

**Gaining Optimism After Weight Loss Surgery (GOALS) II: Randomized Controlled Trial
of a Positive Psychology-based Intervention to Increase Physical Activity After Bariatric
Surgery**

NCT04868032

Study Protocol and Statistical Analysis Plan

6-14-2024

I. BACKGROUND & SIGNIFICANCE

A. Historical Background

Metabolic and bariatric surgery (MBS) is the most effective treatment for severe obesity, but 25% of surgical patients do not achieve long-term weight loss maintenance.——¹⁻³ Obesity affects more than 30% of U.S. adults and has been deemed a major public health issue, costing more than \$150 billion in healthcare and lost productivity in 2008.^{4,5} MBS is effective for severe obesity, often resulting in cost-effective, sustained weight loss.^{—2,3,6,7} Remission of weight-related comorbidities (e.g., type 2 diabetes, hypertension, high cholesterol) is associated with weight loss, so weight loss maintenance is vital for preserving these improvements in health.² However, 25% of MBS patients do not maintain the expected weight loss.——^{1-3,8,9} Given the significant systemic and individual cost of MBS, poor outcomes for so many patients are of major public health concern.

Physical activity is critical for weight loss maintenance and improved health after MBS. Physical activity is particularly important in post-MBS patients because of their increased risk of weight-related disease.——¹⁰⁻¹³ Post-MBS patients are recommended to engage in 150 minutes per week of moderate to vigorous physical activity, and even higher levels may be needed to control weight.——¹⁴⁻¹⁷ Unfortunately, **89-97% of post-MBS patients do not meet this recommendation.**——¹⁸⁻²⁰ MBS clinics typically provide more support for nutrition than for physical activity, and while dietary adherence is critical to the success of MBS patients, low physical activity is independently linked to medical sequelae. Increasing physical activity, even without weight change, can improve insulin sensitivity, cardiorespiratory fitness, blood pressure, and blood lipids, all of which confer a lower risk for cardiac and/or metabolic disease.——²¹⁻²⁴ Behavioral interventions to improve physical activity after MBS show promise, but the evidence is still limited by a lack of trials that are well-powered with long-term follow-up.——²⁵⁻²⁷ Further, in-person post-operative interventions have struggled with attendance, with common barriers including living long distances from the clinic and lack of time off from work.——²⁸⁻³¹

Emotional factors play a role in physical activity engagement and health outcomes. Psychological distress predicts lower physical activity levels and less weight loss in post-MBS patients.³² Although most MBS patients do not meet criteria for a depressive disorder, they experience more depressive symptoms than the general population.^{33,34} Conversely, positive psychological constructs such as optimism and positive affect are associated with improved health independent of depression but have not been examined thoroughly in MBS patients.——³⁵⁻³⁸ These constructs are associated with physical activity in older adults and cardiac patients, suggesting that physical activity is a pathway by which positive psychological states can improve health.——³⁹⁻⁴³

Positive affect during physical activity predicts future physical activity. A systematic review of 24 studies found that positive affect *during, but not after*, physical activity predicted increased future physical activity, supporting the “upward spiral” theory of lifestyle change.^{44,45} This theory posits that by experiencing positive affect during the act of a health behavior, nonconscious motives increase one’s likelihood of repeating that behavior. Over time, health behaviors become reinforcing rather than burdensome. However, sedentary women with obesity have been found to experience lower pleasure during physical activity compared to sedentary lean and overweight women.⁴⁶ **MBS patients may be missing out on this “upward spiral” due to emotional barriers to physical activity**, such as feeling too overweight, shame about appearance, and weight stigma.^{47,48} This group would benefit from new skills to increase positive affect during physical activity.

Positive psychology (PP) interventions target positive emotions and may be particularly effective for increasing physical activity in post-MBS patients. PP programs use structured tasks, such as imagining an ideal future, expressing gratitude, or using personal strengths, to increase the frequency and intensity of positive psychological states (e.g., optimism, positive affect, gratitude). A meta-analysis of 51 studies of more than 4000 participants found that PP interventions enhance well-being and improve depressive symptoms for up to 6 months.^{49,50} PP interventions have also been shown to improve physical activity in patients with cardiometabolic disease.^{51–53} PP can improve physical activity directly by affecting well-being, particularly if it targets positive affect during physical activity engagement.^{44,54} However, PP may be particularly effective in combination with an adherence-based program such as motivational interviewing (MI).⁵⁵

Motivational interviewing (MI) may enhance the effects of PP in post-MBS patients. Dr. Huffman’s group developed a combined positive psychology-motivational interviewing (PP-MI) intervention to improve health behaviors in patients with type 2 diabetes, heart disease, and heart failure with promising findings from pilot studies (3.1a).^{52,53,56} MI is a technique that focuses on clarifying motivation, addressing ambivalence, and setting achievable goals. MI is used widely to help patients increase physical activity,⁵⁷ but its effect size has been small to moderate when used alone in medical populations.⁵⁸ Because low optimism and depressive symptoms are associated with poor outcomes with MI,^{59–61} a focus on increasing self-efficacy, motivation, and optimism through PP may enhance the effects of MI.⁶²

Remote intervention delivery could fill a care gap post-MBS. MBS centers often serve large geographic areas, yet require frequent, time-consuming, and expensive visits. Attendance is particularly low post-operatively.^{29,63} Therefore, a remotely delivered intervention is likely to be more feasible and increase access to care.⁶⁴ PP-MI has been delivered via phone with high feasibility and acceptability, with use of activity trackers to allow participants to use their own objective data and set effective goals to increase activity.⁶⁵

B. Preliminary Studies

PP-MI interventions to promote physical activity in other populations. Our group has tested PP-MI for health behavior change in randomized pilot trials patients after an acute coronary syndrome, in those with type 2 diabetes, and in patients with heart failure, with medium-to-large effect size changes in objectively measured physical activity in the PP-MI condition compared to the control.^{51,53,66,67}

PP pilot studies in post-MBS patients. To examine the relevance of PP-MI for post-

MBS patients, we first conducted a survey study of members of online MBS support forums. In 95 respondents, positive affect and optimism were positively associated with adherence to MBS health behaviors and physical activity, supporting the idea that promoting positive psychological states could improve behavioral adherence and physical activity.³³

We also completed a qualitative study of 23 MGH Weight Center post-MBS patients that involved semi-structured individual interviews asking about participants' experiences with physical activity before and after surgery, their barriers and facilitators to activity, the types of emotions they experience in relation to physical activity, and their ideas and preferences about the planned intervention.⁶⁸ Interviews were transcribed and coded using inductive and deductive methods, and themes that emerged have informed the adaptation of PP-MI for this population.

C. Rationale/Potential Benefits/Overview of Proposed Research

Given: (a) the relationship between psychological well-being and health behavior adherence, (b) the preliminary efficacy of PP-MI interventions in other populations, and (c) the identified emotional barriers to adherence specific to the post-MBS population, this intervention, customized to apply to the unique experiences of post-MBS patients, has the potential to increase physical activity and reduce adverse events in a high-risk, high-yield population of patients. This would have direct benefits to patients and would impact public health, given that nonadherence to health behaviors is a major public health problem among patients with obesity.

II. SPECIFIC AIMS

We will conduct a one-arm proof-of-concept trial to refine the newly adapted intervention and study procedures, followed by a pilot randomized controlled trial (RCT) to test feasibility, acceptability, and preliminary efficacy of the refined intervention compared to a physical activity education control condition.

Specific Aim 1: To pilot the adapted post-MBS PP-MI intervention with exit interviews for further refinement (N=10).

Hypothesis: We will recruit 10 participants and collect feedback from them that will aid in study refinement.

Specific Aim 2: To conduct a pilot RCT comparing the newly adapted post-MBS PP-MI intervention to a physical activity education control condition (N=50).

Hypothesis 1: The intervention will be feasible ($\geq 7/10$ sessions completed by $\geq 50\%$ of participants) and acceptable (ease/utility rating average of $\geq 7/10$ on 0-10 scale [0 = not at all, 10 = very much]).

Hypothesis 2: PP-MI will have a larger positive effect on accelerometer-measured physical activity and psychological outcomes (e.g., positive affect, depression, motivation) than the control at 10 and 24 weeks.

Hypothesis 3: PP-MI will have a larger effect on weight, waist circumference, body composition, blood pressure, lipids, A1c, CRP, and 6-minute walk test performance than the control at 10 and 24 weeks.

III. PARTICIPANT SELECTION

A. Inclusion/Exclusion Criteria

Inclusion criteria: Participants eligible for this study must meet the following criteria:

1. Adult (age 18+)
2. History of MBS (gastric bypass or sleeve gastrectomy) at MGH or BWH 6-12 months prior to study enrollment. *Note: because there have been fewer surgeries than usual in the past year due to the Covid-19 pandemic, we will expand eligibility to surgery 3-15 months prior to enrollment if we have difficulty recruiting sufficient numbers.
3. Low physical activity, defined as <200 minutes/week self-reported moderate-to-vigorous physical activity on the International Physical Activity Questionnaire Short Form,⁶⁹ plus a desire to increase physical activity.
4. Access to telephone for study sessions
5. Able to read and speak English

Exclusion criteria:

Participants will be excluded if they have:

1. Cognitive deficits precluding participation or informed consent, assessed using a six-item screen⁷⁰ designed to assess suitability for research participation.
2. Illness likely to lead to death in the next 6 months per chart review
3. Inability to be physically active (e.g., severe arthritis)
4. Participation in another program targeting physical activity besides the standard offerings at the surgery center.
5. Severe psychiatric conditions expected to interfere with study participation, as determined by chart review (e.g., recent psychiatric hospitalization, active substance use disorder, psychosis).

B. Sources of participants and recruitment methods

Lists of participants who had surgery in the appropriate time frame at MGH or BWH will be identified via searches in RPDR. After these lists are generated, study staff will conduct a manual electronic chart review to verify eligibility criteria and physician linkage.

For patients who have not opted out of receiving research invitations, study staff will send a research invitation through Patient Gateway and/or paper mail. The research invitation will describe the study, the procedure to opt out of further contact, and whom to call for further information. These letters will be sent from a central location at MGH.

Should study staff receive no reply within two weeks, staff members will call the patient on the phone to assess interest in the study and to describe the study over the phone. If the patient remains interested, staff will confirm eligibility and assess for exclusion criteria. If the patient remains interested and appears eligible, study staff will schedule an initial study visit at the MGH TCRC to complete the consent procedures and conduct the initial study visit. We will then mail or e-mail participants a consent form to look over ahead of time, so that they may prepare questions for the first visit. We will follow the MGB IRB guidelines around email contact, specifically that we will send all emails via an encrypted, SEND SECURE system, or that we

will send them in a non-encrypted manner but only with the person's approval and understanding of the risks associated with non-encrypted email (i.e., that there could be loss of confidentiality).

In addition, referral by providers at the patients' surgery center will be encouraged. For directly referred patients, we will send opt-out letters as above. Finally, we may use hospital press releases or RSVP for Health to publicize the study.

IV. PARTICIPANT ENROLLMENT

A. Methods of Enrollment

Study staff will assess eligibility via phone interview/record review. Patients who are eligible after the phone screen and still interested in participating will attend a baseline in-person visit at which time informed consent will be obtained by a trained study staff member (PI or research coordinator; see below for details) and their baseline assessment will occur. For the RCT, randomization will occur at Visit #2, when participants return their accelerometer after wearing it for 1 week.

B. Procedures for obtaining informed consent

If patients, as identified above, meet study criteria and remain interested in the study, the coordinator or other study staff will mail or send an electronic copy of the IRB-approved consent form for patient review, and will schedule an in-person visit at MGH. We will follow the MGB IRB guidelines around email contact, specifically that we will send all emails via an encrypted, SEND SECURE system, or that we will send them in a non-encrypted manner but only with the person's approval and understanding of the risks associated with non-encrypted email (i.e., that there could be loss of confidentiality). This will be discussed as part of the phone screen. This will allow patients to have adequate time to read the consent form. Informed consent will be obtained in person at MGH during the initial baseline visit by a trained study staff member (PI or research coordinator). Before collecting any data, the study coordinator will review the consent form during the study visit and will allow the patient to ask any questions he or she may have; the study PI will also be available to answer any questions. To ensure that participants have the capacity to provide informed consent, we will ask potential participants to describe their understanding of the study's purpose and their role. They will also be asked for their permission to be contacted about participation in future studies. We will not exclude patients on the basis of race, ethnicity, or gender.

C. Treatment assignment/randomization

Proof-of-concept trial: For the initial trial, all participants will receive the PP-MI intervention and there will be no randomization.

Pilot RCT: For the RCT, at Visit #2 after it is confirmed that participants collected sufficient physical activity data on the accelerometer, participants will be assigned to PP-MI or the physical activity education control condition. Regarding randomization, participants will be randomized 1:1 using a random number generator in Stata. No study staff or investigators will be aware of a participant's condition until consent and all baseline assessments have been

completed; participants and study staff will learn of the participant's study condition contemporaneously.

V. STUDY PROCEDURES

A. Study visits and parameters to be measured

Enrollment/Baseline Assessment (Visit #1): Patients who are interested in participating in the study and are eligible per the phone screen will come to the MGH TCRC for their initial study visit. At this time, informed consent will be obtained by a trained study staff member (PI or research coordinator). After providing informed consent, participants will provide demographic and medical information (e.g., medical comorbidities, weight history) and complete self-report measures to assist in characterization of the sample.

Furthermore, height, weight, body mass index (BMI), waist circumference, body composition, and blood pressure will be obtained, and 5 mL of blood will be drawn for measurement of lipids, A1C, and CRP. We will also ask participants to report their weight at home the next day, for consistency. We also will perform a six-minute walk test⁷⁶ (6MWT) to assess functional exercise capacity. Finally, we will provide participants with an Actigraph GT3X+ accelerometer,⁷⁷ which they will be asked to wear for 7 days (minimum acceptable use is 4+ days with 10+ hours of recorded data). Participants will be given the option to complete Visit 2 remotely. If the participant chooses to complete the visit remotely, they will be given all the materials needed to mail the Actigraph back during their first visit.

Randomization/Intervention Introduction (Visit #2; In person or remotely): For participants who complete this visit in person, this visit will take place approximately 1 week after Visit #1. Participants will return their accelerometer and study staff will check for sufficient wear time. If wear time is insufficient, the participant will be asked to wear it for another week and delay their Visit #2. If there is sufficient wear time, the participant will then be randomized to PP-MI or the control (RCT only). Participants will next be provided with a Fitbit Inspire 3 to track activity, regardless of their study condition. They will set up the Fitbit with the research coordinator, using a study-provided login so that the study staff can access participants' Fitbit data during the study. After the study ends, participants will keep the Fitbit and will be instructed to change the account to a private one for ongoing personal use.

For those participants who complete Visit 2 remotely, once the Actigraph is received back through the mail, the research coordinator will check for sufficient wear time. If wear time is insufficient, the participant will be asked to wear it for another week and delay their Visit #2. If there is sufficient wear time, the participant will then be randomized to PP-MI or the control (RCT only). They will then be mailed the appropriate study materials; a Fitbit Inspire 3, physical activity educational materials and the study manual (PP-MI group only). The study coordinator will schedule a virtual meeting either through videoconferencing or the phone to show participants how to set up their Fitbit, using a study-provided login so that the study staff can access participants' Fitbit data during the study. All videoconferencing will be conducted through HIPAA- compliant Mass General Brigham Zoom accounts that have several privacy features. Participants will be remunerated \$100 after this visit.

10-Week Follow-Up (Visit #3): At 10 weeks, (after completion of the intervention for those receiving PP-MI), participants will wear the accelerometer for 7 days (the device will be

mailed to them so they can start wearing it the day after their final intervention call if in PP-MI, or at the 10-week mark for those in the control). They will then return to the TCRC for another in-person assessment where they will return the accelerometer and repeat all measures done at Visit #1. For the proof-of-concept trial only, at this time participants will also complete an exit interview with a staff member who has not been in contact with them previously to provide feedback about their experience in the study. Participants will be remunerated \$60 (proof-of-concept trial) or \$100 (RCT) for this visit.

24-Week Follow-Up (Visit #4; RCT only; in person or remotely): For participants who complete this visit in person, this visit will occur at week 24, and will involve the same procedures and assessments as Visit #3, including mailing an accelerometer to participants ahead of time and asking them to wear it for 7 days prior to the visit. For participants who choose to complete this visit remotely, certain information will not be collected (e.g., 6MWT, blood pressure, body composition). Instead, the participants will be asked to complete the questionnaires via a secure online data collection system (REDCap). Participants will be asked to report their height, weight, and take waist measurements themselves (we will mail them a scale and tape measure if needed). To keep waist measurements consistent, we will also be sending them instructions created by a TCRC nutritionist, on how to take these measurements. The Actigraph will be sent to them through the mail along with a prepaid envelope so that they can mail it back after using the device for 7 days. Laboratory requisition orders will either be mailed along with the Actigraph or sent via email to participants. They will be instructed to go to a local Quest Diagnostics Service Center to complete the labwork. At this time, or shortly afterward by phone, participants will also complete an exit interview with a staff member who did not deliver their intervention, to provide feedback about their experience in the study. For participants who have already completed visit #4, we will reach out by phone call and/or email to ask if they are interested in completing an exit interview at this time. Participants will be remunerated \$100 for this visit.

For participants who withdraw prior to completing the intervention: In the event that a participant withdraws from the study prior to completing all 10 weeks of the intervention, we will ask them to complete a different exit interview that is specifically for participants who decide not complete the study, in order to better understand their reasons for withdrawing. We will schedule these interviews as close as possible to the time that a participant withdraws. For those participants who have already withdrawn, we will send them an opt-out letter followed by a phone call after two weeks inviting them to complete the exit interview. All exit interviews will be scheduled with a staff member who has not been in contact with them previously. Participants will be remunerated \$50 for this phone call.

B. Drugs to be used

No drugs will be administered.

C. Devices to be used

No medical devices will be used.

D. Procedures/surgical interventions, etc.

Intervention: PP-MI participants (all participants in the proof-of-concept trial and those randomized to PP-MI in the RCT) will receive a written treatment manual at Visit #2 that has detailed information about each session's topics. The intervention consists of 10 weekly phone sessions (30-45 minutes each). Each session includes a combination of a new psychological skill designed to increase positive emotions experienced during physical activity, a motivational skill designed to boost physical activity, plus setting a physical activity goal for the next week using information from their Fitbit. The sessions will be structured such that they begin with a review of the past week's activity (using Fitbit data plus any supplemental tracking) and determining whether the participant met their goal. The prior week's physical activity and psychological topics will also be reviewed, with discussion of how they used these skills, the positive emotions they experienced, and how they can continue to integrate the skills. Next, the new topics will be introduced and the participant will set a new physical activity goal for the upcoming week. A motivational interviewing approach will be used for all topics.

Proof-of-Concept Trial Intervention Weekly Topics (see full manual attachment for further detail):

Week	PP Topic	Physical Activity Topic
1	Noticing the positive during activity	Getting started with increasing physical activity
2	Gratitude for health-related positive events	Pros and cons of change and SMART goals
3	Positive reappraisal part 1	Barriers and problem-solving
4	Positive reappraisal part 2	Strength Training and Equipment
5	Review PP skills, choose one to integrate into daily life	Review and reflect on progress
6	Using perseverance	Neighborhood and social resources
7	Focusing on meaning during physical activity	Reducing sedentary time and moving in small ways
8	Remembering past successes around physical activity	Managing slips
9	Using a personal strength to achieve an activity goal	Finding new routes
10	Wrap up and plan for the future	Wrap up and plan for the future

RCT Weekly Topics (Refined based on proof-of-concept trial):

Week	PP Topic	Physical Activity Topic
1	Noticing the positive during activity	Getting started with increasing physical activity

2	Gratitude for positive events	Pros and cons of change and SMART goals
3	Positive reappraisal part 1	Barriers and problem-solving
4	Positive reappraisal part 2	Strength Training and Equipment
5	Using perseverance	Neighborhood and social resources
6	Review PP skills, choose one to integrate into daily life	Review and reflect on progress
7	Focusing on meaning during physical activity	Reducing sedentary time and moving in small ways
8	Remembering past successes around physical activity	Managing slips
9	Using a personal strength to achieve an activity goal	Finding new routes
10	Wrap up and plan for the future	Wrap up and plan for the future

Physical Activity Education Control (RCT only): Participants randomized to this condition will be provided with a Fitbit and will be provided with educational information about physical activity and its benefits at 4 timepoints throughout the intervention period (in person at randomization visit, mailed or emailed at week 3, week 6, and week 9), but will not receive any intervention phone calls or the written manual. This information will include publicly available infographics from the Centers for Disease Control plus psychoeducation used in MGH-affiliated primary care offices. This psychoeducation discusses overcoming barriers to physical activity and gives instructions for simple strength exercises that can be completed at home. These same emails are sent to PP-MI participants as well. All participants will receive a phone call from a study coordinator at, or around, the midpoint of the intervention period to ensure that they are receiving these emails and information. They will use the study-provided login on their Fitbit for the duration of the study as in the intervention group.

E. Data to be collected and when the data is to be collected

Baseline characteristics: To allow us to better understand our study population, we will record subjects' baseline characteristics (e.g. age, gender, race/ethnicity) during their initial visit.

Feasibility and acceptability: We will ask participants receiving PP-MI to rate each topic on ease and usefulness on a scale from 0-10 (0=not at all easy/helpful, 10=very easy/helpful). We will also collect exit interview data from proof-of-concept trial participants to get more detail about what they liked or did not like about the study overall and any suggestions they have for improvement.

Self-report measures: These will be collected at baseline, 10 weeks, and (RCT only) 24 weeks.

- Positive and Negative Affect: Positive Affect Scale (PANAS)⁷⁸
- Optimism: Life Orientation Test – Revised (LOT-R)⁷⁹
- Depression and Anxiety: Hospital Anxiety and Depression Scale (HADS)⁸⁰
- Motivation (stage of change): University of Rhode Island Change Assessment (URICA)⁸¹

- Self-Efficacy (general and exercise-specific): General Self-Efficacy Scale⁸² and Self-Efficacy for Exercise Scale⁸³
- Internalized Weight Bias: Weight Bias Internalization Scale – Modified (WBIS-M)⁸⁴
- Exercise Identity: Exercise Identity Scale (EIS)⁸⁵
- MBS-specific Diet and Vitamin Adherence: Bariatric Surgery Self-Management Questionnaire⁸⁶
- Physical Activity and sedentary time (self-reported): International Physical Activity Questionnaire (IPAQ)⁶⁹
- Household Members Survey
- Social Support and Eating Habits Survey⁸⁷
- Social Support and Exercise Survey⁸⁷
- Physical Activity Enjoyment Scale (PACES)⁸⁸
- 12-item Short Form Survey (SF-12)⁸⁹
- Barriers to Being Active Quiz (BBAQ)⁹⁰

Objectively-measured physical activity: These measures will be collected at baseline, 10 weeks, and (RCT only) 24 weeks using the Actigraph GT3X-BT.

- Moderate-to-vigorous physical activity in met-minutes/week and mean minutes/week
- Light physical activity in met-minutes/week and mean minutes/week
- Steps in mean number/day
- Sedentary time in mean minutes/day

Health-related measures: These will be assessed at baseline, 10 weeks, and (RCT only) 24 weeks.

- Weight, height, body composition, and waist circumference, assessed by trained MGH TCRC nurses during in person visits. Weight, height, and waist circumference will be measured and self-reported by the participant during remote visits.
- Blood pressure (in mm Hg), assessed via MGH TCRC nurses using their protocol during in person visits. Blood pressure will not be collected during remote visits.
- Lipids, A1C, and CRP via blood draw by MGH TCRC nurses during in person visits. Phlebotomists at Quest Diagnostics Service Center will complete the labwork for remote visits.
- Six-minute walk test, assessed by MCH TCRC nurses using their established protocol during in person visits. Six-minute walk test will not be completed during remote visits.

All participants will be asked to complete all measures at all time points, if possible. However, should a participant decline a certain measure or choose not to attend a follow-up visit, we collect as much data as possible from that person and proceed with all collected data. While we will try to avoid it, we expect there will be missing data in this study.

VI. BIOSTATISTICAL ANALYSIS

A. Specific data variables being collected for the study

We will collect data from 12 participants in the proof-of-concept trial (assessments at baseline and 10 weeks plus weekly session ratings and exit interviews), and from 58 participants

in the RCT (assessments at baseline, 10 weeks, and 24 weeks plus weekly session ratings). Assessments will include the measures detailed above.

B. Study endpoints

Proof-of-concept trial: the primary goal of this phase is to refine the intervention to a place where it is feasible and acceptable. We will aim to obtain follow-up data from at least 10 participants. Feedback from this trial will inform any necessary further modification of the intervention or procedures prior to beginning the RCT.

Pilot RCT:

The pilot RCT aims to enroll and randomize 58 participants with the goal of obtaining follow-up data from at least 50 participants.

C. Statistical methods

Proof-of-concept trial:

This small proof-of-concept trial is designed to test initial feasibility and acceptability of the newly developed intervention and to refine the intervention as needed.

Feasibility. Descriptive statistics will be used to calculate proportions to test feasibility, defined as % of sessions completed.

Acceptability will be measured with means and standard deviations of participants' ratings of session ease and utility on a 0-10 scale (0 = very difficult/not at all useful, 10 = very easy/very useful). Cutoffs will not be used to determine feasibility and acceptability for this study as the sample is so small, and the goal of Aim 2 is to refine the intervention content and procedures. Rather, completion rates and participant ease and utility ratings will be examined in combination with open-ended feedback to inform further refining.

Exploratory outcomes. For physical activity and all other psychological, behavioral, and health-related outcomes, we will model within-subjects pre-post changes in each outcome using a mixed effects regression model with a random intercept for each participant, to account for missing data. Given the sample size, tests of statistical significance will be exploratory. However, the effect size (Cohen's d) of the within-subjects change in each outcome measure from baseline to 10 weeks will be estimated to assess for a signal of intervention effect.

Pilot RCT:

Feasibility. Descriptive statistics will be used to calculate proportions to test feasibility, defined as % of sessions completed. These will be compared to the hypothesized target of $\geq 50\%$ of participants completing $\geq 7/10$ sessions.

Acceptability will be measured with means and standard deviations of participants' ratings of session ease and utility, compared to our hypothesized target of $> 7/10$ for each rating.

Exploratory Outcomes. For physical activity and other psychological, behavioral, and physiological outcomes, we will model changes in each outcome using a mixed effects regression model with a fixed effect of treatment condition and a random intercept for each participant to identify the difference between groups accounting for the repeated measures on each participant and missing data. In addition to tests of statistical significance, which will be exploratory given the sample size, we will calculate effect sizes to estimate the magnitude of

effect of the intervention. All tests will be considered significant based on a two-tailed alpha level of 0.05.

D. Power analysis (e.g., sample size, evaluable subjects, etc.)

Proof-of-concept trial: We have not conducted a power analysis for this study because the primary aim is to establish and refine procedures, troubleshooting any unexpected problems. We anticipate a sample of N=10 to be sufficient to do this, although will consider expanding the sample if initial results do not show changes in outcome measures in the expected direction.

Pilot RCT: This feasibility study (N=50) is not designed to detect significant between-group differences in 10-week physical activity and other outcomes; rather its primary aim is to measure feasibility and acceptability of the intervention. We will examine effect sizes of intervention outcomes in addition to p-values due to low power.

VII. RISKS AND DISCOMFORTS

A. Complications of surgical and non-surgical procedures, etc.

Blood sampling. We will collect blood at Visits #1, #3, and (RCT only) #4. Risks of venous blood sampling include pain, bruising at the phlebotomy site, and emotional discomfort from the process. More rarely, participants may become lightheaded or experience syncope, or have an infection at the site. We will minimize these risks by ensuring that blood samples are drawn by study staff who have received specific training in phlebotomy (TCRC research protocol nurse **and phlebotomists at Quest Diagnostics Centers**) and have specific experience with this procedure. Procedurally, we will make sure participants are seated comfortably during and after the sampling, and we will temporarily (or permanently) halt blood draws if patients voice pain or discomfort. If participants experience problems after blood draws (e.g., concerns about infection), they will be able to reach a study physician at any time, who can help to assess the situation over the phone or arrange to have the participant seen by their own physician or by study physician staff to assess any problems.

B. Drug side effects and toxicities

No specific medications are being studied or administered solely for research purposes in this study.

C. Device complications/malfunctions

We will be utilizing two devices that measure physical activity in this study: the Actigraph GT3X-BT accelerometer and the Fitbit Inspire 3 activity tracker. These devices pose minimal risk. The accelerometer (ActiGraph GT3X-BT) used to measure activity is small, light, and without sharp edges. Immersing the device in water for a prolonged period may render it unusable but does not pose a shock risk. The Fitbit provided to participants for activity self-monitoring similarly poses minimal risk, given that it has no sharp edges, no potential to cause shocks, and no other known risks. We will educate participants about the use of both devices when providing the devices to them, and study staff will be available to troubleshoot any problems that arise during their use.

D. Psychosocial (non-medical) risks

Confidentiality. To minimize confidentiality-related risks, we will use participant ID numbers—as opposed to identifiable personal data or medical record numbers—on all study documents. We will use locked cabinets and offices as well as password-protected databases to store personal information. Information from self-report assessments will be collected and stored using the secure, HIPPA-compliant, firewalled, and password-protected REDCap system. REDCap is a free web-based application developed for management of research and clinical data; it has separate password-protected data collection repositories for each trial. We have used this system for numerous prior studies without difficulty. Accelerometers will be labeled only with participant numbers; they will be connected to staff computers via USB, and staff will utilize the password-protected Actigraph software downloaded onto our local computers to obtain activity data. No personally identifiable information will be recorded physically or electronically onto the accelerometers or within the software program.

Participants will be asked to create a Fitbit account using a username and password that the study team provides, so that the study staff can access their physical activity information for the duration of the study. We will create this account together with them at Visit #2, to ensure that they do not enter identifying information (e.g., their name) into the account. When the study is over, participants will be instructed to change their username and password so that the study no longer has access to their account.

Digital recordings of PP-MI sessions will be collected using portable recorders. Randomly-selected sessions will be reviewed for competence and adherence to the protocol by Dr. Rachel Millstein, our lab's behavioral intervention expert, using fidelity scales created for this intervention. All recordings will be downloaded immediately from the recorders and the electronic files will be kept within the firewalled, password-protected shared file area for fidelity review. Recordings will contain no personally identifiable information. We have used all of these methods to maintain confidentiality in prior projects using the same measures, data repository, accelerometers, and recorders.

We will ensure that contact with participants is confidential by using only the phone numbers and other contact information that are specifically allowed by the participants and not leaving study-related messages for them unless expressly allowed by participants. Upon enrollment, we ask all participants if it is acceptable to leave voice messages on their phones, as well as the appropriate times to call them. We adhere to any and all patient requests regarding contact.

Physical activity safety. To ensure that patients can safely participate in physical activity, we will confirm with the patient's surgery center clinician (physician, nurse practitioner or psychologist) that the patient is able to participate in a physical activity promotion program prior to approaching the patient. We will describe to the clinician the plan for setting goals to increase physical activity, and will ask if there are any specific instructions or cautions to be conveyed to participants. This information will be recorded in the REDCap system so interventionists can use this information when developing plans with the patient at phone sessions. We will provide education to all participants about symptoms that could be concerning during activity (e.g., chest pain, dyspnea), including when to report symptoms to their primary care provider and when to present to the emergency room.

Depression/anxiety symptoms and suicidal ideation. Participants will complete the

Hospital Anxiety and Depression Scale (HADS) as part of assessments; although this is a symptom measure and is not used to make a diagnosis of depression, for participants with HADS depression subscale scores of 10 or more, the study PI (Dr. Feig) will call the patient to assess for suicidality using the suicide item from the PHQ-9. For patients without active suicidal ideation, we will encourage them to discuss their symptoms with their primary care provider and/or surgery center psychologist. For participants who have active suicidal ideation or are otherwise considered to be at high risk (e.g., due to combinations of depression symptom severity, history of prior attempt, and passive suicidal ideation), the study PI (Dr. Feig) will perform a separate assessment and will arrange for urgent evaluation (e.g., in an emergency department) if clinically indicated, with consultation from a study psychiatrist (Dr. Huffman or Dr. Celano).

We will ask participants to report adverse events they may have experienced at any time throughout the study. Any adverse events will be reported to the PI and to the IRB according to MGB HRC guidelines, and any events requiring immediate clinical follow-up will be addressed by the study PI by directly contacting participants.

E. Radiation Risks

There will be no radiation exposure in this study.

VIII. POTENTIAL BENEFITS

A. Potential benefits to participating individuals. All participants will receive serial assessments of medical, psychiatric, and functional status, allowing them access to emergent care if required. All participants in the proof-of-concept trial and some in the RCT will also receive our PP-MI intervention, which has shown to improve physical activity and psychological well-being in studies of other populations (type 2 diabetes, heart disease, metabolic syndrome). Participants in the physical activity education control condition of the RCT will be provided with educational information about physical activity and its benefits and a Fitbit Inspire 3 that they can keep, which could help them with tracking and increasing activity.

B. Potential benefits to society. Participation in physical activity (and other health behaviors) is crucial in preventing weight regain and onset of comorbidities for patients who have had MBS. Existing complex health behavior interventions can be difficult to implement in real-world settings, and more straightforward interventions, like MI, may require additional components to increase engagement and boost efficacy. By completing this project, we will learn whether the PP-MI intervention is feasible and well-accepted by post-MBS patients who have low physical activity. We will also examine whether the intervention is associated with increased physical activity (objectively measured by accelerometer), psychological well-being, and other outcomes in this cohort.

This knowledge could be of substantial importance. If the PP-MI intervention proves to be feasible, well-accepted, and effective in this study and larger follow-up studies, it may be possible to implement this easily-delivered program as part of a clinical care package for post-MBS patients who have low physical activity. This, in turn, could lead to better long-term weight loss outcomes after surgery, greater self-care, and fewer complications in a vulnerable population at high risk of complications and mortality. Therefore the knowledge gained from this initial study may ultimately translate to substantial benefit for future patients and public health.

IX. MONITORING AND QUALITY ASSURANCE

A. Independent monitoring of source data

All source data (e.g., chart review data and participant self-report) will be entered into the REDCap database. At intervals throughout the study, the PI (Dr. Feig) will review this data to ensure that it is being entered correctly and will perform ‘test downloads’ of the data to ensure that it can be captured in the statistical package to be used in this study.

B. Safety monitoring (e.g., Data Safety Monitoring Board, etc.)

Safety monitoring will be performed by Dr. Feig (PI), who will ensure that the study team is adequately identifying, reviewing, and reporting adverse events and unanticipated problems to the MGB Institutional Review Board (IRB). The PI will submit an annual progress report to the NHLBI confirming adherence to the data and safety monitoring plan, including a summary of any data and safety monitoring issues that occurred since the previous reporting period, as well as any changes made to the protocol and any new and continuing IRB approvals since the last filed report.

Monitoring mechanism. The PI will take primary responsibility for data safety monitoring. Monitoring will occur on an ongoing basis by the PI and study staff, using an Adverse Event log. A committee of mentors will assist the PI as an internal data and safety monitoring team in the event of questions around adverse events. This committee will include Dr. Jeff Huffman (psychiatry, primary mentor), Dr. Christina Psaros (psychology, co-mentor), and Dr. Anne Thorndike (internal medicine, co-mentor).

Monitoring intervals. Monitoring of adverse events will occur on an ongoing basis by the PI and the study staff, based on information gathered from participants at assessment visits and weekly phone sessions. More systematic weekly meetings for review of feasibility/acceptability information and minor IRB deviations will be held between Dr. Feig and study staff, including the lead research coordinator. Dr. Feig will then discuss any potential issues regarding data safety or protocol deviations with mentor Dr. Huffman during weekly supervision meetings. This allows the team to review this information and make adjustments to procedures as required. Furthermore, journal clubs are held within the study team monthly. These include discussions of related projects and timely studies (e.g., studies of physical activity in related patient populations, studies of positive psychological interventions). These ongoing, weekly, and intermittent reviews ensure that the study procedures minimize research-related risk by reviewing specific outcomes linked to the project and by reviewing relevant literature to ensure that interventions are best practice. Dr. Feig (study PI) is responsible for directly reporting any serious study-related adverse events to the NIH/NHLBI. If there are no such events, a yearly report summarizing adherence to the DSMP, review of study-related enrollment and issues during the study period, and any relevant changes to the protocol, will be sent to NHLBI.

Information to be monitored. Information to be monitored will include: (a) an evaluation of the progress of the research study, including assessments of data quality and timeliness, and participant recruitment, accrual and retention consistent with plans for diversity and generalizability, (b) a review of study safety data—adverse event and minor deviation information—to determine whether the study should continue as originally designed, be changed, or be stopped, (c) review of procedures to maintain participant confidentiality (e.g., ensuring study databases have no personal identifying information, using study participant

numbers on communications about the study), and (d) an assessment of external factors or relevant information (e.g., developments in the literature, results of related studies, etc.) that may have an impact on the safety of participants or on the ethics of the research study, such as through the journal club listed above.

C. Outcomes monitoring

The research team will meet on a weekly basis to review study progress. The study team will also discuss any procedural difficulties, recruitment issues, randomization issues, and adverse events at this meeting (and before if needed). If there are consistent issues with the logistics, feasibility, or acceptability of the assessment visits or intervention calls (e.g., participant complaints about length of visits, frequent missed calls), we will review our methods and alter the study protocol as needed. For this pilot study, we will not plan to perform interim analyses. However, we will review feasibility/acceptability ratings of phone sessions in an ongoing manner, and if they are consistently low for a certain topic during the proof-of-concept trial, we will review and alter that topic accordingly. This is in line with the purpose of this proof-of-concept trial, to trial and refine the newly developed intervention and study protocol.

D. Adverse event reporting guidelines

We will follow all PHRC guidelines with respect to reporting unanticipated problems, including adverse events. Specifically, when a serious or nonserious adverse event occurs, the PI will review the event to determine if it was possibly or definitely related to participation in the research. For all unanticipated problems and unexpected adverse events deemed related or possibly related to the research, we will complete and submit an “Other Event report through Insight/eIRB” as soon as possible and within 5 working days/7 calendar days (as defined in the May 2017 Reporting Unanticipated Problems Including Adverse Events report). At Continuing Review, we will provide a summary of all unanticipated problems as per PHRC protocol. Finally, if there are unanticipated problems, especially if serious or recurrent, the PI (Dr. Feig) will amend the protocol if it is deemed necessary to protect the safety and welfare of the participants.

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