. After signing informed consent, they will obtain clinically indicated pre-treatment laboratory studies if they have not had the requisite laboratory examinations done within the previous 6 months. A number of research measures are included in the protocol (Table 2). These measurements are designed to provide data that may help improve the long-term treatment outcomes and to better understand the prevalence of adiposity-related conditions in this population and their response to weight loss.

In addition to cognitive and behavioral therapy concepts taught in group classes, a nutritional intervention designed to reduce energy intake and a physical activity prescription to increase activity will be incorporated. We include an option for weight management pharmacotherapy if deemed appropriate by the participant's primary care provider in conjunction with a co-investigator physician. At the time this protocol was being developed, only orlistat was approved by the Food and Drug Administration for long-term obesity treatment. The education group classes were designed to be 1 h in duration and held 0700–0800 h (before work), 1200–1300 h (lunch hour) or 1600–1700 h (after work). Participants were invited to join the group that best fit their schedule after completion of the entry questionnaires.

1.1.1.2. Eligibility criteria.

Inclusion criteria:
- Adult ages 18–65 years
- Body mass index (BMI) 27–39.9 kg/m^2 (the BMI criteria was modified to include those with a BMI up to 49.9 kg/m^2 based upon a requests from referring providers).
- Able to provide informed consent
- Referred from a primary provider after screening with the PHQ-9 to exclude severe depression.

Exclusion criteria:
- Any active health problem that prevents physical activity
- Previous obesity surgery
- Current participation in a program specifically to lose weight
- Use of weight loss medications within the previous 30 days
- Presence of current nonspecific suicidal thoughts as defined by the PHQ-9 (see below)
- Presence of a clinically significant psychiatric condition (psychosis, bipolar disorder or depression) that is insufficiently controlled to allow participation in the study
- A known history (past 24 months) of substance use disorder
- Women who are currently pregnant or lactating
- A major cardiovascular event within the previous 3 months - including cardiac arrhythmia, congestive heart failure, acute coronary syndrome, stroke, transient ischemic attack or peripheral vascular disease and advice from their primary care physician or

cardiologist of major contraindications for exercise
- A known history of any condition or factor that the investigator judges to preclude participation or adherence to the study.

1.1.1.3. Recruitment. Participants in the study are enrolled primarily from the Mayo Clinic Employee and Community Health (ECH) practice and Olmsted Medical Center primary care clinics, both in located in Rochester, MN. The participants can be referred to the program by their primary care provider or may self-refer with documented permission from their primary care provider.

1.1.1.4. Informed consent. This protocol was reviewed and approved by the Mayo Clinic Institutional Review Board. All participants provide written, informed consent. Because of the need to assess the long-term outcomes, the consent includes permission for investigators to use Mayo Clinic electronic medical records (EMR) for research specifically related to this program. Participants can withdraw permission by notifying the IRB of their desire to do so.

1.1.1.5. Potential outcomes and study measures. Entry and outcome measurements will include weight, BMI [5], blood pressure [5], waist circumference, hip circumference, neck circumference, participant retention and dropout rates. Periodic follow up of vital signs and laboratory test results is done using the Mayo Clinic electronic medical record (EMR), including a review of both dropouts and those that complete the program. Information from the questionnaires and EMR will be used to track changes in laboratory results, sleep and mood for those that remain in the program for one year.

1.1.1.6. Measurements. A number of research measures are included in the protocol (Table 2). These measurements are designed to provide data that may help improve the long-term treatment outcomes and to better understand the prevalence of adiposity-related conditions in this population and their response to weight loss.

Weight will be measured by calibrated scales as previously described [6]. Waist and hip circumferences will be measured using standardized methods by trained personnel [7]. Neck circumference will be measured using the same tape measure. The Endo-PAT procedure [8,9] (Itamar Medical, Caesarea, Israel) will be completed for the first 100 participants (Table 2).

Body composition will be measured by air displacement plethysmography using the BodPod (Life Measurement Inc, Concord, CA). The device will be calibrated before each test against a standardized cylinder. We will obtain each subject's fat mass and fat free mass based on the following Siri equation: Body Fat = $(4.95/\rho$ - $4.50) \times 100$.

Physical activity will be monitored by asking each participant to acquire a pedometer or other device.

Self-monitoring of dietary quality will be done by either a smart phone application or manual paper records depending upon the volunteer's access to technology.

1.1.1.7. Research surveys for psychological phenotyping. After signing informed consent, participants are sent 3 e-mail links unique to their identity to allow them to complete the on-line surveys. Potential volunteers who do not complete the surveys are not considered enrolled in the study and are not invited to participate in the program. The survey data is directly entered into the Scientific Data Management System (SDMS) to facilitate data collection and management. A list of the surveys we selected is provided in Table 1. The types and numbers of surveys include: physical activity readiness [10], eating behavior [11–13] and attitudes [14], sleep quality [15,16], quality of life [17], gastrointestinal symptoms [18,19], personal [20] and family history [21] of alcohol and drug use [22], anxiety [23], stress [24], impulsivity [25], resilience [26] and history of childhood abuse (1 question). Some of the questionnaires contain sensitive or personal questions (Table 1). However, because the data is reviewed