Study Title: Positive Psychology Intervention for Patients Post-bariatric Surgery and Their Partners

NCT Number: NCT05958615

Document Date: 5/27/2025

Evaluation of feasibility, acceptability, and preliminary efficacy of a dyadic positive psychology intervention for patients post-bariatric surgery and their partners: A pilot randomized controlled trial

Protocol Summary

IRB Approval Date of Current Version:	5/27/2025
University of Utah IRB #:	IRB_00165737
Sponsor:	NIH NATL CTR FOR ADVNCING TRANSLT SCNCES
Principal Investigator:	Larissa McGarrity
Internal Staff and Sub-Investigators:	**Site Name** / **Staff Names** University of Utah Larissa McGarrity Paige Martinez Anna Ibele Jacob Wilson Brian Baucom Abbie Paxman Heidi Hansen Lisa Aspinwall Kathryn Bee Ella Gaskin Alexandra Terrill

This document was created using the ERICA Online System at the University of Utah. The document is created from study information approved by the IRB on the date listed above. Any alteration to the original content of this document may not be considered to represent the study as approved by the IRB.

Background and Introduction

Bariatric surgery is the most effective intervention for severe obesity and associated co-morbidities. However, around 2 years after surgery, a substantial proportion of patients struggle with weight regain, psychological complications (e.g., disordered eating, depression), and relationship challenges. To achieve optimal long-term outcomes, a biopsychosocial focus and treatment approach is critical. Existing interventions primarily target weight, occur at the individual patient level, use a risk-based or problem-focused lens, and are inaccessible to the average patient. In contrast, this proposed research will test feasibility, acceptability, and preliminary efficacy of an intervention **to improve psychosocial health, occurring at the dyadic (patient and partner) level, using a strengths-based or positive psychology lens, and remotely-delivered for accessibility**. This multi-faceted approach is needed to address the high rate of psychiatric disorders and lack of social support among bariatric surgery patients that compromises long-term surgical outcomes. Patients in relationships report inconsistency in support provision from partners, lose less weight than those not in relationships, and are at elevated risk of divorce post-surgery. The investigator(s) research has demonstrated declines in relationship satisfaction from before to after surgery, and associations with elevated levels of binge eating, anxiety, and social stress 2 years after surgery. The investigator(s) has also documented the importance of adaptive coping, social support, and resilience for improved mental health and eating behaviors in this stigmatized population. In combination, existing research supports the need for dyadic-level and strengths-focused intervention to prevent exacerbation of psychological distress and difficulties in long-term weight management.

The investigator and research team have utilized pilot grant funding to adapt an evidence-based dyadic positive psychology intervention (dPPI) for post-bariatric surgery patients and their partners. This intervention was developed in a two-phase, mixed-methods study. The investigator first obtained feedback from 6 patients and partners in focus groups about relationship health following bariatric surgery and intervention needs. The investigators then asked these couples to pilot test 4 adapted intervention modules and obtained quantitative and qualitative feedback, which suggested high satisfaction with and benefit from the intervention modules. This study resulted in a finalized 8-module, remotely-delivered dPPI with content consisting of activities (expressing gratitude, practicing acts of kindness, fostering relationships, focusing on the positive, savoring, working toward goals, meaning finding/values, planning for the future) completed individually and as a couple. The dPPI is now ready for formal testing of feasibility, acceptability, and preliminary efficacy in a pilot randomized clinical trial (RCT).

Grant Congruency: Per the study team, the grant award and proposal (IRB application) are in line with each other.

Purpose and Objectives

Aim 1. **Evaluate preliminary <u>efficacy</u> of the dPPI on mental health of couples (patients post-bariatric surgery and their partners) in a pilot RCT of 40 couples.** (dPPI= dyadic positive psychology intervention; RCT= Randomized controlled trial)

-The primary outcome for preliminary efficacy testing is changes pre to post intervention in mental health (depressive symptoms of patients and partners).

-Secondary outcomes include resilience, relationship satisfaction, eating and physical activity behaviors, and weight maintenance.

Hypothesis: 1: Depressive symptoms significantly improve in the dPPI group compared to the control group for both patients and partners.

Hypothesis 2: The dPPI improves resilience, relationship satisfaction, adherence to eating and physical activity behaviors, and weight maintenance.

Aim 2. **Determine <u>feasibility</u> and <u>acceptability</u> of the dPPI as well as the RCT design.**

-Measures of feasibility and acceptability will include the proportion of couples in each group who initiate and complete the program, number of weekly activities completed, and ratings of satisfaction with the intervention. These metrics will be crucial for future grant funding efforts.

Study Population

Age of Participants: 18 years of age and older

Sample Size:
At Utah:
All Centers: 80

Inclusion Criteria:
Inclusion:

Male or Female individuals age 18+

Between 1 to 3 years post-bariatric surgery, or who's partner is 1 to 3 years post-bariatric surgery

Individuals who were, and still are, in a relationship with the same significant other at the time of the surgery

Exclusion Criteria:
Exclusion:

Couples in which both members have undergone bariatric surgery

Current participation by patients or partner in another intervention study

Design

Randomized Trial
Prospective Social/Behavioral Intervention or Experiment
Phase I Clinical Trial
Phase II Clinical Trial

Study Procedures

Recruitment/Participant Identification Process:

Records of patients who have previously had bariatric surgery performed 1-3 years ago at the University of Utah will be reviewed by the study team to determine which patients meet inclusion criteria. All patients between 1 to 3 years post-surgery (either roux-en-Y gastric bypass or sleeve gastrectomy) from the University of Utah Bariatric Surgery Clinic will be identified based on the RedCap database maintained by the research team.

Patients who are potentially eligible will be contacted by email by the study coordinator, who will facilitate additional eligibility/screening questions, which will include some level of baseline mood or relationship challenges utilizing the PHQ-2 questionnaire combined with the following question: “Many patients after bariatric surgery struggle with adjusting to all the lifelong behavior changes and may even experience depressed mood in the years post-surgery. Partners can experience some of these same feelings. Sometimes new relationship dynamics and challenges come up. Have you or your partner experienced any mood changes since surgery, difficulties coping with the lifelong changes, or relationship challenges or stressors?” to ensure that eligibility criteria are met. After it is determined that patients are eligible, they will be asked to provide contact information for their romantic partner to allow for enrollment and communication with both.

Recruitment and enrollment in the study will be on a rolling basis, continuing until at least 24 patient and partner couples (48 participants) have completed the intervention and associated surveys. It is anticipated that 35 couples will need to be enrolled in order to achieve the 24 couples completing an adequate number of surveys (defined as 6 out of 8 weeks) to evaluate our aims, based on Dr. Terrill’s previous work conservatively estimating 70% retention.

It is the study teams intent not to use the University of Utah Hospital/Clinics EMR however it may be necessary to use the EMR to gather updated email, physical address and marital status. For the most part it is the study teams plan to strictly use the bariatric surgery database for this project. No partner/spouse information will be utilized through the EMR system at all.

Requesting aSpanish Inclusion Exemption:

The study team is fully aware that Spanish is the second-most common language spoken in Utah, we are supportive of this initiative by the University and the IRB. The Department of PM&R research are looking at ways to fund this new implementation of including Spanish-Speaking individuals in research and ways to accommodate and fund this requirement into future research. For this particular project we will not be able to implement the inclusion of Spanish Speaking individual due to the uses 8 educational animated video modules that would all need to be translated, along with nearly 20 surveys with only a handful of surveys that have been validated in Spanish. The surveys do require a large amount of self-reported, written data collection from participants and the options for translating responses back into English are not feasible. Lastly, the REDCAp built this project is extremely complicated and complex with nearly 3,000 fields, eight arms and took nearly 5 months to build. The grant monies that supports the study, has been allocated per the funding organizations requirements.

Informed Consent:

Description of location(s) where consent will be obtained:

Consent will take place electronically online via the University of Utah REDCap system.

Description of the consent process(es), including the timing of consent:

Because all study activities are designed to be remotely administered, and our participant may be located outside the Salt Lake area given the catchment area for the University of Utah's Bariatric Surgery program, consent will be obtained using IRB-approved electronic methods. An informed consent document will be provided through REDCap and can be signed electronically by each member of the participant dyad after they have had time to read it and ask questions. During the consent process, the potential participant will be informed of the overall purpose of the study, what participation would entail in terms of intervention participation and data collection, the randomization process (including they could be randomized into a waitlist control condition), potential risks, potential benefits (to self and society), and how they will be reimbursed for their time. They will also be informed that their participation would be entirely voluntary and that they can drop out at any time, and that their withdrawal or limited participation will not affect the health care services they are currently receiving or any services that they might be eligible for in the future, through the Comprehensive Weight Management Program, University of Utah, or otherwise. They will be informed that all their information will be confidential and secure. If the potential participant desires, they will be given additional time to decide if they want to participate and then will be contacted 2-3 days later to learn of their decision. For this project, if the participant would like to participate in this study, after reading the IRB approved cover letter and proceeding to the survey's/questions they will be agreeing to all that is being asked of them in the consent cover letter. No actual signature will be required.

Procedures:

Bariatric surgery records will be reviewed and potential participants and their significant others will be contacted for enrollment. All patients between 1 to 3 years post-surgery (either roux-en-Y gastric bypass or sleeve gastrectomy) from the University of Utah Bariatric Surgery Clinic will be identified based on the RedCap database maintained by the bariatric surgery

research team. Those who were in a romantic relationship at the time of surgery (information maintained in the database) will be contacted for potential participation by email and screened for eligibility criteria. Those who meet criteria will be asked to provide contact information for their romantic partner as well for enrollment.

It is the study teams intent not to use the University of Utah Hospital/Clinics EMR however it may be necessary to use the EMR to gather updated email, physical address and marital status. This will only be for an as need purpose, the study teams plan is to strictly use the bariatric surgery database for this project. **No partner/spouse information will be utilized through the EMR system.**

Willing participants and their partners will each be sent a survey link which includes a consent cover letter. This electronic survey will serve as the baseline assessment for all participants. The survey consists of measures regarding physical and emotional health, and questions regarding their relationship with their partner. This survey will take each person around 60 minutes to complete.

All aspects of the study and intervention will be administered remotely. Couples will be randomized 1:1 to intervention versus waitlist control groups. After baseline data collection, couples assigned to the intervention group will have 8 weeks of ReConnect (the intervention) followed by 8 weeks of follow-up surveys. Couples assigned to the control group will have 8 weeks of waitlist control surveys followed by 8 weeks of ReConnect (the intervention). All participants (intervention & waitlist control group) will be asked to complete 8 weeks of assessments followed by 8 more weeks of surveys for a total of 16 weeks of surveys. This design offers opportunities to assess within and between group comparisons evaluating the efficacy of the intervention. In addition to testing efficacy of ReConnect, this trial will allow us to assess processes critical for success of the large-scale R01 trial, including feasibility and acceptability metrics. Patients and partners will also complete brief weekly check-in surveys via REDCap.

Intervention Description:

The RCT design and all intervention components will be delivered remotely to ensure accessibility, reach, and that the sample is reflective of the target population. To begin the intervention, participants will be sent a link to access and view an introduction video online for an overview of the study and initial training. The same information will be available in print copy for future reference. The introduction will explain the purpose of the intervention (to promote resilience in couples after bariatric surgery), format and structure (8 weekly modules), and what to expect each week. ReConnect is organized into weekly modules. Each module features 1) psychoeducational materials (both in writing and via QR code linking video) about a general topic related to resilience, coping, support, and/or overall well-being of the individual and couple, tailored for the bariatric surgery context; 2) instructions and guidance on PPI activities that relate to that week's theme; 3) choices of PPI activities that relate to the week's theme or topic for patients and partners to practice both individually and as a couple; and 4) additional resources relevant to the theme. The modules will include up to 10 example activities and participants will be asked to choose one or more of the activities to perform individually at least twice for 15 minutes, and as a couple at least twice for 15

minutes. Participants are encouraged to do these activities especially on “difficult or bad” days, when feeling down or unmotivated. Activity choices are available because existing research suggests practicing a variety of self-selected PPI activities produces more sustained improvements in mood and well-being.(Lyubomirsky & Layous, 2013)

Participants will receive a booklet by mail and a PDF by email of the full intervention and PPI activities that will guide them through the 8 weeks. We will also send each intervention module separately at the beginning of each week, including hyperlinks and QR codes for additional resources and instruction videos. Each week a brief online video will explain the week’s theme and instruct them to select their activities. The weekly modules are estimated to take 75 minutes total to complete, including 4 15 minute activities (2 individual, 2 as a couple) and 15 minutes to review the psychoeducational materials for the week. To track activities, participants will receive an email prompt to remind them to complete activities mid-week and a final email at the end of the week with a secure survey link to log any that were completed (via Research Electronic Data Capture [**REDCap**]). Questions will assess the type and number of activities completed, ratings of satisfaction with the intervention, brief mood screening, and opportunities to provide qualitative feedback for that week’s modules.

Patient Survey:

Baseline Activities & Surveys

-Screening, Inclusion/Exclusion, ICF

-Relationship Questions

-PHQ-9

-Mental Health

-Dyadic Adjustment Scale

-Bariatric Surgery Related Questions

-Conner-Davidson Resilience Scale 25 (CD-RISC-25)

-Godin Leisure Time Exercise Questionnaire

-The Short Healthy Eating Index Survey

-Dyadic Coping Inventory (DCI-short)

-Positive Affect and Well-Being Short Form (PAWB)

-Weight-Loss Related Behavior Self-Efficacy

-Psouni 2016 Intentions Scale

-Duke Social Support and Stress Scale (DUSOCS)

-Emotional Eating Scale

-Demographics and General Questions

Week #1 weekly survey for intervention & waitlist group

Week #2 weekly survey for intervention & waitlist group

Week #3 weekly survey for intervention & waitlist group

Week #4 weekly survey for intervention & waitlist group

Week #5 weekly survey for intervention & waitlist group

Week #6 weekly survey for intervention & waitlist group

Week #7 weekly survey for intervention & waitlist group

Week 8 Surveys

-Reconnect Questions (Intervention Group)

-PHQ-9

-Mental Health

-Dyadic Adjustment Scale

-Bariatric Surgery Related Questions

-Conner-Davidson Resilience Scale 25 (CD-RISC-25)

-Godin Leisure Time Exercise Questionnaire

-The Short Healthy Eating Index Survey

-The Short Healthy Eating Index Survey

-Dyadic Coping Inventory (DCI-short)

-Positive Affect and Well-Being Short Form (PAWB)

-Weight-Loss Related Behavior Self-Efficacy

-Psouni 2016 Intentions Scale

-Duke Social Support and Stress Scale (DUSOCS)

-Emotional Eating Scale

Week #9 weekly survey for intervention & waitlist group

Week #10 weekly survey for intervention & waitlist group

Week #11 weekly survey for intervention & waitlist group

Week #12 weekly survey for intervention & waitlist group

Week #13 weekly survey for intervention & waitlist group

Week #14 weekly survey for intervention & waitlist group

Week #15 weekly survey for intervention & waitlist group

Week 16 Surveys

-Bariatric Surgery Related Questions

-Reconnect Question (Waitlist Group)

-PHQ-9

-Mental Health

-Dyadic Adjustment Scale

-Bariatric Surgery Related Questions

-Conner-Davidson Resilience Scale 25 (CD-RISC-25)

-Godin Leisure Time Exercise Questionnaire

-The Short Healthy Eating Index Survey

-The Short Healthy Eating Index Survey

-Dyadic Coping Inventory (DCI-short)

-Positive Affect and Well-Being Short Form (PAWB)

-Weight-Loss Related Behavior Self-Efficacy

-Psouni 2016 Intentions Scale

-Duke Social Support and Stress Scale (DUSOCS)

-Emotional Eating Scale

Inclusion of People Who Speak Spanish in Research Exemption:

The study team is requesting an exemption to include Spanish or Non-English speaking individuals in this research project.

- This study includes approximately 26 surveys, of those 26 surveys there are only a couple of surveys that have been translated and validated in the Spanish language. There for an exemption is being requested.
- For this research project utilizing grant funds the study team has created eight weekly animated videos/modules in English that lead up to the required study weekly measures. There are no funds or time to have these videos translated and approved to include Non-English speaking indiviudals.
- The current enrollment as of 11-Jun-2024 is 27 couples (54 individuals) with the goal of 35 couples or 70 individuals, better enrollment than we had anticipated
- The NIH grant funded the printing of 70 manuals/booklets (28 page) with study activities that the couple are required to explore during 8 weeks out of the 16 weeks of this study, all in English, there are no funds to have this translated into Spanish.
- A REDCAp database has been created with 8 arms that took approximately 4 months to build and test. There were no funds to support this endeavor other than departmental. There are 2,103 data fields, the complexity of this REDCAp alone would prohibit Non-English speaking individuals from participating.

The PM&R department is aware of this new requirement, working towards additional funding to support this relatively initiative is underway however for this project there are too many obstacles to over come to include Spanish Speaking individuals. Study staff are looking for ways to be compliant in the future however at this time, for this project it is not able to enroll Spanish/Non-English speaking individuals into this study team, formally requesting an exemption.

Procedures performed for research purposes only:

Statistical Methods, Data Analysis and Interpretation

For **Aim 1**, mixed linear effects regression models will be fitted to each outcome. The patient and partner will be nested within dyad, with the mixed effects approach accounting for lack of independence. In each model, the pre-intervention outcome will be included as a covariate to adjust for any baseline difference (e.g., depressive symptoms pre-intervention controlled in model fitted to depressive symptoms post-intervention). This approach is more statistically powerful than a change analysis (e.g., depressive symptoms post-intervention minus depressive symptoms pre-intervention to achieve a depression change score) and avoids regression toward the mean bias. Treatment group will be the primary predictor variable (1=ReConnect Intervention, 0=Waitlist Control). While controlling the baseline differences, this “analysis of covariance” approach tests a group difference in improvement from baseline. To assess intervention efficacy for patients or partners, a separate model will be fitted to each intervention condition or patient/partner subgroup, while making comparison to the control

group. The p values will be adjusted for two comparisons using Hochberg's multiple comparison procedure while adjusting for the patient-partner correlation to improve statistical power. Additional exploratory analyses will be conducted to determine whether mood changes in one partner are associated with mood changes in the other partner over time. This analysis will be conducted using PHQ-9 scores in the Actor-Partner Interdependence Model (APIM) Framework. In APIM models, the couple is the unit of analysis.(Cook & Kenny, 2005; Kenny et al., 2005) In this model, the predictor variables are a patient and partner's depressive symptom scores at weekly intervals. The outcome variables are a patient and partner's weekly depressive symptoms. This analysis can determine the correlation between couples' scores at each time point (interdependence effects), so a specific growth-curve structure does not need to be specified. The model examines how one's own score predicts one's following week score (actor effects) and how one's weekly score predicts the following week's score of the other partner (partner effects). These analyses are run simultaneously in a structural equation model with repeated measurements, using as many weeks as are available for each couple, so drop-outs are not an issue. Although there will likely not be statistical power to make definitive conclusions for this exploratory test with the planned sample size, this analysis will further assist with proof-of-concept needed for the larger future RCT. For **Aim 2**, response, recruitment, and attrition rates will be calculated to measure feasibility. If any of these metrics are below target (recruitment < 35 dyads; attrition > 20%; response to outcome assessments < 90% of active participants; response weekly check in surveys < 70%), we will determine barriers, and re-evaluate the study design, recruitment and screening strategies, and method of intervention delivery. We will also evaluate number contacted versus enrolled, reasons potential participants provided for declining enrollment, and ability to recruit a diverse sample representative of bariatric surgery patients in this region for the future, large-scale R01 effectiveness RCT. Acceptability of ReConnect will be assessed in the weekly check-in surveys and post-intervention with a satisfaction survey. Participants will rate on a 1-10 Likert scale how satisfied they were with content and structure of the intervention, as well as perceived benefits. Participants will also be asked in the final survey to provide any qualitative feedback regarding perceived positive and/or negative effects of the intervention.