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Methodology of a multispecialty outpatient Obesity Treatment Research Program

Dalia S. Mikhail[a], Teresa B. Jensen[b], Todd W. Wade[b], Jane F. Myers[b], Jennifer M. Frank[b], Mark Wieland[c], Don Hensrud[a], M. Molly McMahon[a], Maria L. Collazo-Clavell[a], Haitham Abu-Lebdeh[a], Kurt A. Kennel[a], Daniel L. Hurley[a], Karen Grothe[d], Michael D. Jensen[a,*]

[a] Division of Endocrinology, Mayo Clinic, 200 1st St SW, Rochester, MN 55905, USA
[b] Department of Family Medicine, Mayo Clinic, 200 1st St SW, Rochester, MN 55905, USA
[c] Division of Community Internal Medicine, Mayo Clinic, 200 1st St SW, Rochester, MN 55905, USA
[d] Department of Psychiatry and Psychology, Mayo Clinic, 200 1st St SW, Rochester, MN 55905, USA

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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.

* Corresponding author. Endocrine Research Unit, 200 1st St SW, Rm 5-194 Joseph, Endocrine Research Unit, Rochester, MN 55905, USA.
E-mail addresses: mikhail.dalia@mayo.edu (D.S. Mikhail), jensen.teresa@mayo.edu (T.B. Jensen), wade.todd@mayo.edu (T.W. Wade), myers.jane@mayo.edu (J.F. Myers), frank.jennifer2@mayo.edu (J.M. Frank), wieland.mark@mayo.edu (M. Wieland), hensrud.donald@mayo.edu (D. Hensrud), mcmahon.molly@mayo.edu (M.M. McMahon), collazoclavell.maria@mayo.edu (M.L. Collazo-Clavell), abulebdeh.hs@mayo.edu (H. Abu-Lebdeh), kennel.kurt@mayo.edu (K.A. Kennel), hurley.daniel@mayo.edu (D.L. Hurley), grothe.karen@mayo.edu (K. Grothe), jensen@mayo.edu (M.D. Jensen).

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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

Table 1
Required questionnaires.

	Baseline	24 weeks	48 weeks
1.Yale Food Addiction Scale (YFAS) *	x	x	x
2.Barratt Impulsiveness Scale (BIS) *	x		x
3.Family/personal history of addiction *	x		x
4.Alcohol Use Disorders Test (AUDIT) *	x		x
5.Drug use	x		x
6.Childhood Trauma (1 question) *	x		x
7.Self-efficacy for eating	x	x	x
8.Self-efficacy for physical activity *	x	x	x
9.Binge Eating *	x	x	x
10.Generalized Anxiety Disorder (GAD-7) *	x	x	x
11.Perceived Stress Scale (PSS) *	x	x	x
12.CD Resilience Scale (CD-RISC 10) *	x		x
13.Weight Management Support Inventory (WMSI) *	x		x
14.Health Survey Questionnaire (HSQ) *			x
15.European Quality of Life-5 (EQoL-5D) *			x
16. Physical Activity Readiness Q (PAR-Q) *	x		x
17.The Three Factor Eating Questionnaire (TFEQ-R18v2) *	x	x	x
18.Pittsburgh Sleep Quality Index (PSQI) *	x		x
19.Night Eating Questionnaire (NEQ) *	x		x
20.Berlin Questionnaire *	x		x
21.Reflux Symptom Questionnaire (RSQ) *	x	x	x
22.Gastrointestinal Symptom Rating Scale (GSRS) *	x	x	x

collectively rather than individually, we can assure volunteers that their privacy will not be jeopardized. We obtained a Certificate of Confidentiality for this study.

1.1.1.8. Interventions. The comprehensive lifestyle intervention group meetings are held weekly for the first three months, biweekly for the following three months, and monthly for the last six months. During meetings, food intake diaries may be evaluated and physical activity (pedometer or activity monitor data) may be reviewed.

1.1.1.8.1. Nutrition intervention approach for weight management. A tiered nutrition intervention was selected because some patients may have greater success with one approach than another. Fig. 1 outlines our tiered approach to nutrition intervention.

The planning group consensus was to base the initial dietary program upon a "volumetrics" approach. Low-energy-dense diets incorporated into weight loss programs encourages reduced energy intake without reducing food volume, helping to minimize the feelings of hunger and food deprivation [27]. The diet includes increased vegetables, legumes and fruits and lesser amounts of energy dense foods. A detailed outline of the nutrition intervention approach follows:

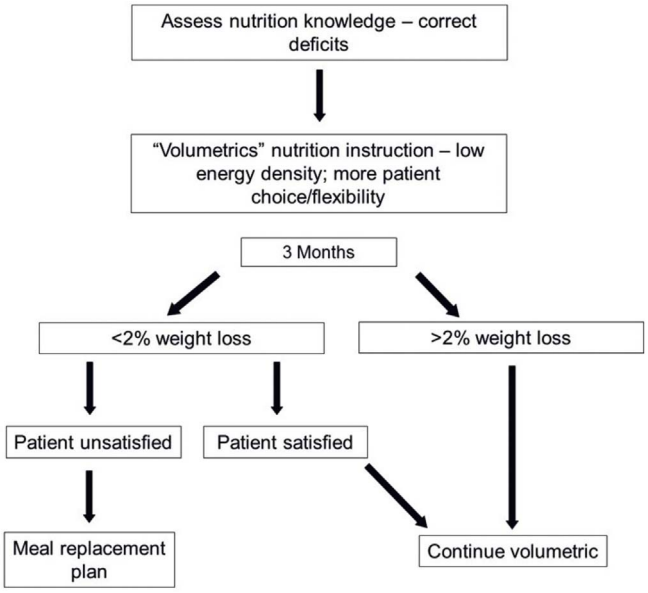

Fig. 1.. Nutrition intervention approach for weight management.

1. Energy density principles: Energy density is defined as the ratio of energy to food volume. This will be explained to participants as amount of calories per volume of food consumed; stressing upon the fact that foods with high fiber and high water content are low energy density foods while foods high in fat and low in water content are high energy density foods. We will emphasize the concepts that a high *volume* of food intake can allow satiety while consuming fewer calories and thus aid weight loss. Participants will be given examples of foods on both ends of the energy density spectrum. They will also be taught how to interpret energy density by looking at food labels and comparing the number of grams and number of calories in one food serving [27].
2. Meal Replacements: Patients who are not successful with weight loss after 3 months of nutrition, activity and behavior interventions may transition to the second nutrition intervention tier – a meal replacement approach. The 3-months' time interval is selected to allow sufficient participation in cognitive behavioral group classes to increase the likelihood of success with the volumetric approach. Meal replacements have been shown to be an effective weight-loss strategy as most meal replacements are calorie-controlled [28]. If employed, the most common strategy is 1–2 meal replacements per day, with a healthy 3rd meal. This 3rd meal will be recommended as a balanced, nutritious meal with a selection of protein, vegetables,

Table 2
Program schedule.

Weeks	−2	−1	0	4	8	12	16	20	24	28	32	36	40	44	48
Phone Pre-Screen for study criteria	x														
Informed consent		x													
Medical History	x														
Height		x													
Blood Pressure (BP)		x	x			x			x			x			x
Weight			x	x	x	x	x	x	x	x	x	x	x	x	x
BMI			x	x	x	x	x	x	x	x	x	x	x	x	x
Circumferences - waist, hip and neck			x			x			x			x			x
Fasting blood glucose			x												x
Serum total, HDL and LDL-cholesterol			x												x
Serum triglycerides			x												x
Serum Alanine Transaminase (ALT)			x												x
Serum Aspartate Aminotransferase (AST)															
Stool samples			x			x									x
Endo-PAT			x						x						x

whole-grain starch, and optional calorie controlled additions such as dessert.

1.1.1.8.2. Physical activity intervention for weight management. The weight management protocol emphasizes physical activity as an important element of maintaining a healthy weight and improving overall health. The elements of physical activity addressed for participants in the protocol include:

1. The type of activity – we emphasize walking as the primary recommended activity except when the patient has physical limitations that preclude walking. Second choice activities will be at the discretion of the interventionist and will be designed to approximate the same amount of activity as walking.
2. a) The preferred activity is walking, with monitoring using a pedometer or other device. At the beginning of the intervention, we ask participants to provide their step count data weekly for entry into a database. The eventual recommended goal is 10,000 steps per day. We recommend participants employ their step counting device on a daily basis.b) For participants unable to walk due to orthopedic limitations we will ask them to choose an alternative activity, such as bicycling or swimming, and to track the amount of time and intensity of that activity. The targeted amount of activity will be equal to the energy expenditure equivalent of 10,000 steps per day. Adjustments to these goals will be based upon clinical indications as determined by the primary care provider and the interventionist.
3. Achieving goal activity – the approach involves an initial 1–2 weeks of baseline assessment followed by gradual increases to achieve goal amounts of activity. The rate of progression is based upon the participant's tolerance and ability to work greater amounts of activity into their daily routine.

1.1.1.8.3. Behavior protocol. We will include the standard elements of cognitive behavior therapy for weight management – self-monitoring, managing expectations, goal setting, stimulus control, stress reduction, problem solving, social support, cognitive restructuring, and relapse prevention. Self-monitoring is a key component, as frequent, consistent self-monitoring for dietary intake is associated with greater weight loss [29–31] We also focus on motivational enhancement strategies (a patient-centered approach that promotes behavior change through exploring ambivalence in a non-judgmental, but directive manner) throughout the program. We adapted intervention materials from the Diabetes Prevention Program, as well as evidence-based mindfulness modules and strategies to enhance motivation [32–35].

1.1.1.8.4. Pharmacotherapy intervention for weight management. The protocol for weight management intervention includes the option for pharmacotherapy as a treatment for weight loss or weight loss maintenance.

Program goal for implementing pharmacotherapy:

1. Participants will need to complete 6 months of nutrition/behavioral/activity intervention before considering orlistat.
2. If the participant is unsuccessful with weight loss efforts (i.e. losing < 5% body weight within 6 months) orlistat will be considered if the following criteria are met: BMI > 30 kg/m^2 without metabolic complications and < 5% weight loss or BMI 27–30 kg/m^2, with metabolic complications and < 5% weight loss.
3. If orlistat is considered, the participant will contact their primary care provider to assure that there will be no contraindications to prescribing the medication (e.g. planned pregnancy, use of cyclosporine, severe liver disease, calcium oxalate kidney stones) and for participants to receive adequate education of potential medication side effects and the use of vitamin supplements.
4. If orlistat is prescribed the participant will have a consultation with the research dietitian to receive dietary instructions on how to minimize side effects during orlistat use.
5. If orlistat is used and there is insufficient weight loss (< 5% of initial weight) after 3 months, the medication will be stopped.

1.1.1.8.5. Participant safety.

1. In addition to confirming with the primary care provider any safety contraindications to activity, the participants receive an activity evaluation and education to avoid activity-related injury. Subjects who are Mayo employees or their dependents will be able to use resources at the Mayo Clinic Dan Abraham Healthy Living Center (DAHLC) for their activity evaluation and education. In addition, Mayo patient education resources will be provided to all participants. Participants who are not eligible for DAHLC support will receive counseling and advice from a research dietician.
2. We will provide subjects who cannot or do not wish to use the DAHLC with educational support similar to those available at the DAHLC.
3. The Department of Psychiatry and Psychology reviewed current literature through Google, OVID and PSYCH INFO databases for English language articles and found no evidence that any of the screening questionnaires have been shown to provoke a state of mind requiring urgent intervention. A variety of terms were used to review the literature (i.e., “impact of psychological assessment,” “emotional response to research questionnaires,” “impact of psychological research/screening”).

1.1.1.8.6. Program improvement plan. In order to improve the outcomes from this new program we request direct participant feedback with regards to what aspects were helpful and which were not; in essence forms of focus group. We will also assess whether any of the pre-intervention survey results are predictive of early dropout or success and then, if the findings can be replicated, use those surveys as screening tools for entry of future participants. We plan to eventually incorporate survey research tools to determine whether the concepts we are teaching have been well-learned by the participants and whether better knowledge is associated with better outcomes. Finally, we will continue to monitor the literature for evidence that alternative diet approaches are promising and, if so, implement randomized trials within the overall protocol.

1.1.1.8.7. Biostatistical considerations. All analyses will be performed utilizing two-sided tests with a significance level α of 0.05. Relevant p-values and 95% confidence intervals (CI) will be reported. Univariate analyses will be reported as proportions and mean where appropriate, accompanied by standard deviations. Multivariate analyses will be performed to control for confounders. Demographic characteristics of participants will be expressed as means plus and minus standard deviation. Average weight loss will be expressed as percentage of original body weight change and 95% CI. Means will be compared between “completers” and “drop outs.” Student t tests will be used to compare means and calculated p-values. Odds ratios will be used to assess the likelihood of a psychological assessment tool to predict drop outs. The means of different physiological indices will be compared between completers and dropouts with P values calculated. Because this is not a randomized, prospective trial the statistical analyses will be required to employ adjustments for multiple post-hoc comparisons when testing for associations. The primary prospective hypothesis is that participants who drop out of the program will not lose as much weight as participants who do not drop out. The weight loss for participants who drop out will be obtained from medical record review.

2. Discussion

Our comprehensive lifestyle intervention for weight loss is in line with the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society [4]. The task force recommends that the principal components of an effective high-intensity, on-site comprehensive lifestyle intervention include: a) prescription of a moderately reduced-calorie diet, b) a program of

increased physical activity, and c) the use of behavioral strategies to facilitate adherence to diet and activity recommendations. It is also recommended that programs have at least 6 months of high intensity sessions (14 sessions or more in 6 months) to be effective [4]. There is also evidence that one year programs are superior to 6 month programs. In addition, low-to moderate-intensity lifestyle interventions for weight loss provided to overweight or obese adults by primary care practices alone have not been shown to be effective [4,36]. The Obesity Treatment Research Program at the Mayo Clinic, Rochester, Minnesota will provide a unique research model for a high intensity, comprehensive lifestyle treatment program for the medical management of obesity. The research protocol is developed to yield information that will provide for more focused interventions to future participant groups based on evidence from the preceding groups. Specialists in Endocrinology, Sleep Medicine, Gastroenterology, Cardiology, Psychology and Primary Care Internal Medicine and Family Medicine will participate and collect data from the participants. The protocol includes the ability to enroll up to 500 participants over 5 years.

We suggest that this protocol is unique in several aspects. First, the design allows for the development of a program that acts as a backbone for additional research assessments that are incorporated both at the beginning and later as the program evolves. Second, we employ a comprehensive group of surveys before enrollment that allow us to develop psychological, eating behavior, social, sleep and gastrointestinal phenotyping data that may serve to identify factors that can predict early dropout, poor weight loss or extreme success. The use of a web linked survey result entry system will significantly reduce data entry work load, reduce cost, decrease risk of mistaken entries, and enable us to import metrics directly to electronic data sheets ready for statistical analysis [37]. Another unique aspect of this protocol is that we will collect weight loss data for drop outs through access to the EMR. There is very little research in the literature regarding predictors of who drops out from lifestyle intervention programs [38–40]. This aspect of the protocol will enable us to understand treatment results for both completers and drop outs for extended periods of time as data suggests that 80% of Olmsted County residents are seen at least once in the health care system within one year [41].

This program is initiated with funding support from the Mayo Clinic Rochester Department of Medicine as one of their research efforts. In this way, the initial participants will not have to pay for the services. The goal is to refine and improve the program in order to be able to document success, thereby allowing it to serve as a contract program for research studies sponsored by industry, NIH and professional societies, as well as to attract clinical referrals from insurance providers or patients who are willing to pay out-of-pocket.

3. Conclusion

Although there are many different options for the treatment of obesity, there has been little study as to how to select the one(s) most appropriate for an individual patient. Our comprehensive lifestyle program protocol was developed using a multispecialty approach with the goal of collecting data that will allow modification of the program and the different arms to test hypotheses based on review of outcomes. This can lead to stepwise iterations and improvements in long term outcomes based upon the comprehensive intake and follow up data. This is a consensus driven protocol developed by both specialists and primary care providers, and therefore includes multiple research aspects.

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