

Development of a weight maintenance intervention for bariatric surgery patients

Title: Development of a weight maintenance intervention for bariatric surgery patients

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Purpose. Bariatric surgery is the most effective treatment for patients with severe obesity, defined as class II obesity (body mass index [BMI] 35-39.9 kg/m²) with an obesity-related comorbidity or class III (BMI \geq 40 kg/m²) obesity. When compared to non-surgical treatment options, bariatric surgery results in greater weight loss, comorbidity remission, and quality of life improvement, and is associated with an extended lifespan. Many patients regain weight following bariatric surgery, which is associated with recurrence of obesity-related comorbidities such as diabetes. A major factor in undesirable weight regain is suboptimal patient adherence to post-operative dietary and physical activity recommendations. To improve patient adherence to recommended lifestyle behaviors, effective behavioral interventions are needed.

In this pre-post, within-subject pilot study, we will enroll Veterans one year following bariatric surgery and deliver an abbreviated behavioral weight loss maintenance intervention for 16 weeks. Specific aims are:

Aim 1: Refine telephone intervention scripts to address dietary, mobility, and behavioral issues specific to bariatric surgery patients.

Aim 2: Evaluate feasibility of conducting a multi-site trial, as indicated by recruitment and outcome assessment rates.

Aim 3: Evaluate intervention acceptability, as indicated by intervention adherence rates, pre-post changes in weight and process measures, and feedback from post-intervention qualitative interviews.

The VA performs ~450 bariatric operations per year across 17-21 sites. In a recent State-of-the-Art Conference on weight management co-led by Health Services Research and Development (HSR&D) and by our operations partner, the National Center for Health Promotion and Disease Prevention (NCP), the bariatric surgery committee strongly agreed that future priorities for VA include increasing the number of sites that offer bariatric surgery and identifying strategies to help veterans maintain weight loss resulting from surgery. Our intervention, if effective, can help increase VHA's return on investment as the bariatric surgery volume increases over the next decade.

Background and Significance. Our conceptual model (Table 1) specifies cognitive and behavioral factors involved in initiation and maintenance of health behaviors. This model was used to design the weight loss initiation and maintenance interventions of the two-phase MAINTAIN trial, which involved a weight loss initiation program followed by randomization to maintenance intervention or usual care among patients losing at least 4 kg in the initiation phase. In modifying the intervention for bariatric surgery patients, there will be a health behavior initiation phase to ensure that patients initiate the recommended health behaviors (e.g., increased protein intake, elimination of high-calorie beverages, monitoring of caloric intake). Following initiation of these health behaviors, the interventionist will teach patients skills to maintain those new habits, thereby reducing weight regain.

Table 1: Initiation and Maintenance Constructs

Initiation	Maintenance
Self-regulatory focus: approach a more favorable health state	Self-regulatory focus: avoid reverting to a less favorable health state
Favorable expectations about future outcomes of the behavior change	Satisfaction with outcomes of the behavior change
Action self-efficacy	Maintenance and recovery self-efficacy
Goal setting/action planning	Maintenance and relapse prevention planning
Monitoring by interventionist and self	Self-monitoring
Social support derived from social network, interventionist, and other participants	Social support derived primarily from social network

Design. This pilot study will be a within-person, pre-post design involving a 16-week intervention delivered starting one year after surgery (Figure 2). Patient outcomes will be assessed at baseline and 16 weeks. Participants will continue usual follow-up care with their primary care physician.

Figure 2: Study flow



We will recruit patients from four VA sites that perform bariatric surgery (Table 2).

Table 2: Bariatric Surgery Sites Agreeing to Participate in Pilot Intervention Study

VA Hospital	VISN	2015 Bariatric Surgery Volume	2016 Bariatric Surgery Volume (estimated)
VA Boston Healthcare System	1	25	25
VA Ann Arbor Healthcare System	11	55	100
VA Palo Alto Healthcare System	21	30	40
VA Long Beach Healthcare System	22	10	20

Patient eligibility criteria will be determined by electronic data abstraction using CDW:

- Bariatric surgery at one of the 4 VA sites
- Laparoscopic Roux-en-Y gastric bypass (RYGB) or laparoscopic vertical sleeve gastrectomy (SG) six to 18 months prior to the time of data pull
- No procedures to prevent gastric cancer
- No revisional bariatric surgery

The list of patients meeting those criteria will also include full name, social security number, address, phone number, surgery type, and surgery date. Eligible patients will receive a recruitment letter from study staff at the Madison VAMC. Two weeks after recruitment letters are mailed, the project coordinator (PC) will call patients to confirm eligibility, describe the study and obtain telephone consent. If a patient consents to be in the study, a consent form will be sent to their address to review. Once patients have provided consent, the PC will administer several baseline measures orally and schedule patients for their first intervention call. This first screening, consent, and baseline measures call will not be audio-recorded. Responses will be recorded in RedCap. All subsequent intervention calls and participant interviews will be recorded but not transcribed. Instead, relevant notes from the intervention calls and the

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participant interviews will be recorded in RedCap. We will remind each participant that they are being recorded on each call, and obtain their verbal consent for recording. Patients may opt out of the study at any time, as indicated in our telephone scripts.

Additional patient eligibility criteria will be determined by telephone screening:

- English as preferred language
- Regular access to a telephone
- No hearing impairment
- No cancer not in remission

Maintenance intervention.

The first intervention telephone call will occur one week following the baseline assessment. Calls will be made weekly in the first month (weeks 1, 2, 3, 4) and biweekly calls during months 2-4 (weeks 6, 8, 10, 12, 14). The intervention will be scripted to ensure reproducibility and to facilitate dissemination and implementation.

Intervention content. The goal of this intervention is to increase adherence to recommendations that patients are already receiving from their bariatric team as part of standard of care. The first 4 calls of the intervention will review key concepts typically taught to patients in a bariatric surgery program, including specific recommendations for diet, physical activity, and vitamin/mineral supplementation. Subsequent calls will address maintenance skill building and anticipatory problem solving based on the processes outlined in our conceptual model and operationalized in our MAINTAIN protocol. Relapse prevention planning will help patients identify situations in which overeating is common in the bariatric population (e.g., loss of control eating related to emotions, disinhibition). These four areas and their intervention implications are provided in Table 3.

Table 3. Incorporating Behavior Maintenance Strategies into the Weight Maintenance Intervention

Strategy	Intervention Implication
Satisfaction with outcomes of behavior change	✓ Patients list the perceived benefits and cost of having changed their behavior ✓ Patients reflect on satisfaction with past outcomes
Self-monitoring	✓ Patients identify frequency of weighing ✓ Patients identify method for logging weight ✓ Patients develop threshold for determining when a lapse occurs and return to dietary self-monitoring if this threshold is exceeded
Recovery self-efficacy/relapse planning	✓ Patients prepare contingency plans for high-risk situations ✓ Patients imagine and role-play responses for hypothetical situations
Primary source of support is social network	✓ Patients identify supportive members of their social networks. ✓ Patients share goals with spouses, friends, coworkers ✓ Patients suggest specific supportive behaviors (e.g., check-in calls, exercise dates)

Measures. Our tracking database will capture the number of recruitment letters mailed, number of recruitment calls attempted and completed, number of patients consented, number of intervention calls delivered, and number of outcome assessment calls completed. As each

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intervention call will be recorded, we will also have data on the duration of each call. The RD will record the amount of time spent preparing for the call and conducting any follow-up activities. The following measures will be administered by telephone at weeks 0 and 16. Each patient will receive \$25 for each assessment.

Recovery self-efficacy refers to confidence to get back on track once relapse has occurred. We will measure recovery self-efficacy for dietary behavior and physical activity separately using 3-item measures developed by Schwarzer.¹ Response scales range from 1 (*not at all true*) to 4 (*very true*). Internal consistency for the diet measure of 0.93 has been reported, and 0.71 for the exercise measure.

Satisfaction with outcomes of weight loss. Five items will assess satisfaction with outcomes of changes in the domains of enjoyment of food, health, physical attractiveness, fit of clothes, physical fitness, ability to complete tasks requiring physical exertion, social life, and positive feedback about weight loss.² Response scales range from -4 (I am extremely unhappy about this change) to +4 (I am extremely happy about this change). We obtained internal consistency of 0.86 in our MAINTAIN trial.³

Self-monitoring of weight. A single item will assess frequency of self-weighing during the intervention (During the last four months, how often did you weigh yourself? *Daily, nearly every day, 3 or 4 times a week, once or twice a week, 2 or 3 times a month, once a month, less than once a month, never*)

Weight from EMR. We will calculate and report % weight loss and % excess weight loss, both from start of the intervention and prior to surgery, as these outcomes are important to bariatric surgeons.

Dietary intake will be assessed with 24-hour recalls conducted by the intervention registered dietitian. We will use the VA-approved Food Processor Software on (staff name) located in (location).

Daily physical activity will be assessed by the short version of the International Physical Activity Questionnaire (IPAQ).⁴ Analyses will focus on total physical activity as well as walking given that moderate or vigorous physical activity may not be feasible for this population.

Qualitative interviews to assess experience with the intervention. Semi-structured qualitative interviews will be conducted within two weeks of the final outcome assessment by Dr. Voils or McVay or the PC. A semi-structured interview guide will be created, organized around the theoretical constructs indicated in our model. We will conduct interviews with approximately 20 patients. Participants will receive \$25 for completing the qualitative interview.

Analyses.

Aim 1: Refine telephone intervention scripts to address dietary, mobility, and behavioral issues specific to bariatric surgery patients.

During study start-up, the team will have weekly calls in which intervention content is discussed and modified (e.g., a threshold for indicating relapse will be identified). The RD will conduct self-study and receive training from Dr. Funk in dietary issues specific to bariatric surgery patients. All intervention calls will be recorded. Each week, Drs. Voils and McVay and the RD will meet to review calls. Dr. Funk will listen to a portion of the calls as well. All calls for

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the first 5 patients enrolled will be reviewed so that changes to the script can be made if necessary. The script will be revised iteratively until the team feels that patients understand and can engage with the content. Changes may be made to enhance comprehension of intervention material, ability to engage in the recommended behavioral skills, or to address any clinical issues that are identified. The final product from this aim will be a standardized intervention script that will be used in a future IIR to evaluate the efficacy of the intervention.

Aim 2: Evaluate feasibility of conducting a multi-site trial, as indicated by recruitment and outcome assessment rates.

As stated previously, we will use an electronic data pull to identify patients who have had surgery as well as their surgery date. We will create a custom tracking database that will import data from the data pull and create a flag that alerts study staff when patients are due for each intervention call. We will examine the dates of surgery to determine how frequently cases are performed.

From our tracking database, we will calculate the recruitment rate as [# of participants who consent to the study/# of patients to whom letters were mailed]. We will further identify the rate of drop-out following consent to inform allocation of effort to recruitment in the future IIR. The outcome assessment retention rate will be calculated as [#of participants who complete the 16-week outcome assessment call /number who were eligible upon completion of the baseline assessment].

Aim 3: Evaluate intervention acceptability, as indicated by intervention adherence rates, pre-post changes in weight and process measures, and feedback from post-intervention qualitative interviews.

Intervention adherence. For intervention adherence, we will calculate for each participant the mean (and standard deviation) number of intervention calls that were completed. Given our previous experience with telephone-based interventions, we expect high rates of intervention adherence. In Dr. Voils' CouPLES trial, which involved 10 monthly telephone calls, the mean number of completed patient calls was 7.9 out of 9. In MAINTAIN, the mean number of completed calls was 6.95 (SD=1.75) out of 8.

Pre-post changes in quantitative measures. Weight measurements will be pulled from the VA CDW files. For each patient, baseline weight will be defined as the closest weight prior to the baseline survey assessment. We will assess the feasibility of this definition. Because of the shortened follow-up for this pilot, we anticipate patients will only have on average 1-3 follow-up weights. We will examine descriptively change in weights as well as each survey construct that is measured during telephone-based assessments. For the psychosocial measures, we will calculate total scores according to author instructions. For all measures, we will calculate descriptive statistics and plot the baseline and follow-up weights/scores, which will provide descriptive information on whether and to what extent patients experienced change. From the descriptive data, we will determine how each construct is operationalized in this patient population (e.g., floor/ceiling effects, skewed or highly variable distributions, etc.). For each variable, we will calculate the standardized difference between means, which will enable us to compare magnitude of changes across different measures. Although we will not be powered to detect statistically significant differences, the confidence intervals will provide information on the potential range of effect sizes, which will inform the power analysis for the future IIR.

Post-intervention qualitative interviews. We will use a directed form of qualitative content analysis to code the interview transcripts,⁵ which will include *a priori* codes (based on theoretical constructs discussed in the interview guide) and emergent codes (anything not covered by the initial codes). Participant reactions to the intervention will be organized for analysis by key

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maintenance constructs (i.e., satisfaction with outcomes of behavior change, relapse prevention, self-monitoring, and social support) as well as suggested changes to the intervention. Dr. Voils and the PC will use consensus to develop the coding framework.⁶ They will first code transcripts independently and meet to resolve discrepancies through discussion until they agree on definitions and rules for applying the codes (*a priori* and emergent). They will use this process with half of the transcripts and review the findings with the rest of the research team. The PC will then code the remainder of the transcripts and revisit the prior transcripts to make sure that the codes were consistently applied. ATLAS.ti (v. 6.1) will be used to manage coding of transcripts.⁷

Sample size considerations. A power calculation will not be performed given that we are not evaluating statistical significance of the intervention in this pilot; rather, we are seeking an indication of feasibility and acceptability. We will enroll 30 patients, which will be adequate to evaluate the feasibility and acceptability of the intervention.

Safety Monitoring Plan. Study staff will report any adverse event or unanticipated problem to the PI immediately. Study staff will review all such events and determine the likelihood they were due to the study. The PI will report any serious, unexpected, and study-related adverse event or unanticipated problem to the local IRB according to the institution's requirements. The IRB will review all adverse events during continuing review, which will occur at least annually. If a Veteran reports that they are suicidal during a phone call, we will use a standard script given to us by the Madison VA Research Office.

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