



Rationale and design of a feasibility and acceptability RCT of romantic partner and support figure attendance during bariatric surgery visits

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ABSTRACT

As US obesity rates increase, more patients, particularly females, are seeking out bariatric surgery. As bariatric surgery patients' social supports have been vastly understudied, clinicians and researchers have limited information about how to include support figures, including romantic partners, in the surgery process. To address this gap in knowledge, we are conducting a four-arm randomized controlled trial to assess the feasibility, acceptability and preliminary efficacy for the inclusion of romantic partners and support figures throughout the bariatric surgery process for a group of 110 women age 18 years or older. Patients will be randomized based upon their cohabitating romantic relationships at baseline. Female patients who have a cohabitating romantic partner will be randomized to one of two arms: partner attended (PA), and partner attended treatment as usual (PA-TU). To provide greater detail about social support during the bariatric process, interested patients (female or male) not in cohabitating romantic relationships will be randomized into support figure attended (SFA) and SFA-TU arms. Four data collection points are planned, including 4-months pre-surgery, 2 weeks pre-surgery, 2 weeks and 2-months post-surgery. Feasibility and acceptability of support figure/partner attendance collected at the final data point. Patients and support figures/partners will complete weight status, health behaviors, support for behavior change and relationship quality assessments at each time point. The rationale, design, theoretical framework, and methodology for the study are described. The results of this study will identify how support figures/partners influence patients' health behavior change and weight loss, and how relationships change over the surgery process.

1. Introduction

The prevalence of class 3 obesity (body mass index (BMI) ≥ 40) has increased among American adults [1]. As of 2014, approximately 8% of adults were classified as having class 3 obesity [1]. Bariatric surgery (bariatric surgery) is the most effective treatment for short- and long-term weight loss for severely obese adults [2]. In 2017, 228,000 bariatric surgeries were performed in the U.S [3]. Patients typically lose 50–75% of their excess body weight during the first-year [2]. However, a consistent U-shaped weight loss trend emerges after two years, where 30–50% of patients begin to regain weight [4–6]. The pattern of weight regain suggests that more intensive interventions are needed to help

patients achieve long-term behavior change and weight loss maintenance. Interventions which explore patients' social supports (e.g., romantic partners, adult children, parents) in the bariatric surgery process have the potential to provide patients with short-term support for behavior change and weight loss, and long-term support in weight maintenance.

Although research has examined social support within the bariatric surgery population (e.g., bariatric support groups), few studies have assessed support from individuals who have not undergone bariatric surgery. Ferriby and colleagues [7] reviewed 13 articles published between 1990 and 2013, which detail associations between romantic relationships and patient post-surgery weight loss. Overall, married

Abbreviations: BMI, Body Mass Index; BS, Bariatric Surgery; PA, Partner Attended; PA-TU, Partner Attended Treatment as Usual; SFA, Support Figure Attended; SFA-TU, Support Figure Attended – Treatment as Usual

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patients lost less weight than single or divorced peers. Furthermore, pre-surgery candidates who reported higher anxiety in romantic relationships had higher BMIs and exhibited higher rates of disordered eating [8]. Conversely, married patients in stable relationships from pre- to post-surgery have better long-term weight loss and maintenance compared to those who were single or divorced [9,10]. These studies are not without limitations, including samples of primarily White/Caucasian, married couples, and assessment of only the patient's perspective. Additionally, past studies did not assess social support for behavior change, and how relationship quality and support affect patients' and partners' behavioral changes longitudinally.

Studies assessing patients' general support figures is less common, and those that have been conducted have limited generalizability. Slotman [11] found that patients with family members who had bariatric surgery had increased weight loss at six-months and one-year post-surgery compared to case-matched controls. Rebibo and colleagues [12] found that patients with family members who had a history bariatric surgery lost more weight at two-years post-surgery and missed fewer appointments compared to case-matched controls. These articles included both patients and family members who underwent bariatric surgery and were not specific about the relationship types included (e.g., couples or parent-child). Woodard and colleagues [13] assessed how family members' attendance at bariatric surgery appointments affected those members not having surgery; obese family members lost weight and reported less screen time and emotional eating over 12-months. Tymoszyk and colleagues [14] investigated the impact of social support and frequency of social interactions on post-surgery weight loss; patients who received more social support and had at least one social interaction per month had an increase in total percent weight lost post-surgery. In spite of growing recognition of the importance of social support, the extent to which specific support figures and relationship types may contribute to improved outcomes has yet to be adequately delineated and warrants further inquiry.

2. Purpose and justification

2.1. Purpose

To address current gaps in the literature about influences of romantic partners and support figures on patient weight loss and behavior change across the bariatric surgery process, we are conducting a four-arm randomized controlled trial (RCT) to assess feasibility, acceptability, and preliminary efficacy for the inclusion of romantic partners and support figures throughout the pre-surgery and post-surgery bariatric surgery process. Female patients in cohabitating, romantic relationships will be randomized into partner attended (PA) arm and treatment as usual (PA-TU) arm. Patients (female or male) not in cohabitating romantic relationships will be randomized into support figure attended (SFA) and SFA-TU arms.

The overarching objective of this study is to understand the feasibility and acceptability of including support figures/partners in the bariatric process. Further, the study aims to provide preliminary evidence for the inclusion of partners/support figures in the pre- and post-surgery process, including subsequent impact on post-surgery patient and partners/support figures behavior change and weight loss, and relationship outcomes. This is the first known study to prospectively examine patients and their partners/support figures from pre- to post-surgery while collecting dyadic assessments of weight status, behavior change, support, and relationship outcomes. By collecting dyadic data, the study will be able to determine the effect of partner/support figure attendance on patients, partners/supports, and relationship outcomes, as well as the bidirectional effects that patients and partner/supports have on each other. Further, group differences in weight loss, behavior change, and relationship outcomes will be examined based on relationship type (i.e., partner, support figure) to determine the unique contribution of each relationship type. Below we describe the rationale,

design, and methodology for the proposed study.

Justification for female patient, Partner Attended (PA) arm. In the US, females undergo the majority of bariatric surgeries performed annually (73%) [15]. Additionally, in the general adult weight management literature, the inclusion of support figures, both romantic partners and general support figures (e.g. friends, parents, siblings, etc.) resulted in weight loss for both patients and their supports [16,17], but specifically female patients lost more weight when they participated with their supports compared to male patients who lost more weight when they participated independently [16,18,19]. Research that has been conducted on the supports of female patients has focused on their spouses/romantic partners. Because the majority of patients are female that undergo bariatric surgery, and prior research has been conducted with female surgery patients and their spouses, we have separated out female patients who are cohabitating with their romantic partners to further the evidence in this developing area.

Justification for Support Figure Attended (SFA) arm. It is unclear how different support figures and relationships influence support provided to patients and whether this makes a difference in short- and long-term weight loss and behavior change. Previous studies have analyzed patient-partner/spouse dyads [17,18] or patient-family member dyads [11–13,16,19], but the inclusion of diverse types of dyads, including romantic partners, family members, and non-related supports yet to be explored. By including diverse types of patient-support figure dyads in our study we will seek to quantify different types of support figures (parents, children, friends, relatives) and depict the support they provide, their own weight loss, and perspectives of relationship changes as well as influences on patient outcomes to provide valuable information about how the inclusion of specific types of supports can be tailored to promote patient weight loss and behavior change in future interventions.

2.2. Theoretical framework

Social Cognitive Theory (SCT) posits that individuals learn new behaviors by observing actions (social modeling) and perceived consequences of those actions from people around them prior to determining whether to adopt new behaviors themselves [20]. With respect to obesity and weight loss management, romantic partner/support figures' health behaviors influence each other and how one views themselves in light of their partners/support figures behavior [20]. Additionally, patients are more likely to model those whom they spend more time with, emphasizing the influence of romantic partners, family members, and close support figures, particularly if they are sharing the same living environment. Family Systems Theory (FST) posits that couples/families are bidirectional systems with reciprocal interactions occurring between members, where one member's behaviors shape and are shaped by the other member [21,22]. For patients undergoing bariatric surgery, their partner/support figure can either support or hinder their efforts at behavior change and ultimately weight loss, by either encouraging or resisting adoption of new health behaviors. Relationship stability and quality influences the potential of how supportive partners/support figures are in the bariatric surgery process. Romantic partners/support figures witness first-hand required behavioral changes patients are required to make prior to bariatric surgery (SCT). Partners/support figures respond by either resisting change by trying to maintain their status quo or by adapting and supporting the patient through both words, gestures, and changing their own health behaviors (FST). If the non-surgical partner/support is resistant to change, they may be threatened by the patient's behavioral changes and weight loss and may respond with conflict and frustration that the patient is doing new things and experience new health benefits that can further complicate their relationship quality. If the partner/support figure adapts and embraces changes the patient is undertaking, both patients and partners/supports may have better outcomes and improved relationship quality (see Fig. 1).

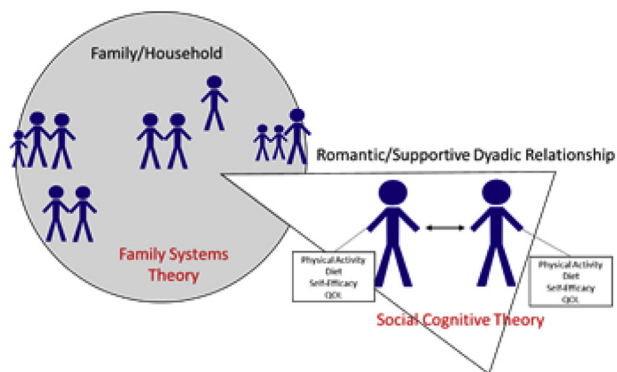


Fig. 1. Theoretical model.

2.3. 3 specific aims

Aim 1: To assess feasibility and acceptability of attendance in the PA and SFA arms. Feasibility will be assessed by attendance rates at four pre-surgery classes and clinic visit assessment time points. Perceived fiscal and time involved (i.e., paid work hours lost) in the study will be assessed at the final assessment point. Acceptability will be assessed from patient and partner/support figure interviews about perceived barriers and benefits to attendance, and alternative mediums to engage partners/support figures (i.e., patient portals, phone/text, email, telehealth).

Aim 2: To evaluate the effect of partner/support figure attendance on patient weight loss, behavior change, and relationship outcomes over time. Estimates of effect size and variance in patient weight loss (% excess weight loss [%EWL]) and behavior change (self-reported diet and physical activity) will be collected from pre-surgery educational classes through two months post-surgery for comparison of the PA and PA-TU, SFA and SFA-TU arms.

Hypothesis. Patients in the PA and SFA arms will experience increased weight loss, physical activity frequency, and higher compliance to post-surgery dietary recommendations compared to patients in the PA-TU and SFA-TU arms.

Sub-aim 2.1. To evaluate the effect of attendance on partner

and support figure weight status. Partners and support figures in all arms will have their weight status measured at the same time points as the patient. Because it is largely unknown if support figures could benefit from intervention along with the patient or if support figures' weight status is similar to the patients, we will describe support figures' weight status (healthy weight, overweight, obese), and if their weight status changes over time.

Sub-aim 2.2. To determine the preliminary effect of attendance on patient and partner/support figure perspectives of relationship outcomes. Patients and partners/support figures in all arms will complete self-report measures of relationship quality, attachment security, and perceived social support over time to determine the effect of attendance (PA and SFA) on patient and partner/support figure perspectives of relationship outcomes.

Hypothesis. Patients and partners/support figures in the PA and SFA arms will report increased relationship quality, attachment security, and perceived social support compared to partners/support figures in the PA-TU and SFA-TU arms.

Aim 3: To explore differences between support types in PA and SFA arms on patient weight loss. It is unknown whether the type of support (partner/spouse, other support figures) has an influence on patient weight loss and their perception of support for behavior change; thus, we will compare patient outcomes between the PA and SFA arms on patient %EWL and perceived social support across the four assessment points in the study.

2.4. Study design

The study design is a four-arm RCT that uses simple randomization and follows participants over the course of six months. Participants will be initially recruited prior to attending a mandatory, pre-surgery class (*Life After Surgery*) which is typically scheduled two months prior to bariatric surgery. Potential participants will be contacted by telephone one and two weeks prior to their first *Life After Bariatric Surgery* class. During recruitment telephone calls, potential participants will be introduced to the study and if they are interested will be consented and then randomized. The randomization study design is shown in Fig. 2, where female and male consenting patients are sorted into each study arm, either PA and PA-TU or SFA and SFA-TU.

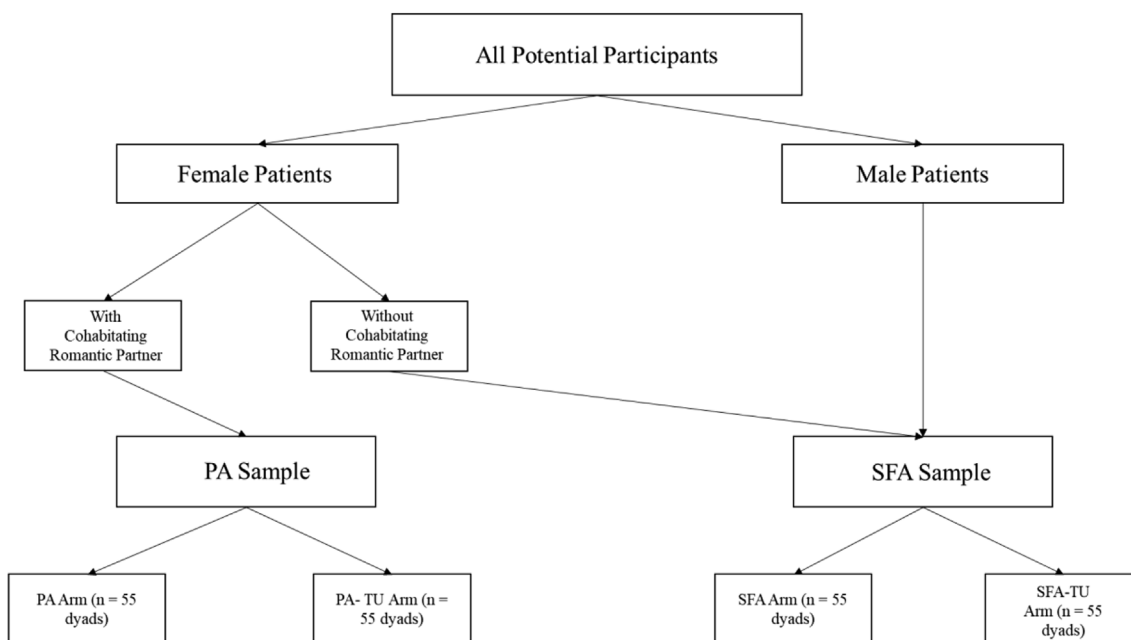


Fig. 2. Recruitment scheme.

Table 1
Description of each Arm's inclusion and exclusion criteria for both patients and partners.

Arm	Inclusion Criteria	Exclusion Criteria
PA/PA-TU Arms:		
Patient	<ul style="list-style-type: none"> • ≥ 18 years of age • speak and read/write English • seeking bariatric surgery • identify as female • have a romantic partner living with them the majority of the week (≥ 4 days), for at least 6 months 	<ul style="list-style-type: none"> • known terminal health diagnosis for (i.e., cancer) • known history of domestic violence or abuse between the patient and partner • romantic partner lives outside the home ≥ 4 days per week
Partner	<ul style="list-style-type: none"> • ≥ 18 years of age • speak and read/write English 	<ul style="list-style-type: none"> • known terminal health diagnosis for (i.e., cancer) • known history of domestic violence or abuse between the patient and support figure • history of bariatric surgery
SFA/SFA-TU Arms		
Patient	<ul style="list-style-type: none"> • ≥ 18 years of age • speak and read/write English • seeking bariatric surgery • identify a support figure who lives in the home with them the majority of the week (≥ 4 days) for at least 6 months 	<ul style="list-style-type: none"> • known terminal health diagnosis for (i.e., cancer) • known history of domestic violence or abuse between the patient and support figure • support figure lives outside the home ≥ 4 days per week
Support figure	<ul style="list-style-type: none"> • ≥ 18 year years of age • speak and read/write English 	<ul style="list-style-type: none"> • known terminal health diagnosis for (i.e., cancer) • known history of domestic violence or abuse between the patient and support figure • history of bariatric surgery

Note. PA is defined as partner attended arm, PA-TU is defined as partner attended – treatment as usual arm, SFA is defined as support figure attended arm, and SFA-TU is defined as support figure attended – treatment as usual arm.

The pre-surgery *Life After Bariatric Surgery* class is offered in both in-person and online formats. Once participants provide verbal consent during the recruitment telephone call and are randomized into a study arm, research team members will meet with them one-on-one (in-person session) or send them a survey using a pre-paid envelope (online). The first time point (T1) survey packet contains written consent documentation as approved by The Ohio State University's Institutional Review Board and self-report measures (see below for details). Research team members will meet participants again at their pre-surgery appointment (T2), two-week (T3) and two-month post-surgery (T4) appointments on unit to administer the three additional research packets. In addition to the self-report measures, interested participants in the PA and SFA arms, only, will be invited during the two-week post-surgery data collection (T3) to schedule semi-structured interviews at the two-month post-surgery data collection (T4) to discuss the acceptability and feasibility of partner/support figure attendance. All participants in the PA and SFA arms will also receive open-ended questions to complete at two-month post-surgery data collection (T4) along with the self-report measures that also assess acceptability and feasibility.

2.5. Program description

Location: The University Hospital Center, where recruitment will take place, offers both non-surgical and surgical weight management programs. The bariatric surgery Program is an American Society for Metabolic Bariatric Surgery/Surgical Review Corporation certified Bariatric Center of Excellence. The Center includes board certified bariatric surgeons, endocrinologists, psychologists, nurse practitioners, nurses, dietitian, exercise physiologists, behavioral therapists, and support staff, as well as patient-centered support groups. This integrated team focuses on the needs of individual patients to promote and maintain a healthy weight with an overarching goal of achieving general health improvements in each patient. The Center conducts over 400 bariatric surgery annually.

Treatment as Usual: The requirements of the program include patient attendance at routine pre-surgery education classes and pre- and post-surgery clinical visits, in addition to individual health insurance mandated requirements. Specifically, pre-surgery, all patients must take the *Life After Bariatric Surgery* class. This class is approximately 60-min in length and discusses dietary, exercise, and behavioral lifestyle changes recommended for long-term success post-surgery. The

class is led by a senior dietitian conducted in person or on-line, roughly two months prior to surgery. Typically, a month following the completion of the class, patients meet with their surgeon to confirm the type of surgery they will have, schedule a surgery date and initiate a very-low calorie diet (i.e., “liver shrink” diet). At two weeks and two months after surgery, patients are scheduled for clinical visits to meet with their surgeon and dietitian to ensure proper healing and to help transition back to solid food consumption.

Partner/Support Figure Attendance: Patients who are randomized into the PA or SFA arms will be instructed to bring their partner/support figure to all of their standard clinical appointments, including the *Life After Bariatric Surgery* Class and pre- and post-surgery clinical visits. This will start at the *Life After Bariatric Surgery* class (pre-surgery) with patients bringing partners/support figures to the in-person class or to have the partners/support figures watch the online course with them, and continue to attend the clinical appointments before and after surgery with them.

2.6. Enrollment, recruitment, consent, retention plan

We plan to enroll every consecutive patient and partner/support figure dyad meeting our inclusion/exclusion criteria over the course of 12 calendar months. In our prior work conducted at the same location, we were successful in recruiting robust sample sizes of patients in romantic relationships (ranging from 150 to 300 patients [8,23]) and family relationships (ranging from 200 to 300 patients [24,25]) in less than 12 months. However, these studies only assessed patients' perspectives of their relationships and were all cross-sectional designs. The current study is the first to our knowledge to request a) assessments from both patients and their partners/support figures, b) obtain assessments longitudinally from partners/support figures at four separate time points, and c) ask that partners/support figures randomized to the PA and SFA arms attend clinical visits with patients. As the present trial is feasibility pilot study, that requests the involvement of both patients and partners/support figures, our anticipated enrollment is stated to conservatively align with the listed specific aims.

Prior to the start of their pre-surgery class, research team members will contact eligible patients who will be attending the *Life After Bariatric Surgery* class in the upcoming two weeks. During the initial recruitment call, potential participants will be screened for interest and study inclusion and exclusion criteria. See Table 1 for inclusion and

Table 2
Data collection timepoints and measures employed.

Variables	Measures	Who	T1	T2	T3	T4
Preliminary Efficacy (All arms)						
Weight	BMI (height, weight), BMI change, %EWL	Patient	X	X	X	X
Weight Loss Efforts	Strategies for Weight Management scale ^a	Partner	X	X	X	X
Diet	Adherence Item ^b	Patient	X	X	X	X
Physical Activity	Physical Activity Record ^c	Patient	X	X	X	X
Support for Behavior Change	Social Support and Eating Habits Survey & Social Support and Exercise Survey ^f	Patient, Partner	X	X	X	X
Family Functioning	Family Assessment Device- General Functioning Subscale ^g	Patient, Partner	X	X	X	X
Preliminary Efficacy (PA/PA-TU arms)						
Relationship Quality	Abbreviated Dyadic Assessment Scale ^d	Patient, Partner	X	X	X	X
Relationship Security	Relationship Structure Questionnaire ^e	Patient, Partner	X	X	X	X
Feasibility (PA/SFA only)						
	Attendance	Patient,		X	X	X
	Time costs	Partner				
	Financial costs					
Acceptability (PA/SFA only)						
	Open Ended Question, Semi-structured interviews	Patient, Partner				X

Note.

^a Lytle, Moe, Nanney, Laska, & Linde, 2014.

^b Sarwer et al., 2008.

^c Bouchard et al., 1983.

^d Busby, Christensen, Crane, & Larson, 1995.

^e Fraley, Heffernan, Vicary, Brumbaugh, 2011.

^f Sallis, Grossman, Pinski, Patterson, Nader, 1987.

^g Epstein, Baldwin & Bishop, 1983.

exclusion criteria for partner and support figure arms. Type (e.g., Roux-en-Y gastric bypass, sleeve gastrectomy) of bariatric surgery to be performed is not an inclusion or exclusion criteria. To be included in the PA/PA-TU arms, romantic partners need to be cohabitating, but there is no inclusion or exclusion criteria based on marital status (i.e., married or cohabitating).

During the recruitment telephone call, if patients indicate they are interested in the study, the research team member will ask to speak to their partner/support figure to explain the study. If their partner/support figure is not home, the research team member will call back at a time convenient to the partner/support figure. Patients and partners/support figures will provide verbal consent over the telephone. After consent has been received, patients will be randomized to either the attendance (PA, SFA) or treatment as usual arms (PA-TU, SFA-TU) arms. PA/SFA participants will be asked to bring their partners/support figures to the first of four mandatory pre-surgery classes, if attending in person, or have them watch the online videos with them, if taking the class online.

Those in the PA and SFA arms attending in-person classes will sign consent forms and complete the first data point materials packet (T1) prior to the class in clinic. Patients in the PA-TU and SFA-TU arms will sign consent forms and complete first data point materials in-person and be given a packet of the materials, including the consent form, to bring home to their partner/support figure along with a pre-paid envelope. PA/SFA-TU partners/support figures will be instructed on the phone and reminded in the packet to complete the materials independently and return the materials within a week of the class. In all arms, if the patient is attending the classes online, regardless of the SFA and PA partner and support figure attendance, the research team member will mail the packet of materials to the dyads home with a pre-

paid return envelope.

Those in the PA/SFA arms will bring their partners/support figures to their routine visits within the bariatric surgery unit starting after the first Life After Bariatric Surgery class (or time point 1 – T1), while those in the PA-TU and SFA-TU arms will be told to follow standard care procedures, which do not specify anything about attendance of others at the appointments. At the pre-surgery appointment, which occurs roughly one-month post-T1 and one month prior to surgery, all participants will complete T2 measures. The materials are the same as at T1, excluding demographic questions. The procedures for T1 will be the same at T2 for partners/support figures, meaning patients and partners in PA/SFA arms complete the packets in person and patients in PA-TU/SFA-TU complete theirs in person and are giving their partners/support figures to take home and mail back. At the two-week post-surgery appointment, T3 materials will be collected which are the same as those assessed at T2. At the two-month post-surgery appointment, T4 measures will be assessed. Materials packets will be the same as at T2-3, with the addition of feasibility and acceptability prompts included in the PA/SFA arms. Further, if the PA/SFA dyads are interested in being interviewed, semi-structured interviews will be conducted at this point to gain more detail on the barriers and benefits to partners/support figure attendance and to inquire about other means of engaging partners/support figures in the bariatric surgery process (e.g. telehealth sessions, partner/support figure only support groups, etc.). Interest in the semi-structured interview will be assessed by an additional question at the end of T3 materials, asking “Are you interested in participating in a 30-min interview regarding your experience in the study? The interviews will take place after your two-month appointment adding an additional hour to the appointment length.”

2.7. Measures

The intention of the study is to examine acceptability, feasibility, and preliminary efficacy of partners/support figures' attendance during routine bariatric surgery health visits on patients' weight loss, dietary compliance, physical activity levels, romantic relationship quality, perceived social support, family functioning, and attachment security. See Table 2 for all measures and timepoints administered.

Sociodemographic items assessed at T1 include participants' self-reported: age, sex, height (feet, inches), weight (lbs), weight status (i.e. normal weight, overweight, obese, etc.), ethnicity, race, number of children, relationship status/length, educational level, income, bariatric history in the family, and members of the household. With the exception of bariatric surgery history and household members, all other sociodemographic questions were drawn from the 2017 National Institutes of Health's Health Information National Trends Survey [26]. At T2-4, height and weight will be recorded from the patient's electronic health record.

Health literacy will be assessed using three established one-sentence proxy items 24. Questions are assessed using a 5-point Likert scale (1 = *always/extremely confident*, 5 = *never/not at all confident*): “How often do you have problems learning about your medical condition because of difficulty understanding written information?”, “How often do you have someone help you read hospital materials?”, and “How confident are you filling out medical forms by yourself?” This measure has been found to be reliable in a general clinical sample (Cronbach's alpha = .79-.80 [27])

Feasibility will be assessed using patient and support figure appointment attendance, and perceived fiscal and time involvement in the study in the SFA arm.

Attendance. In the PA/SFA arms patients and partners/support figures' attendance will be coded by the research team in the patient's electronic medical record at each of the scheduled visits starting from the first visit after T1 out to T4. Attendance at the appointment will be coded 0–2; if no one attended the appointment, the couple would receive a 0, if only the patient attended, the couple would receive a 1, and

if both attended, the dyad would receive a 2.

Time and Fiscal costs. Time and financial costs of the PA/SFA arm will be assessed at T4 using two items rated on a 5 point Likert scale (1 = *strongly disagree*, 5 = *strongly agree*). The time costs question will tentatively read, "My attendance at these visits has been a time burden for me/us?" The financial costs question is, "My attendance at these visits has cost us/me financially?" Partners/support figures will be asked to elaborate in free text on their answers.

Acceptability will be measured at T4 using open-ended questions and semi-structured interviews with both patients and partners/support figures in the PA and SFA arm. The dyads will complete two questions with a 10 point Likert scale (1 = *extremely dissatisfied/difficult*, 10 = *extremely easy/satisfied*) and four open-ended questions. The two Likert scale prompts are: "How satisfied are you with the patient's weight changes so far?" and "How easy or difficult has attendance been for you?". The four free response prompts for the patients are "What have you liked about having your partner/support figure with you during appointments?", "What have you not liked about having your partner/support figure with you during appointments?", "Is there anything specific that has made it difficult to have your partner/support figure attend?", and "Since you have been seeking surgery, have you changed the way you feed the rest of your family?". The four free response prompts for partners/support figures are "What have you liked about attending appointments with the patient?", "What have you not liked about attending appointments with the patient?", "Is there anything specific that has made it difficult for you to attend?", and "Since the patient has been seeking surgery, have you changed the way you feed/eat with the rest of your family?". The first 15 interested dyads will be consented and interviewed for a total of 30 individual interviews. Questions will assess barriers and benefits to partner/support figure attendance, and alternative mediums to engage partners/support figures (i.e., patient portals, telehealth).

Preliminary Efficacy will be assessed with the following measures.

Weight Loss will be measured for all patients in all arms from T1-T4 using the weight (lb) that is recorded at the appointments and pulled from the electronic medical record. Using the data collected at T1, % EWL will be calculated for each time point; % EWL is calculated by $[(T1 \text{ weight}) - (\text{Follow up (T2-T4) Weight})] / [(T1 \text{ Weight}) - (\text{Ideal Weight})]$. Ideal weight is defined as the weight corresponding to a BMI of 25.

Dietary Compliance will be assessed in all patients in all arms from T1-T4 using a single item used in a previous research study in the bariatric population [28]. The item reads "How well are you following the diet plan given to you by your dietitian/health care provider?" and is answered using a 9 point Likert scale (1 = *not well at all*, 9 = *very well*). This item was selected due to the rapid dietary changes expected to occur at each given time point in the bariatric surgery process, making the data collected from more traditional measures (e.g. 24 h recall, food frequency questionnaires) biased to negative findings regarding the participants dietary choices.

Free Living Physical Activity will be measured using Bouchard's Physical Activity Record (BAR) [29] in all patients in all arms from T1-T4. The self-report measure instructs participants to record physical activity frequency over the course of a three-day (≥ 1 weekend day) period. The research team is aware of the limitations of self-report measures [30]. The use of a self-report measure was selected based on the phase of development and time-limited design of the study. Each day is broken down into 15 min intervals which are rated on a scale of 1-9 based on the intensity of the physical activity (1 = *sedentary*, 9 = *high intensity activity*). The total time spent in the different ratings will be calculated and averaged to produce the overall amount of time spent in low, moderate, and vigorous activities. This measure is reliable in a general population [30] and in adult weight management populations [31,32].

Weight Status Change will be measured using Strategies for Weight Management scale from the CHOICES study [33] (SWM) for partners/support figures in all arms from T1-T4. This measure assesses the

frequency of weight management strategies an individual participated in during the past 30 days. Participants rate the 20 behaviors on a 5 point Likert scale based on frequency (1 = *never or hardly ever*, 5 = *always or almost always*). This measure is reliable within the general population [34] and weight loss seeking individuals [35].

Relationship Quality will be assessed using the Abbreviated Dyadic Assessment Scale (ADAS) [36] for patients and partners (only) in the PA and PA-TU from T1-T4. The ADAS is a self-report measure that assesses the overall quality of a romantic relationship based on the degree of agreement, satisfaction of, and cohesion between partners. The ADAS takes 7 items from the original Dyadic Assessment Scale [37] and asks participants to rate the frequency of a behavior in the relationship or the degree of agreement of a statement using a 6 point Likert scales. Responses are totaled and a score of 15 or lower indicates a clinically distressed couple. The ADAS is reliable in the general population [38] and has been used in populations with obesity-related diabetes (Diabetes Type II) [19,38,39].

Romantic Attachment will be assessed using the Relationship Structures Questionnaire (ECR-RS) [40] for patients and partners/support figures in all arms from T1-T4. The ECR-RS is a self-report measure that assesses the degree of relationship anxiety and avoidance an individual experiences in their relationship. Participants rate the degree of agreement on nine statements using a 7 point Likert scale (1 = *strongly disagree*, 7 = *strongly agree*). The scale consists of two subscales: anxiety (3 items) and avoidance (6 items). Responses are totaled and averaged; scores above 2.86 and 3.57 on the anxiety and avoidance subscales respectively are considered insecurely attached. The ECR-RS has good reliability in the general population [41] and has been used in bariatric samples [10,42,43].

Social Support for Diet and Physical Activity will be assessed from patients and partners/support figures in all arms from T1-T4 using two surveys: Social Support and Eating Habits Survey & the Social Support and Exercise Survey (SSEH & SSE) [44]. The SSEH and the SSE assess the perception of support from friends and family regarding changing dietary and physical activity behaviors, respectively. Participants will report the frequency of 10 eating or food-related behaviors and 13 exercise related behaviors on a 5 point Likert scale (1 = *none*, 5 = *very often*). In the current study, patients and partners will only complete the measure regarding social support from family, specifically their partner. The SSEH and SSE has good reliability in the general population [44] and has been used in bariatric samples [10,45].

Family Functioning will be assessed from patients and partners/support figures in all arms at T1-T4 using Family Assessment Device-General Functioning Subscale [46]. This subscale will be used to measure the current level of emotionality and communication within the family interactions. Participants will rate the degree of agreement on 12 statements regarding family interactions on a 4 point Likert scale (1 = *strongly agree*, 4 = *strongly disagree*). The clinical impairment cut off is a score of 2 or higher. Indicating that the family functioning is impaired [46]. The subscale is valid in both general [47] and bariatric samples [25].

2.8. Analysis plan

Aim 1 will be analyzed using descriptive statistics (frequencies, averages, ranges, etc.) for the self-report measures (feasibility) and content analysis for the qualitative feedback (acceptability). Interviews will be transcribed and coded using content analysis. **Aim 2 and Sub-aim 2.1** will be analyzed using descriptive statistics and independent samples t-tests to assess the differences in behavioral outcomes across the four arms. **Sub-aim 2.2** will be analyzed using independent samples t-tests to determine if there are differences between PA and PA-TU arms and SFA and SFA-TU arms for the listed relationship outcomes. Further, if the sample size is sufficient (i.e., ≥ 50 dyads per arm [48]) we will conduct dyadic data analysis using Actor Partner Interdependence Models to determine reciprocal effects among both members of the

dyad on relationship outcomes over time. We will additionally use Chi-square, independent samples t-tests, and ANOVA to compare specific types of romantic partner dyads (cohabitating, married) and support figure dyads (mother, sister, etc.) to determine if significant differences exist for weight loss, behavioral, and relationship outcomes. Finally, we will use existing clinical cut off scores to determine if there are significant differences in weight loss and behavioral outcomes for dyads falling above or below clinical cut off scores on the Family Assessment Device (SFA, SFA-TU arms), Abbreviated Dyadic Adjustment Scale (PA, PA-TU arms), and Relationship Structures Questionnaire (all arms).

2.9. Funding

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3. Discussion

The purpose of the study is to understand the feasibility and acceptability of including support figures/partners in the bariatric process, and establish preliminary efficacy of the inclusion of partners/support figures on post-surgery patients' and partners/support figures' behavior change and weight loss, and relationship outcomes during the bariatric process. This study will advance the knowledge base regarding inclusion of social supports needed to develop interventions to advance long-term behavior change and weight loss for bariatric surgery patients in the future. Specifically, the study will examine how inclusion of social supports—both romantic partners and support figures—aid patients in their behavior change and ultimately weight loss, while perhaps simultaneously improving their relationships. The inclusion of patients' social supports has been underutilized in previous studies, particularly romantic partners and other family members who patients often interact with daily. If partner/support figure attendance aids in patients' health behavior change and weight loss, the study will provide support the inclusion of partners and family members in the surgery process. Additionally, assessment of both patients' and partners/support figures' perspectives on their relationship from pre-to post-surgery will provide a longitudinal assessment of how romantic and family relationships change throughout the surgery process. This information can be utilized for mental health providers providing mental and relational health services to patients' and their supports. Specifically, the study can identify areas of strength and concern in these relationships which may influence patients' physical health outcomes (e.g. weight loss, dietary adherence, physical activity levels).

The theoretical framework for this study combines both SCT and FST, which inform the behavioral, support, and relational assessments used to track both individual and bidirectional influences between patients and partners/support figures over time. The assessment of relationship outcomes among different support dyads (romantic partners, family members) will provide details about how different kinds of supports can assist or challenge patient weight loss and behavior change. Additionally, the longitudinal assessment of different types of support dyads, will determine potential intervention points to strengthen these relationships when they are vulnerable during the surgery process. Future support interventions could be tailored by relationship type based on the various trajectories between the different support dyads found across the arms of our study. Without understanding how partner/support figure attendance affects patients' behavior change and weight loss and relationship changes overtime, interventions designed prematurely may not target essential behavioral, support, and relationship dynamics. This study will provide a foundation to determine which patient, support figure/partner, and relationship variables may be amenable to intervention throughout the bariatric surgery process.

There are several innovative aspects included in the study that will advance the science on social supports of bariatric surgery patients. First, to our knowledge, the use of both SCT and FST theory to examine the relational process of romantic and support dyads during the bariatric surgery process has not been employed in prior investigations. Assortative mating [17] and behavior theory [19] have been used, yet these theories are limited in their ability to incorporate the larger social context of patients as well as the how the relationship between individuals change over time. Second, the study, being informed by FST, acknowledges that different relationship structures (e.g. romantic relationships, parent-child, sibling relationships) vary in their relationship dynamics (e.g. level of intimacy, relationship quality, argument frequency). By including the addition of the SFA and SFA-TU arms, the study can examine how differing relationship types vary over time. Past studies have examined one group of patients without the comparison of a control arm and utilized mixed patient-support figure dyads (e.g. romantic partners, parent-child, etc.) [11–13,16–18]. Inclusion of both PA and SFA arms and the use of control groups in both of these arms address the limitations of prior studies while also allowing for specific comparison between different dyads. Past studies use one assessment, from the patient's perspective, to monitor relationship dynamics [8,13], limiting our knowledge of the bidirectional influence of partners/support figures and complexity of relationship dynamics. Inclusion of dyadic and several different relational outcomes will allow multiple relational dynamics to be tracked over time by both patients and their partner/support figures. Robust assessments of dyads and multiple relational assessments will provide the foundation for future patient and partner/support figure dyad-based interventions throughout the bariatric surgery process.

3.1. Next steps

The results of this study will provide additional information into areas of interest to the bariatric surgery field, weight loss, and family researchers. It is hypothesized that patients who participate in the PA/SFA arms will demonstrate improve %EWL, dietary compliance, and physical activity. If confirmed, the next step would be to follow patients in both groups for up to one- or two-years post-surgery, to determine if there is a sustained effect of the partner/support figure attendance on long-term weight loss and behavior change outcomes. Longer term follow-up will be able to ascertain the where the benefits of the intervention fall off, thus signaling need for additional intervention (e.g. refresher course on bariatric lifestyle components, effective social support strategies, etc.).

It is reasonable to hypothesize that group differences will be found in terms of relationship outcomes. Specifically, some relationships may experience positive changes in their relationship quality, security, perceived support, and family functioning while others may experience a decline in these variables. These patterns have been observed in past studies that looked at the relationship quality of support relationships post-surgery [8,9]. These trajectories in relationship quality may also map onto weight loss and behavior change outcomes. Some relationships may improve in relationship quality across time and experience increased %EWL and improved behavior change while other relationships' quality may deteriorate over time which may lower %EWL and produce poorer behavior change. It is yet unknown how these different trajectories will map onto the different intervention arms. Further, what produces these differences (i.e. what specific relationship factors change) has yet to be fully investigated. The results of the study will identify predictors of the trajectories. If these predictors are produced, the results may begin to identify sources of resilience or strengths among patients who improve in behavior change, weight loss, and relationship outcomes over time. These points of resilience or strength may highlight important relational processes which could be built upon in future interventions. Further the results of the study may produce differences along relationship type (i.e. romantic partner verse general

support). If these differences are found, they may indicate tailored interventions are needed based on specific relationship types or whether one intervention approach for all support relationships is sufficient.

In addition to continued follow up with the patients, partners/support figures' personal behavior change could be monitored to determine whether there is a ripple effect across family members in terms of health behavior change. As the patients continue to see positive benefits in terms of their own health, they may serve as important models to partners/support figures. Future studies may also want to include more family and household members, as the participating dyads are returning home and interacting with other members. These members may be additional sub-supports that could be utilized to strengthen the dyadic system of patient and partner/support figure. Finally, future investigations should take into account the barriers to attendance and suggestions for partner inclusion provided by patients and partner/support figures in the acceptability and feasibility measures. This information provides important insight into how researchers can reach their target samples as well as provide a larger impact with their studies.

With the completion of this study and addition investigations regarding the inclusion of partners/support figures in the bariatric process, it may be possible to create more holistic interventions and treatment approaches within the field of bariatrics. Previous knowledge has been limited to a patient focused approach. By utilizing the social supports around patients, providers may be able to solicit support that extends beyond the examination room. With support from both the medical and the personal realm, patients may be able to increase their long-term success post-surgery.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.conctc.2019.100422>.

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