Phone Coaching for Weight Loss Maintenance

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Weight Maintenance Rescue Study

Participants from previous studies at the Weight Control and Diabetes Research Center who have completed a 1-year weight loss (WL) program and lost ≥5% of their initial body weight will be eligible to participate in this WL maintenance study (eligible age range: 18-72 years). While attending their 1-year assessment visit, eligible participants will be provided with information about our WL maintenance study and asked whether they would be interested in participating. They will have the opportunity to discuss this study with a member of the research team and if interested, they will sign the informed consent document. For those individuals unable to attend an in-person visit, they will be mailed two informed consent documents and a member of the research staff will review the consent document and all study procedures with him/her via the phone. Further, this individual will have the opportunity to ask questions related to the study prior to signing the informed consent document. Once signed, the participant will mail one of the signed consent documents back to the researchers using a postage-paid envelope. Details for this study are provided below.

Purpose: This WL maintenance study is designed to examine whether the provision of a brief period of phone coaching to individuals who regain ≥1.5% from the start of the maintenance study, prevents further weight regain, compared to individuals who do not receive any coaching.

Design: Participants who lost ≥5% of their initial body weight after completing a 1-year WL program will have the opportunity to enroll in this WL maintenance study. Those signing informed consent will be randomized at baseline (start of maintenance study) to one of 2 conditions: 1) provision of a brief period of phone coaching as soon as they regain ≥1.5% of their starting maintenance weight (Small Regain), or 2) no phone coaching, independent of weight regain (Control). Participants will not be informed of the criteria used to determine who receives phone coaching. Participants will be followed for 1 year and will complete assessments of weight, physical activity and various questionnaires at baseline, 6 and 12 months. They will be compensated $25 in cash for completion of the 6 and 12 month assessments.

WL maintenance program components: All participants will be encouraged to continue to weigh themselves daily and they will be provided with a smart scale, which electronically transmits their weight data via cellular network technology so that it can be reviewed weekly by a member of the research team. If the participant is unable to come to our center to pick up a scale, we will mail the scale to his/her house. All smart scales will be programmed with participant's ID number and no personal identifiers will be utilized. If participant's do not weigh themselves for 7 consecutive days, a member of the research staff will contact the participant and encourage him/her to step on the scale. As part of the study, participants will also be provided with a monthly newsletter which will provide them with helpful strategies for maintaining their weight loss long-term. Smart scales will be returned to research staff at the 12 month assessment visit.

Phone coaching intervention: Participants randomized to the Small Regain group will be contacted by a coach if they regain ≥1.5% of their starting maintenance weight. To ensure that this is true weight regain and not just a fluctuation of weight on the scale, the participant's weight will need to be above the predetermined threshold for 4 consecutive days or if their 7-day average falls above this threshold (whichever occurs first). The coach will serve as a source of support for the participant after a period of weight regain. The coach will seek to establish rapport and encourage the participant while offering a supportive environment to problem solve around barriers to continued weight loss and set goals related getting back on track, which is consistent with the Supportive Accountability Model by Mohr and colleagues. Participants will

also be encouraged to 'go back to the basics' which include meal planning, self-monitoring, and goal setting. While the structure of the coaching calls will be similar across participants, the content will be tailored to the individual. Coaches will set goals with participants on each call and will follow up with them the following week. Calls will be provided for 4 consecutive weeks. The first call will be approximately 20-30 minutes in duration and follow-up calls with be 10-15 minutes. All coaching calls will be recorded for fidelity purposes.

Assessments: Assessments will occur at baseline, 6 and 12 months. This will consist of several questionnaires measures, weight, and physical activity. Brief descriptions of these measures of provided below.

Weight, height, and body mass index. Objective measures of weight and height will be performed using standard procedures. Calculations of body mass index, absolute weight change in kg, and percent weight change from the start of the maintenance period will be calculated.

Physical activity. Physical activity will be objectively-measured for 1 week at each assessment time point using the newest generation of Actigraph accelerometers (Actigraph GT9X Link). Participants will be instructed to wear the accelerometer on their waist during all waking hours, exclusive of bathing and swimming, for 7 consecutive days at each assessment period. Accelerometer data will be processed and analyzed using Actigraph's ActilLife software.

Baseline only questionnaires: At baseline, participants will complete a **Demographics** questionnaire and will also complete a brief questionnaire asking about their weight over the previous 6 months and their weight goals over the next 12 months **(Weight History and Weight Goals Questionnaire).** Cognitive function along dimensions of behavioral regulation and metacognition will also be assessed using the **Behavior Rating inventory of executive functions- adult self- report version (BRIEF-A).**

Perceived support will be measured in three ways. First, all participants will complete the ***Important Others Questionnaire*** which measures the participants perception of the supportiveness of 'important others' which can be a family member, spouse, friend, or coach with respect to their diet and PA behaviors. This will allow for comparisons in perceived support between all three treatment groups which is important for meditational analyses. Further, the **Supportive Accountability Questionnaire** will be used to assess additional aspects of eating and physical activity-related support from friends, family, and coaches. Finally, it is equally important to measure the strength of the coach-participant bond; thus those randomized to Small Regain who receive coaching will also complete the ***Helping Alliance Questionnaire***.

Self-efficacy for diet will be assessed using the ***Weight Efficacy Lifestyle (WEL) Questionnaire*** which assesses one's confidence in their ability to avoid overeating when faced with certain situations. Self-efficacy for PA will be assessed by the **Self-*Efficacy for Exercise Scale*** which evaluates an individual's confidence to exercise when faced with a variety of barriers such as fatigue or a lack of time.

Weight-related behaviors. Important weight-control behaviors will be assessed using the ***Weight Control Strategies Questionnaire*** which consists of 4 subscales: dietary choices, self-monitoring strategies, physical activity, and psychological coping. Reasons why individuals choose to engage in specific behaviors to manage their body weight will be evaluated by the ***Reasons for Weight Management Questionnaire*.** Habit strength for physical activity and healthy eating will be measured using the **Self-Report Habit Index** (one questionnaire for

eating and one for physical activity). This measure captures features of exercise and healthy eating as routine, frequent, and automatic. Coping strategies in response to dietary lapses will be assessed using the **Aftermath of Dietary Lapses Coping Questionnaire**. This questionnaire assesses self-reflective thoughts, compensation by healthy eating, compensation by exercising, self-monitoring, and positive thoughts. Emotional eating will be assessed via the **Palatable Eating Motives Scale.** The use of various technologies and smartphone apps for tracking and monitoring weight related behaviors will be assessed using the **Smartphone and App Usage Questionnaire.**

Psychological constructs. The salience of identifying with exercise as an integral portion of self-concept will be assessed using the **Exercise Identity Scale**. Given that exercise is an important behavior for long-term weight loss maintenance, this scale will assess whether identification as 'an exerciser' predicts long-term physical activity adoption.

Monthly questionnaire. In addition to the abovementioned questionnaires that participants will complete at each of their assessment visits. Participants will also be asked to complete a monthly questionnaire. This will assess weight-related behaviors over the previous month and weight-related intentions for the upcoming month. Participants who complete >70% of these surveys will be provided with a feedback report at the end of the 12-month program.

Data collection and management. All assessment data will be entered into the data management program by a member of the research staff. Range checks will be built into the data entry procedure to alert staff to data that requires additional clarification. Dr. Unick will conduct error checking and preliminary analyses of all data to ensure accuracy. Questionnaire data will be collected using REDCap (Research Electronic Data Capture), which is a secure, web-based application designed to support data capture for research studies and is hosted by Lifespan. It provides an intuitive interface for validated data entry, audit trails for tracking data manipulation and export procedures, and automated export procedures for seamless data downloads to common statistical packages. Only IRB approved research staff will have access to the REDCap platform and staff members will be granted access through a secure login provided by the study PI.

PROTECTION OF HUMAN SUBJECTS

Risks to Subjects

Human Subject Involvement and Characteristics: Participants in this study will be a sample of men and women, aged 18-72 years, who recently completed a 1-year weight loss program and achieved a weight loss >=5% of initial body weight. Further, they cannot currently be enrolled in another weight management program at the time of study entry.

Sources of Research Material: Data will be obtained specifically for research purposes via direct measurement and questionnaires. Height and weight will be directly measured, physical activity will be objectively-assessed using the Actigraph GT9X Link accelerometer, and demographic information, and dietary and weight control practices will be assessed via questionnaire. Daily weights will be collected via Smart Scales, ever time the participant weighs him/herself. Further, intervention adherence data, the number of phone coaching calls completed, the length of each phone call, and interventionist time will recorded.

Potential Risks: The risks associated with this study are quite minimal. The intervention instructs participants to engage in moderate-intensity exercise of 250 minutes/week. Therefore, it is possible that an individual could experience some muscle soreness or an injury as a result of the exercise. Further, the risk of a sudden cardiac event occurring during exercise is very minimal and is estimated to be approximately 1 per every 36.5 million hours of moderate-to-vigorous exertion. In addition, it is possible that participants may engage in unhealthy dietary practices, but this is not likely and precautions will be taken to minimize this risk. Finally, there is the risk that the participant will not maintain their weight loss as a result of this program. However, this is a potential risk for any weight loss maintenance program.

Protection Against Risk: Participants will have their weight objectively-assessed at baseline, 6, and 12-month assessment visits. If the rate of WL is too severe, or if the participant reports unsafe weight control practices at these visits, the Principal Investigator will discuss these issues with the participant. Further, protection against the risk of a breach of confidentiality will be minimized through careful adherence to best practices for data collection and management. Dr. Unick and staff at the WCDRC have extensive history conducting clinical trials and management of identifiable data from participants randomized to a weight management program.

Potential Benefits of the Proposed Research to Subjects and Others

Participants will receive a behavioral weight loss maintenance intervention which teaches healthy eating and exercise behaviors for successful long-term weight loss maintenance. This program has the potential to help participants lead to sustained weight loss long-term and associated health improvements. Thus, while the potential risks of this study are quite minimal, the potential benefits are quite significant.

Importance of Knowledge to be Gained

Effective weight loss maintenance programs are critical for combatting the current obesity epidemic. This study is significant because it seeks to evaluate whether the provision of a brief period of phone coaching, when provided after a period of weight regain, can assist individuals with maintaining weight loss long-term. If effective, this is a model that has great dissemination potential. Findings for this study could have important implications for obesity treatment.

Educational Training of Staff

All investigators and staff will be required to obtain education regarding the protection of volunteers in research from their own institution. The Miriam Hospital follows this plan:
In June, 2005, the Office of Research Administration contracted with CITI, a Collaborative Institutional (modular) Training Initiative program, for our Human Subjects protection and HIPAA training for all research personnel. Currently this program offers our researchers a basic human subject's protection course as well as a refresher course which we require every three years. Documentation of successful completion is automatically generated and should be printed directly by the researcher. For further information regarding Lifespan's Human Subject's Protection: http://www.lifespan.org/research/IRB/MandatoryEdguidance.asp
Additional and continuing education opportunities for clinical researchers include the Office of Research Administration newsletter that is circulated to > 900 recipients every 6 weeks. Relevant information concerning research review is available on the ORA web page at

www2.lifespan.org/research/. In addition to standard institutional research information, the web page contains links to other sites such as CenterWatch, NIH, PRIM&R/ARENA.

Adverse Events and Serious Adverse Events

An adverse event is defined as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. At each assessment visit, participants will be queried regarding any adverse events using an Adverse Events Form. In addition, information about adverse events may be reported by the participant on a coaching call. All interventionists will be trained to identify adverse events and to report any AEs to Dr. Unick using an Interim Adverse Event Form. All AEs will be reported to the IRB, NIH, and Safety Officer as indicated above. The IRB at The Miriam Hospital is a fully authorized Institutional Review Board that provides oversight to research conducted at The Miriam Hospital, Rhode Island Hospital, and affiliated Brown Medical School. It functions in compliance with the congressional statutes governing Assurance of Compliance with Health and Human Services (HHS) Regulations for Protection of Human Research Subjects. This board will be providing oversight to the proposed study.

Serious adverse events (SAEs) are defined as any adverse event that meets any of the following criteria: fatal or life-threatening, result in significant or persistent disability, require or prolong hospitalization, result in a congenital anomaly/birth defect, or are important medical events that investigators judge to represent significant hazards or harm to research subjects. Any adverse event that meets any of these criteria will be documented as an SAE and an SAE form will be completed by the study investigators. Serious adverse events will be reported to the NIH and The Miriam Hospital's IRB within 24 hours of knowledge of the event.

Participant Confidentiality. Participant confidentiality is of utmost importance for this study and guidelines outlined by our IRB will be followed. Participant data confidentiality will be protected through a multi-tiered approach including data collection, data handling, and data distribution processes to ensure anonymity both during and after the study. Participant information collected by the research staff will contain only a non-identifiable study ID. A separate form linking study ID and participant identifiers (name, address, contact names and addresses) will be maintained in a locked file.

Quality Control. All staff involved in data collection will be trained by the investigators and must demonstrate competence in administering all measures. The research assistant will review all assessment data for accuracy and completion. The investigators will conduct error checking and preliminary analyses of all data to ensure accuracy. Hard copies of data will be stored in a locked filing cabinet and electronic data file will be password protected and backed up.