Time Restricted Eating Pilot – Bariatrics

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Abstract

Bariatric surgery patients have a variable course of weight loss, maintenance and regain. Few postoperative interventions have been published, with most using traditional behavioral weight loss programs coupled with cognitive behavioral or acceptance and commitment therapy skills. While behavioral weight management principles can be effective in producing weight loss and maintenance, many people are not able to log their intake to track their energy intake on a regular basis, a skill that predicts success. Therefore, other options are needed to optimize weight outcomes in the bariatric population.

Time restricted feeding is one such approach that may help individuals lose weight and improve metabolic health. There are several forms of this approach, but emerging from the pack is promoting an 8-10 hour eating window. This is in comparison to the average adult eating window, typically spanning 12-15 hours from the first eating episode to the last. We propose a pilot trial of a 10 hour time restricted feeding intervention among post-bariatric surgery patients.

We propose group treatment of 10 post-bariatric surgery patients who are interested in losing or stopping gaining weight. They would participate in weekly sessions for 4 weeks, followed by sessions every two weeks for an additional 8 weeks, for a total of 8 sessions/12 weeks. Weights will be monitored at each meeting. Participants will complete an ASA24 food recall weekly to calculate caloric intake and times of eating. They will also complete a daily query of the number of hours they ate within for the previous day.

Objectives

Overall objectives

To test the effects of a 10-hour time restricted eating intervention before and after the 12 weeks of treatment on weight (primary), caloric and macronutritent intake, and a variety of psychosocial measures, including sleep, physical activity, blood pressure and eating behaviors (all secondary).

Primary outcome variable(s)

Aim 1: (Primary Outcome): To compare changes in body weight over 12 weeks in 10 bariatric patients who have undergone bariatric surgery and have completed the pilot study.

Hypothesis: Participants will achieve weight reduction at 12 weeks.

Secondary outcome variable(s)

Aim 2: (Secondary Outcomes): To compare changes before and after the 12-week intervention in caloric and macronutrient intake, eating behavior, sleep behavior, physical activity, psychosocial outcomes, and metabolic disease risk factors.

Hypothesis: Participants will report lower caloric intake, more favorable changes in macronutrient intake and eating behavior, more positive changes in sleep quality, participate in more physical activity, and experience more favorable improvements in relevant psychosocial variables at treatment end as compared to baseline.

Background

Bariatric surgery is an increasingly utilized treatment for persons with a body mass index (BMI) 40 kg/m2 or 35 kg/m2 in the presence of obesity-related comorbidities. Early results tend to be good, with most patients losing 20-35% of their weight in the first 6-24 months after surgery and experiencing improvements in obesity-related comorbidities. These outcomes, however, are not universal and vary between patients and across surgical procedures. It is estimated that 20-30% of patients experience significant weight regain within the first few postoperative years. Individuals from minority groups appear to be at increased risk for these outcomes. Among individuals who underwent Roux-en-Y gastric bypass (GB), for example, non-Hispanic black and Hispanic patients experienced smaller weight losses than their non-Hispanic white counterparts. Reasons for these suboptimal outcomes are not fully understood, but likely involve both physiological processes and behavioral factors (e.g., failure to make sustained dietary and physical activity changes necessary for weight maintenance). Evidence suggests that preoperative psychosocial status and functioning can contribute to suboptimal weight losses and/or postoperative psychosocial distress. Much of the work in this area has focused on formal psychopathology with particular emphasis on mood disorders as well as binge eating disorder (BED). Individuals who present for bariatric surgery also have high lifetime rates of substance use disorders. Some studies have suggested that the presence of preoperative psychopathology is associated with suboptimal weight losses and less positive psychosocial outcomes.

Participants would be invited to volunteer from our ongoing, lonigitudinal assessment study of 300 bariatric surgery patients (Psychopathology, Disordered Eating, and Impulsivity as Predictors of Outcomes of Bariatric Surgery, Protocol #823735), 65% of whom come from underserved groups. At Penn Medicine's Metabolic and Bariatric Surgery Program, patients undergo a mental health evaluation and are educated about the dietary and behavioral changes required for success prior to surgery. Postoperatively, they are encouraged to return to the bariatric program for annual follow-up visits, attend support groups, and continue with ongoing care from their primary physicians. Unfortunately, these strategies appear to be insufficient in providing many patients with the dietary and behavioral instruction as well as the social support needed for sustained success. Weight regain threatens the health benefits achieved with bariatric surgery and there is great need for the development of postoperative interventions to promote long term success following bariatric surgery.

Time restricted feeding is emerging as one such approach that may help individuals lose weight and improve metabolic functioning. There are several forms of this approach, but emerging from the pack is promoting an 8-10 hour eating window. This is in comparison to an adult's average eating window, which typically spans 12-15 hours from the first eating episode to the last. We propose a pilot and feasibility trial of a 10 hour time restricted eating intervention among post-bariatric surgery patients. The intervention may be particularly acceptable to individuals from underserved groups who may have limited literacy and numeracy, as well as those with limited access to other health-promoting resources.

We propose group treatment of 10 post-bariatric surgery patients who are interested in losing or stopping gaining weight. They would participate in weekly sessions for 4 weeks, followed by sessions every two weeks for an additional 8 weeks, for a total of 8 sessions. Weights will be

monitored at each meeting. Participants will complete an ASA24 food recall weekly to calculate caloric intake and times of eating. They will complete a daily query to report the number of hours they ate within for the previous day throughout the intervention.

Study Design

Phase*

Not applicable

Design

Non-controlled, single arm intervention study

Study duration

- Estimated length of time to enroll all subjects and complete the study
- Length of a subject's participation time in study
- Project date of the proposed study

The study should last 6 months. We will recruit participants from an ongoing assessment study. The intervention will last 12 weeks. We will then analyze the data to use in a grant application for October 2019 and a manuscript.

Resources necessary for human research protection

Given this is a small pilot study and we are drawing from participants who are known to us, Dr. Allison and Dr. McCuen-Wurst, who work on the parent bariatric assessment study, will be the staff most centrally involved. Colleen Tewksbury, PhD, MPH, RD, LDN is a bariatric nutritionist who will be able to contribute to feedback on any dietary issues that arise during the intervention. Maija Bruzas, PhD, Dr. Allison's postdoctoral fellow, will also be trained to deliver the intervention as a back-up interventionist. This will be adequate staffing to complete this brief trial.

Analysis Plan

We will use paired t-test analysis to compare the change in weight, blood pressure, calorie and macronutrient intake, and the change in the survey measures before and after the intervention.