A Randomized Trial of a Pilot Behavioral Support Invention After Bariatric Surgery

NCT03092479

Protocol Version Date: 04/06/2017

IRB Approved: 04/28/2017

Submitted to https://clinicaltrials.gov: 02/14/2019

A Randomized Trial of a Pilot Behavioral Support Intervention After Bariatric Surgery

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1 ABBREVIATIONS USED IN THE PROTOCOL

Abbreviation	Term
AE	Adverse event
BI	Behavioral Intervention
BMI	Body Mass Index
CNWM	Center for Nutrition and Weight Management
EES	Emotional Eating Scale
EMR	Electronic medical record
GHS	Geisinger Health System
GIRB	Geisinger IRB
HIPAA	Health Insurance Portability and Accountability Act
HRQol	Health-Related Quality of Life
IRB	Institutional Review Board
LOCES	Loss of Control Over Eating Scale
MOS	Medical Outcomes Study
NIH	National Institute of Health
PAI	Physical activity index
PHI	Personal health information
PHQ	Patient Health Questionnaire
PI	Principle Investigator
PPAQ	Paffenbarger Physical Activity Questionnaire
QoL	Quality of Life
RYGB	Roux-en-Y gastric bypass
SAE	Serious adverse event
SAS-SR	Social Adjustment Sale
SD	Standard deviation
SF-36	Short Form Health Survey
STAI	State-Trait Anxiety Inventory
UC	Usual Care
WEL	Weight Efficacy Life-Style

2 ABSTRACT

Rationale: Bariatric surgery patients may experience significant psychosocial changes after surgery, but little psychological support is available beyond support groups postoperatively. Psychosocial changes after surgery, including mood fluctuations, interpersonal issues and substance use, have the potential to lower quality of life and interfere with adherence to the postoperative diet and lifestyle, diminishing weight loss outcomes.

Objective: We will evaluate the effect of a postoperative support program targeting quality of life, psychosocial functioning and adherence to behavior change in Geisinger Health System (GHS) bariatric surgery patients.

Design and Methods: This prospective, randomized pilot trial will evaluate a comprehensive postoperative behavioral support intervention using a 4-month bi-weekly program (BI group) in 40 bariatric surgery patients (all procedure types) from the GHS Center for Nutrition and Weight Management (CNWM), compared to 40 usual care (UC) patients that completed bariatric surgery within one year. The primary outcome will be the difference in quality of life (as measured by the Short Form-36) between groups, as well as differences in psychosocial functioning (mood, eating behaviors) and adherence (diet, physical activity, appointments). Secondary outcomes will include patient satisfaction, treatment feasibility and attrition. Outcomes will be assessed at baseline and treatment completion (4 months). The intervention (BI group) will focus on addressing psychosocial changes after surgery, strategies for postoperative diet and adherence, and preventing weight regain. Patients will collaboratively set goals for diet, physical activity, adherence and other behavioral changes tailored to the needs of each participant. Intervention patients will attend 8, one-hour bi-weekly treatment sessions in a 4-month time period.

Significance: Knowledge gained will help to fill the gaps in understanding regarding the psychosocial benefits of enhanced behavioral support following bariatric surgery, as well as to improve the quality of patient care at GHS and address the obesity epidemic by providing patients the best possible opportunity for long-term weight loss success.

3 BACKGROUND AND SIGNIFICANCE

Bariatric surgery is the most effective long-term treatment for obesity[1], but weight-loss trajectories after surgery vary greatly[2]. Bariatric surgery requires adherence to a highly regimented, lifelong postoperative diet and lifestyle to achieve and maintain optimal weight loss[3]. However, numerous behavioral and psychosocial factors[4,5] may contribute to difficulties with compliance, contribute to weight regain, and jeopardize the long-term success of these procedures. While most bariatric surgery programs and third-party payers require psychological evaluations[3,6] before surgery to identify psychosocial and behavioral factors that may contraindicate surgery[3] or be associated with suboptimal weight losses[4], little psychological support beyond support groups is provided after surgery to help patients adjust to the significant psychosocial changes that may occur after surgery, including the possibility of substance use problems[7], marital or relationship changes[8], fluctuations in mood[8] and even suicidality[9], or to support the patient to implement and sustain the behavioral changes necessary for postoperative weight loss success[3].

Our ability to predict which patients may struggle with weight or psychosocial concerns postoperatively is limited. More than two-thirds[4,5] of bariatric surgery patients have experienced at least one lifetime mental disorder. Further, a subgroup of patients without known or reported pre-surgical mental health issues experience some degree of psychosocial or behavioral concerns following surgery, which in turn may impact weight and functional outcomes. In a recent survey of more than 150 bariatric surgery patients in Pennsylvania[10], patients reported concerns about their eating behaviors and expressed interest in participating in postoperative programs targeted the prevention of weight regain.

Bariatric surgery patients are expected to lose 30-40% of their initial total body weight, depending on surgery type[1,11]. Courcoulas et al.,[2] identified five distinct weight loss trajectories among patients who have undergone Roux-en-Y gastric bypass (RYGB), suggesting significant variability in weight-loss results. In this investigation, greater than 20% of patients initiate weight regain one year after RYGB and virtually all patients regain some weight after two years[2]. Adams et al.[12] found that at six years after surgery, only 76% of RYGB patients maintain

greater than 20% weight loss[12] and almost all regained up to 10% of their weight. The etiology of this 10% regain is unclear and may be physiological as much as psychosocial or behavioral. Modifiable psychosocial risk factors, including depression[4], binge eating behaviors[13], poor social support[5] and high life stress[5], likely contribute to difficulties with postoperative compliance, and in turn, poorer weight outcomes. Psychiatric disorders are associated with general medical non-compliance[14,15] and they may play a role in difficulties with postoperative compliance. Several studies indicate[5,16,17] that psychiatric co-morbidity, including depression and anxiety, may relate to postoperative weight loss, but other studies do not find strong associations[18]. Sarwer and colleagues[19] found psychiatric medication use to be higher in bariatric surgery patients than the general population. Disordered eating is also common among candidates for bariatric surgery[20] and likely contributes to suboptimal outcomes or weight regain postoperatively.

A recent meta-analysis[21] evaluated the efficacy of behavioral support programs after bariatric surgery on postoperative weight loss. In the studies included, behavioral treatment resulted in greater weight loss compared usual care or no treatment. Patients who received behavioral lifestyle interventions also showed lower levels of maladaptive eating patterns, higher levels of physical activity, better postoperative psychosocial functioning, and greater adherence to postoperative dietary recommendations than controls; however this meta-analysis[21] identified several areas for future study, particularly the need to study the impact of these programs on more aspects of psychosocial functioning (e.g. quality of life, interpersonal relationships, self-efficacy/esteem), psychopathology (e.g. depression, anxiety, eating disturbances) and physical activity after surgery.

Obesity is associated with diminished quality of life (QoL)[22] and QoL[23] is frequently cited as a primary reason that patients pursue bariatric surgery. Evaluating QoL emphasizes patient experience and perception and provides a measurement of treatment efficacy beyond weight loss. In this application, we propose to evaluate the effect of an innovative postoperative support program targeting quality of life, psychosocial functioning and adherence to behavior change in Geisinger Health System (GHS) bariatric surgery patients.

4 HYPOTHESIS AND SPECIFIC AIMS

The objective of this randomized controlled trial is to evaluate the efficacy and feasibility of a 4-month postoperative behavioral intervention (BI) program on psychosocial functioning and compliance in 40 bariatric surgery patients compared to a control group undergoing usual care (UC, n=40).

Knowledge gained will help to 1) fill the gaps in understanding regarding the psychosocial benefits of enhanced behavioral support following bariatric surgery; 2) improve the quality of patient care at GHS and beyond; and 3) address the U.S. obesity epidemic by providing bariatric surgery patients the best possible opportunity for long-term weight loss success. Data will be used for future NIH grant applications (R21, R01) needed to evaluate this program in larger and more diverse cohorts, as well as for manuscript development.

4.1 Hypothesis

We hypothesize that BI patients will experience significant improvements in psychosocial functioning and better compliance compared to UC. As secondary outcomes, we will evaluate within group changes (BI group) from enrollment to completion of 4-month intervention program as well as outcomes in higher risk versus lower risk patients based on their initial preoperative psychosocial evaluations. We hypothesize that the BI group will display higher levels of dietary adherence and physical activity and attend more postoperative appointments, compared to UC.

4.2 Specific Aim 1

To assess the efficacy of a 4-month behavioral intervention (BI) program after bariatric surgery on psychosocial functioning compared to usual care (UC). Psychosocial outcomes assessed will be quality of life (primary), mood (depression/anxiety), eating behaviors, self-efficacy and interpersonal functioning using standardized measures.

4.3 Specific Aim 2

To evaluate the efficacy of a 4-month behavioral intervention program on postoperative dietary and lifestyle adherence compared to the UC.

4.4 Specific Aim 3

To assess the feasibility of a 4-month behavioral program in postoperative bariatric surgery patients. We will evaluate recruitment, attrition, safety and patient/provider satisfaction in the BI group.

5 PRELIMINARY DATA

Modifiable psychosocial risk factors, including mood disorders[4], likely contribute to difficulties with postoperative compliance as psychiatric disorders are associated with general medical non-compliance[14,15]. In the GHS bariatric surgery research database (N=3,695), 43% (n=1,580) have at least one psychiatric diagnosis before surgery (ICD-10) and 56% (n=2,045) took at least one psychiatric medication (Table 1). While the rates of psychiatric disorders in bariatric surgery patients are high, particularly depression and anxiety, few programs provide psychological support for patients after surgery beyond monthly support groups.

Table 1: Select psychiatric diagnoses from the EMR in GHS bariatric patients before surgery (N=3,695)

Depression (311)	1,005	27.20%
Anxiety (300)	317	8.60%
Non-dependent Drug Abuse (305)	226	6.10%
Episodic Mood Disorder (296)	196	5.40%
Adjustment Reaction (309)	145	3.90%
Personality Disorders (301)	23	<1.0%
SSRI/serotonin modulators	1,574	42.60%
SNRI	517	14.00%
Misc. Antidepressant	346	9.50%
Tricyclic Agents	267	7.20%
Benzodiazepines	121	3.30%

At GHS, patients considering bariatric surgery undergo preoperative psychological evaluations to evaluate their readiness for surgery. All patients are then given a "traffic light" status (red, yellow, or green) according to their readiness. Patients given a "green" light are cleared for surgery, while "yellow" light patients (~25%) have preoperative milestones that require further attention before surgery (i.e., preoperative weight gain, psychiatric issues that require collateral information or referrals to mental health treatment, and difficulty adopting dietary changes before surgery). We believe that the proposed intervention may be particularly effective in patients that initially received a yellow light, but we will include both initial green and yellow light patients for this pilot study and then evaluate outcomes by light status as a secondary analysis

6 STUDY DESIGN

6.1 Description

This prospective, randomized pilot trial will evaluate a comprehensive postoperative behavioral support intervention using a 4-month bi-weekly program (BI group) in 40 bariatric surgery patients (all surgical procedure types) from the GHS Center for Nutrition and Weight Management (CNWM) compared to 40 usual care (UC) patients. Participants will be randomized to BI or UC using a computer program. Treatment will occur in two session periods to accommodate patients who complete surgery during the study duration.

We will recruit preoperative bariatric surgery patients who are close to their surgery date as well as those who completed bariatric surgery within 18 months. Participants will not be consented until surgery completion. Patients will be recruited via U.S. mail, as well as at support groups/classes and clinic appointments. We anticipate that of the ~25 surgeries conducted monthly, recruitment will take approximately 6 months to recruit 80 patients on a rolling basis. We will run two, possibly three, biweekly groups simultaneously if needed to accommodate patients available for day or evening groups. The primary outcome will be the difference in quality of life postoperatively, between groups, as well as differences in psychosocial functioning (mood, eating behaviors) and adherence (diet, physical activity, appointments). Outcomes will be assessed at time of enrollment and then at after completion of 8 treatment sessions (BI group). Final outcomes assessments will be distributed to BI and UC patients at the same time to maintain consistent data collection intervals between the groups. Secondary outcomes will include patient satisfaction.

6.2 Study Population

6.2.1 Approximate Number of Subjects

Approximately 80 Geisinger bariatric surgery patients will participate in this study.

6.2.2 Inclusion Criteria

- Age 18-65 years
- BMI≥35 kg/m^2 at time of surgery

- Primary bariatric surgery completion ≤ 18 months
- Understanding of informed consent

6.2.3 Exclusion Criteria

- Pregnancy
- Revision of bariatric surgery
- Significant cognitive impairment that prevents informed consent

6.3 Recruitment

All bariatric surgery candidates that have been cleared by psychology for surgery (~4-6 weeks before surgery), as well as those who completed bariatric surgery but are less than or equal to 18 months post-surgery, will be informed of the study either via mailed letters (see Attached Recruitment Letter), at support groups/classes or at individual pre or postoperative appointments by study staff.

Mailings will be the primary method of recruitment for patients that have completed bariatric surgery within the last 18 months. A list of names, medical record numbers, addresses, phone numbers, and return appointment dates of those who meet the inclusion and exclusion criteria will be pulled by a data analyst. This information will be used for recruitment purposes. Potentially eligible patients will be called by a member of the study team to discuss the study in more detail, answer any questions, and if interested, a study visit will be scheduled to review the consent form in detail. Patients that agree to participate will then complete the baseline surveys at that time or can take the surveys home to complete and return in a pre-paid envelope. (See Attached Telephone Screening Script/Surveys)

Patients that have not yet completed bariatric surgery will be approached at either a support group/class or at an individual appointment. If they are approached at support group/class, they will be presented the information about the study in a group setting and given a copy of the consent form that can be taken home for consideration. If they are interested in participating, they will be approached to go over the consent form in detail and sign consent at their first post-operative appointment. After the consent is signed and before randomization occurs, the baseline surveys will be completed either in the clinic or they can opt to take the surveys home to complete and return in a pre-paid envelope.

Patients (both pre-op and post-operative) may also be approached at individual appointments. Pre-operative patients would be informed about the study. If they are interested in participating, they will be approached to go over the consent form in detail and sign consent at their first post-op appointment. After the consent is signed and before randomization occurs, the baseline surveys will need completed either in the clinic or they can opt to take the surveys home to complete and return in a pre-paid envelope. Post-operative patients could sign consent that day if interested in participating in the study. Once consent is signed and before randomization occurs, baseline surveys will be completed either in the clinic or they can opt to take the surveys home to complete and return in a pre-paid envelope.

All participants will be randomized following consent and completion of baseline surveys so they will not be aware of which group they are in while completing baseline surveys.

6.4 Study Duration

6.4.1 Approximate Duration of Subject Participation

Subjects will participate in the study for approximately 6-8 months. This includes recruitment and 4 months of group-based treatment or a waiting period for the control group.

6.4.2 Approximate Duration of Study

This study will be completed in approximately one year. The end of the study is the last visit of the last subject or end of collection of data from the patient's electronic health record.

6.5 Procedures

Following enrollment and completion of baseline surveys, participants will be randomized using a computer program developed by the study biostatistician to the BI or UC groups.

Behavioral Intervention: Participants that are randomized to the intervention group will be able to begin treatment sessions at different times points to accommodate new bariatric patients that complete surgery during the study duration. During the course of the study, there will be two 4-month bi-weekly session periods with at least two separate groups per session period. Therefore, there will be at least 4 time points that new patients can begin the process to complete all 8 individualized sessions. We estimate 10-15 patients per bi-weekly group for 60-minute sessions. The intervention will be structured such that each session will function independently (Table 2).

Table 2. Treatment Session Chart

First Round				
Month	**Week**	**Session #**	**Group #**	**Milestone**
March	Week 1	1	Group 1	First session initiation
	Week 2	1	Group 2	
	Week 3	2	Group 1	
	Week 4	2	Group 2	
April	Week 5	3	Group 1	
	Week 6	3	Group 2	
	Week 7	4	Group 1	
	Week 8	4	Group 2	
May	Week 9	5	Group 1	
	Week 10	5	Group 2	
	Week 11	6	Group 1	
	Week 12	6	Group 2	
June	Week 13	7	Group 1	
	Week 14	7	Group 2	
	Week 15	8	Group 1	
	Week 16	8	Group 2	First session surveys complete
Second Round				
July	Week 1 Session start delay due to July 4th holiday.			
	Week 2	1	Group 1	Group 1 start
	Week 3	No group meeting		
	Week 4	2	Group 1	
August	Week 5	1	Group 2	Group 2 start
	Week 6	3	Group 1	
	Week 7	2	Group 2	
	Week 8	4	Group 1	
September	Week 9	3	Group 2	
	Week 10	5	Group 1	
	Week 11	4	Group 2	
	Week 12	6	Group 1	
October	Week 13	5	Group 2	
	Week 14	7	Group 1	
	Week 15	6	Group 2	
	Week 16	8	Group 1	Group 1 complete
	Week 17	7	Group 2	
November	Week 18	No group meeting		
	Week 19	8	Group 2	Group 2 complete

*A group three may be added to a session period to accommodate patient schedules if needed.

The intervention will focus on addressing psychosocial changes after surgery, strategies for postoperative diet and adherence, and preventing weight regain (Table 3). Patients will collaboratively set goals for diet, physical activity, adherence and other behavioral changes tailored to the needs of each participant. Session content and intervention duration are evidence-based, derived from a meta-analysis of post-operative interventions aimed at using behavioral management strategies to enhance weight loss following bariatric surgery[20].

Confidentiality and group parameters and expectations will be introduced at the beginning of each session where new patients can start (treatment sessions 1&4 of first 4-mo bi-weekly session and treatment session 1 of second 4-mo bi-weekly session). Participants will be provided information regarding prevention of weight regain and resources for tracking and self-monitoring weight, diet and physical activity. Motivation for weight loss and participation in the group will also be discussed.

Sessions will contain a uniform structure to allow for easy transition of members in and out of the group. Sessions will start with an introduction of new members and review of participant progress on their goals and action plan or homework from the previous session. The majority of the session will be spent introducing and discussing new material and participants will be asked to develop a new action plan and state their goals at the end of the session. Make-up sessions will be offered for participants who miss a group.

Table 3. Intervention Content

Session	Primary Content
1	Preventing malnutrition (vitamins, protein intake, etc.)
2	Address problematic eating patterns after surgery (grazing, loss of control over eating, scheduling and emotional eating) Part 1
3	Address problematic eating patterns after surgery (grazing, loss of control over eating, scheduling and emotional eating) Part 2
4	Physical activity for health and wellness (w/side benefit of weight maintenance)
5	Managing special occasions: holidays, family gathering, restaurant eating, and vacations
6	Relationships and social support after bariatric surgery
7	Body Image
8	Taking stock and maintaining progress (relapse prevention)

The full Group Session Interventional Outline is attached.

A member of the research team will remind the participants that randomize to the Intervention Group the day before each session either via phone or email (if participant chooses email communication they will provide the study team with their email address).

Should any participant express significant psychiatric distress in group, such as emotional reactions to weight loss or how relationships are affected, the group leader (a clinical psychology resident) will assess the participant immediately after group and consult with the study PIs (Dr. Campbell or Dr. Lent). The group leader and study PI(s) will refer the participant for further treatment as appropriate. The group leader may also ask disruptive participants to leave group at any time.

Usual Care:
Participants randomized to usual care will complete surveys at postoperative clinic visits or if necessary, via mail. Upon study completion, patients randomized to usual care will be offered the 8 sessions provided to the BI group. This group will run after all study data have been collected.

Table 4. Compensation and Reimbursement

Behavioral Intervention Group	Compensation(Surveys) Reimbursement (Sessions)	Usual Care Group	Compensation (Surveys)
Baseline Surveys	$50	Baseline Surveys	$50
Session 1	$15	N/A	N/A
Session 2	$15	N/A	N/A
Session 3	$15	N/A	N/A
Session 4	$15	N/A	N/A
Session 5	$15	N/A	N/A
Session 6	$15	N/A	N/A
Session 7	$15	N/A	N/A
Session 8	$50	Final Surveys	$50
TOTAL	**$205**	**TOTAL**	**$100**

Measures:

Surveys for Aims 1-2 will be administered to all participants at post op baseline (within two weeks of signing consent) and then at the completion of the 8 treatment session timeframe for both the BI and UC groups. Aim 3 measures of feasibility and satisfaction will be administered to BI participants only and at one time point, at study conclusion. Demographic, surgical and medical information will be collected from the EMR including weight (kg), height (cm), age at enrollment, sex, race/ethnicity, surgery type, insurance status, diagnoses and medication. (Surveys are attached).

1. SF-36, Health-Related Quality of Life (HRQoL, primary outcome): As part of the Medical Outcomes Study (MOS), RAND developed the 36-Item Short Form Health Survey (SF-36). The SF-36 is a set of valid, reliable[34-36], and easily administered QoL measures that have been used in obese populations[37,38].
2. PHQ-9, Patient Health Questionnaire (depression): The PHQ-939 is a brief screening tool already integrated into GHS standard of care that screens for depression severity (sensitivity and specificity=88%). Scores of 5=mild depression, 10=moderate, and 15+=severe.
3. State-Trait Anxiety Inventory (STAI, anxiety): The STAI[40] is a 40-item assessment of anxiety symptoms and scored on a 4-point Likert scale. Internal consistency ranges from 0.86-0.95; test-retest reliability range 0.65-0.75 over a 2-month interval It has demonstrated good construct and concurrent validity[40], and has been used in patients with obesity[41].
4. Weight Efficacy Life-Style (WEL)[42]: The Short form WEL is a 8-item measure that evaluates an individual's sense of self-efficacy in resisting the urge to eat in various situations. Internal consistence ranges from 0.70-0.90 and it has demonstrated sensitivity to change following weight loss interventions with obese populations.
5. The Paffenbarger Physical Activity Questionnaire (PPAQ)[43]: The PPAQ is an 8-item, self-administered questionnaire designed to measure participation in leisure time. Respondents report the number of city blocks they walk and flights of stairs they climb on a typical day, as well as to list the frequency and duration of any sports or recreational activities they participated in over the past year. From these questions, a physical activity index (PAI) is computed, providing an estimate of energy expenditure. The PPAQ is used in bariatric surgery research[44].
6. Loss of Control Over Eating Scale-brief[45]: The 7-item version of the LOCES is a brief measure of the experience of loss of control over eating over the past 28 days and is

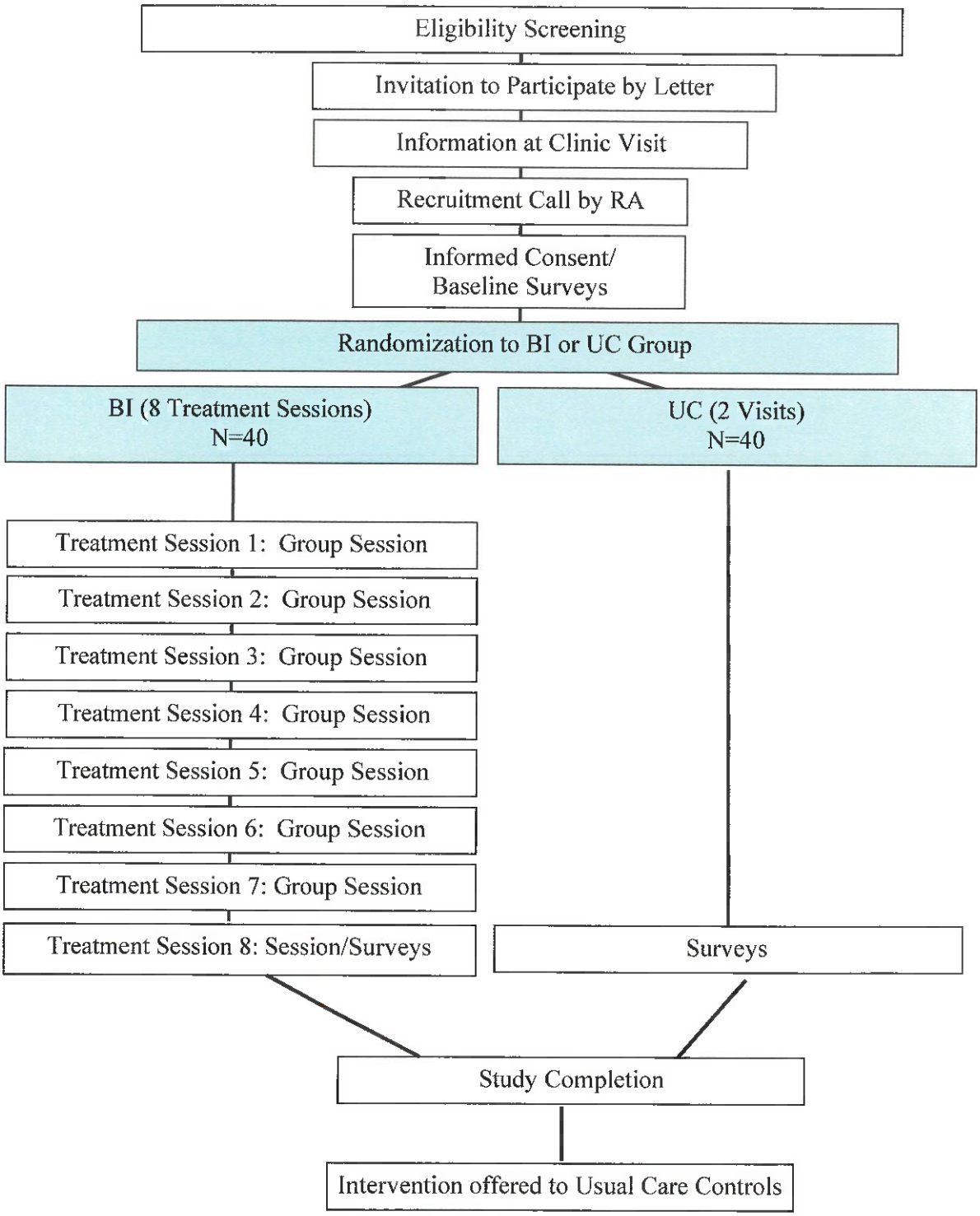
scored on a 5-point Likert scale. The brief version of the full 24-item measure has demonstrated high internal consistency (0.93) and test-retest reliability (r=0.82) among non-clinical populations. The 7-item version is highly correlated with the 24-item version of the measure (r=0.96), which has also demonstrated good convergent and discriminant validity and was subjected to a more rigorous development and validation process than alternative measures.

7. Emotional Eating Scale (EES)[46]. The EES is a 25-item scale that evaluates an individual's urge to eat while experiencing a range of emotions. The measure has demonstrated good discriminate validity, test-retest reliability, and sensitivity to change following treatment for weight loss and/or binge eating.
8. Social Adjustment Scale (SAS-SR)[47,48]: The Short form SAS-SR is a 24-item measure of functioning in 6 social domains and covers four categories: 1) performance at expected tasks; 2) amount of friction with people; 3) finer aspects of interpersonal relations; and 4) feelings and satisfactions. Questions are on a 5-point scale, with higher scores indicating more impairment. The SAS–SR generates 7 mean scores plus an overall mean. Internal consistency for the overall score was moderate (alpha=0.74)[47]. Validity evidence includes appropriate patterns of mean differences, significant correlations with clinical ratings, and sensitivity to change[48,49].
9. Adherence: Compliance with postoperative bariatric surgery clinic appointments, including missed visits/no shows, will be obtained from the EMR. Dietary adherence will be measured by 9-point Likert scale ("How well are you following the diet plan given to you by the dietitian?") developed for use in bariatric surgery research[50].
10. Patient satisfaction: Satisfaction will be measured using bariatric surgery postoperative satisfaction instruments[10,51].

6.5.1 Study Time and Events Table

Study Month	1	2	3	4	5	6	7	8	9	10	11	12
IRB Completion												
Recruitment BI + UC, Baseline Measures (n=80)												
Intervention, BI group (n=20), group 1												
Intervention, BI group (n=20), group 2												
Data Analysis												
Manuscript and Grant Preparation												

Figure 6.5.2: Study Flow Diagram



6.6 Primary Endpoints

The primary endpoint will be quality of life. Obesity is associated with diminished quality of life (QoL) and QoL is frequently cited as a primary reason that patients pursue bariatric surgery. Evaluating QoL emphasizes patient experience and perception and provides a measurement of treatment efficacy beyond weight loss. In this application, we propose to evaluate the effect of an innovative postoperative support program targeting quality of life, psychosocial functioning and adherence to behavior change in Geisinger Health System (GHS) bariatric surgery patients.

6.7 Secondary Endpoints

Secondary endpoints include differences in psychosocial functioning (mood, eating behaviors) and adherence (diet, physical activity, appointments), as well as patient satisfaction, treatment feasibility and attrition.

6.8 Statistics

Craig Wood, the Obesity Institute biostatistician, will perform the statistical analyses for this study.

6.8.1 Statistical Analysis Plan

Randomization will be conducted using randomization schema generated by the Biostatistician. Randomization to UC or BI will occur following consent. It is plausible that yellow light patients may experience greater benefit from the intervention. We will examine the comparability of demographics characteristics between two groups at baseline. If baseline demographic factors are not balanced between the two groups, we will then adjust for these factors during final analyses.

The primary outcomes will be the difference in mean HRQoL scores (emotional scale) as assessed by the SF-36 between the BI and UC groups at postoperative month 4 (assessment time frame will be postoperative month 1 to month 4). Continuous variables will be analyzed using independent t-tests. We will evaluate the appropriate assumptions using Shapiro–Wilk or Kolmogorov–Smirnov tests (normality) and a Brown–Forsythe test or a Q–Q plot (homogeneity of variance). Should the normality assumption be violated, we will then attempt transformations. If necessary, ANCOVA will be used to control for wave (1 vs 2) or other baseline covariates.

Secondary outcomes include differences between groups in the remaining HRQoL scales. Similar methods as described for the primary outcome will be used for the secondary outcomes. Additionally, within group analyses (secondary) will use paired t-tests. Categorical variables will be analyzed by chi-squared tests.

We will conduct intent-to-treat analysis to determine differences in primary and secondary outcomes using data from all randomized participants. Missing data will be handled using multiple imputation[55]. We will also conduct sensitivity analyses such as best and worst case analyses[56].

6.8.2 Statistical Power and Sample Size Considerations

Previous research54 indicates that bariatric surgery patients report mean (SD) SF-36 subscale scores before and after surgery of:

	Preoperative	Postoperative	Effect Size
Role - Emotional	74.9 (34.4)	92.3 (22.1)	0.56 SD
Mental Health	70.5 (17.4)	74.6 (18.9)	0.2 SD
Mental Health Composite Score	48.9 (10.1)	52.1 (8.4)	0.3 SD

We aim for a difference of 2/3 standard deviation in scores between groups at 4 months postoperatively. A sample size of 40 participants per group will have 83% power to detect an effect size of 2/3 SD using a two group t-test with a 0.05 two-sided significance level. If the effect size is small than 2/3 SD, we will still be able to assess the level of confidence on the observed differences that will be used to design a large study. When the sample size in each group is 40, a two-sided 95.0% confidence interval for the difference of two means in mental health composite score will extend 4.4 from the observed difference in means, assuming that the common standard deviation is known to be 10.1 and the confidence interval is based on the large sample z statistic.

6.9 Data Management

6.9.1 Data Collection and Storage

An electronic database will be created and data will be entered into the database by research assistants. The database will be password protected and paper surveys kept in a locked file drawer. Each participant will be assigned a unique study ID number. A list of study ID numbers with associated identifying information (e.g., name, medical record number) will be electronically on a secure, password protected server. Access to the identifiers will be limited to study team members that require use of the identifiers.

6.9.2 Records Retention

Study records will be retained for 6 years. After 6 years, the study-specific database will be deleted and paper surveys shredded.

7 SAFETY MONITORING

This study will examine the effect of a psychological intervention in bariatric surgery patients compared to usual care controls. The proposed assessments are believed to pose minimal risk to participants. Group leaders will continually monitor for adverse events during the study duration, including worsening psychiatric distress and post-operative complications associated with bariatric surgery.

A subject's AEs and SAEs will be recorded and reported from the signing of the informed consent form until completion of study.

7.1 Adverse and Serious Adverse Event Reporting

The research team will notify GIRB of all study AEs & SAEs in accordance with policy guidelines. An SAE will be followed until either resolved or stabilized.

8 PROTECTION OF HUMAN SUBJECTS

8.1 Informed Consent

The informed consent form will be submitted to the IRB for review and approval.

Before any procedures specified in this protocol are performed, a subject must:

- Be informed of all pertinent aspects of the study and all elements of informed consent.
- Be given time to ask questions and time to consider the decision to participate.
- Voluntarily agree to participate in the study.

- Sign and date an IRB-approved informed consent form.

8.2 Protection of Human Subjects Against Risks

All studies with identifiable data carry the risk of the potential loss of privacy. We will address this issue in several ways. First, all PHI will be stored on a secure, password protected network to which only limited number of research staff will have access. For data analysis, all data will be de-identified to the extent possible. Any information made available to other investigators will be in a HIPAA compliant format. PHI taken from the medical record will include name, medical record number, address, date of birth, date and type of surgery, appointment attendance, gender, race/ethnicity, weight, height, medications and medical conditions.

We believe that this study poses a low risk to participants; however, should any participant express significant psychiatric distress in group, including but not limited to suicidal or homicidal thoughts, the group leader (a clinical psychology resident) will assess the participant immediately after group and consult with the study PIs (Dr. Campbell or Dr. Lent). The group leader and study PI(s) will refer the participant for further treatment as appropriate. The group leader may also ask disruptive participants to leave group at any time.

Should a participant report post-operative complications following bariatric surgery, the patient will be referred by group leaders or the study PI to the emergency room or to the bariatric surgery clinic, as appropriate.

8.3 Data Monitoring Plan

Data Collection

An electronic database will be created and data will be entered into the database by research assistants. The database will be password protected and paper surveys kept in a locked file drawer. Each participant will be assigned a unique study ID number. A list of study ID numbers with associated identifying information (e.g., name, medical record number) will be electronically on a secure, password protected server. Access to the identifiers will be limited to study team members that require use of the identifiers.

In any publications or presentations results from this research will be de-identified.

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