Lifestyle Improvement for Teens with Bariatric Surgery

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Protocol Title:	Partnering Lifestyle Intervention with Bariatric Surgery to Maximize Health Outcomes in Adolescents.
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Study Coordinator:	TBD
Population:	☐Ethnically diverse adolescents ranging from 12 to 18 years of age who are severely obese bariatric patients at Children's Health sites in the Dallas-Fort Worth area. ☐Parents/guardians of children that are 18 years of age or older.
Number of Sites:	All Children's Health sites in the Dallas-Fort Worth area (COACH Clinic, Children's Medical Center Dallas, Children's Health Plano, and Children's Specialty Center in Dallas).
Study Duration:	2 years
Subject Duration:	18 months

General Information

Severe obesity, defined as ≥ 120% of the 95th percentile of body mass index (BMI) adjusted for age and sex or a BMI >35 kg/m^2 is the fastest growing subcategory of obesity in the United States (US) pediatric population.[1] Currently ~ 9% of 12-19 year olds have severe obesity, triple the prevalence in 1988-1994. Even more concerning, almost 12% of Non-Hispanic Black and 9% of Hispanic adolescents ages 12-19 have severe obesity compared to 7% of their non-Hispanic white ethnic group counterparts.[2] Severe obesity in adolescence is associated with many cardiometabolic comorbidities, liver and kidney issues, lower sleep quality, as well mental health comorbidities including depression and anxiety, resulting in lower quality of life scores reported in this patient population.[2-5] Moreover, severe obesity during adolescence tracks strongly into adulthood and is associated with adult asthma, arthritis, and poorer cardiometabolic and psychological risk profiles.[6-9] As such, for the first time in decades, the life expectancy of Americans decreased in 2015-2016, a finding many attribute to obesity in addition to issues withopioids.[10]

Background Information

Metabolic and bariatric surgery (MBS) is shown to be safe and efficacious in treating adolescents (defined as ages 12-18 for this application) with severe obesity.[11-13] Alternatively, weight-loss behavioral/lifestyle and pharmacotherapy treatment programs in inpatient and ambulatory settings for

adolescents with severe obesity have not reported similar sustained weight loss trajectories, particularly in the long-term.[14-19] Yet national adolescent MBS rates have not increased at the same rate of that of the severe obesity epidemic, and short-and long-term attrition (both to and from MBS) remains a significant challenge in this patient population. In fact, there is no standardized pre-and post-operative lifestyle intervention that is offered to adolescent MBS patients to support the behavioral changes that must occur to sustain successful weight loss. Given the extensive evidence-bases for (1) outpatient healthy lifestyle intervention to manage obesity[21-30]; and (2) MBS to treat obesity[11-13], there is an opportunity to explore the *combination* or *partnering* of lifestyle intervention and MBS for adolescents with severe obesity to decrease attrition and improve health outcomes. Our team (Messiah et al, 2019)[31,32] has called attention to the imperative need for research focused on the compound effect of MBS and lifestyle management, and how the timing or sequence of these weight loss approaches influence health outcomes. In other words, the field needs to more rigorously develop, evaluate (feasibility, acceptability) and test for when, and for how long lifestyle interventions (1) should be introduced in adolescents with severe obesity before MBS (for those medically cleared and who are planning on having MBS); and (2) should be included, and at what dosage (as well as specific content and timing) after MBS. Moreover, widening obesity-related health disparities warrant particular attention toward at-risk populations including ethnic minorities, and those with low socioeconomic status who are most impacted by the increase in, and comorbidities associated with severe obesity. Specifically, rigorous qualitative and quantitative research designs (e.g. mixed methods) should be applied to the research questions of (1) how lifestyle interventions can be combined/sequenced with MBS over time to optimize health outcomes; and (2) what critical behavioral strategies of lifestyle interventions from previous documented successes among adolescents with obesity can be enhanced, modified and/or adapted to increase the effectiveness (both in the short and long term) in the MBS patient population so they may enter adulthood with sustainable lifestyle skills to achieve healthier BMI developmental trajectories. As such, we propose the following mixed methods specific aims:

Objectives

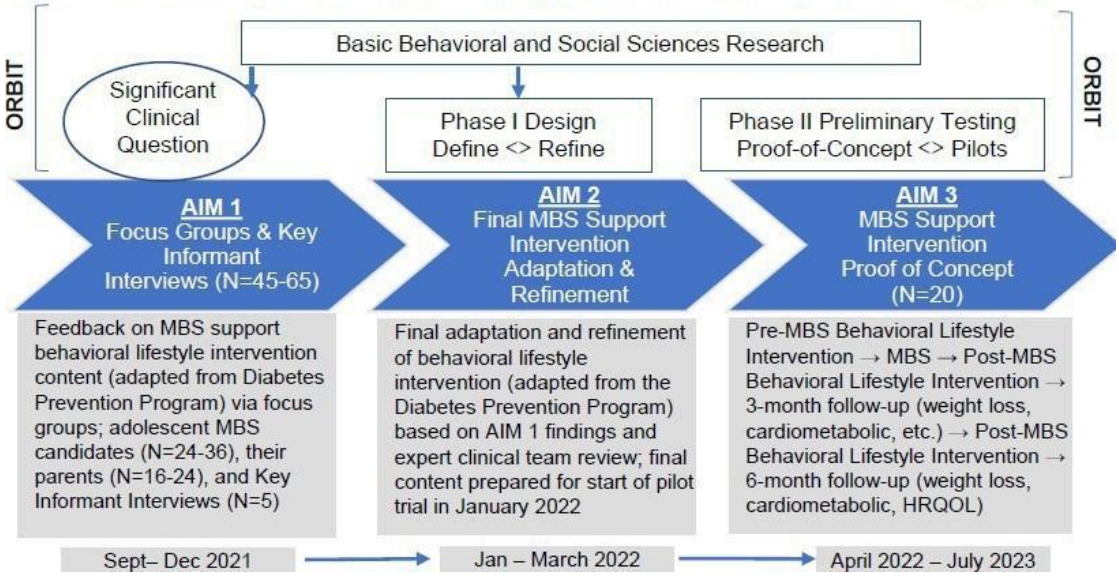
- We will examine how lifestyle interventions combined with bariatric surgery over time can optimize treatment outcomes via the following aims:
- **AIM 1**. Generate qualitative data ***necessary to adapt*** an existing evidence-based healthy lifestyle behavioral intervention's content, strategies and delivery methods to explicitly support pre- and post-MBS, ethnically diverse (non-Hispanic white and black; Hispanic, other), adolescent patients and their families. This formative research will include focus groups, and key informant interviews with adolescents, parents, and clinical team members.
- **AIM 2.** ***Adapt*** the healthy lifestyle behavioral intervention (referenced in AIM 1), as informed by AIM 1 data (and analyses), to support pre-and post-MBS among ethnically diverse adolescent patients and their families.
- **AIM 3.** Conduct a *proof of concept study* to assess feasibility, acceptability, and effectiveness of an MBS-supported healthy lifestyle behavioral intervention (***adapted*** in AIM 2) among adolescent patients, their families, and their clinical team. Compare social determinants of health (SDOH) screening data with a comparable adolescent patient population from Children's Health.

Hypothesis$_1$: Acceptability and feasibility (adoption) of an adolescent-targeted multimedia lifestyle intervention sequenced with bariatric surgery with improve 3-and 6-month post-operative health-related outcomes.

Study Design

- This study will employ a mixed-methods design; AIM 1 will focus on qualitative data collection to inform adaptation of the intervention (AIM 2) and AIM 3 will conduct a pilot of the adapted intervention.

Figure 2. Study Schematic Adapted from the Obesity-Related Behavioral Intervention Trials (ORBIT)[33] that focuses exclusively on the early, pre-efficacy phases of behavioral treatment development.



- A total of 75-85 metabolic and bariatric surgery (MBS) adolescent patients (≤ 18 years old), their parents and healthcare team will be recruited for the study. This will consist of 40-60 focus group participants (adolescent MBS candidates [n=24-36], their parents [n=16-24], and Key Informant Interviews [N=5]) and 20 for the proof-of-concept trial (AIM 3). Participants will be male and female, Hispanic, non-Hispanic black, non-Hispanic white, and mixed/other ethnicity and will be recruited from one MBS practice at Children's Health System of Texas pediatric weight management clinic. We expect > 45% of the sample to be Hispanic, ≥ 30% to be nonHispanic black and 5-10% multiethnic and 70% to be female. All study participants who enter the proof-of-concept trial will be followed for 6 months after MBS. There will also be a variety of adult (parent and clinical team) participants who will engage in key informant interviews. These adults will be the parents of the adolescents (n~5-10) and clinical caregivers (n=5). We will collect and analyze the data from the focus groups and key informant interviews. Based on the information gathered, we will develop *a proof of concept study* that would support bariatric patients' pre- surgery and post-surgery. We will then implement the proof of concept study (AIM 3) enrolling approximately 20 ethnically diverse severally obese adolescent participants who have decided to have bariatric surgery/metabolic bariatric surgery (MBS). We will follow these participants for a period of 18

months. This begins when the patients and their parent/caregiver provide consent to participate in the study. After bariatric surgery they will be followed for 6 months with 3-and 6- month measurement assessments. We will evaluate the effectiveness, accessibility, feasibility, and delivery of the program. We will look to identify what participants liked about the program and what they will recommend for improvements moving forward. We will also gather information about the contribution of the intervention in the patient's weight loss outcomes post- surgery. During this process in Aim 3 we will provide a water bottle at their first clinic visit. Upon completion of the surgery participants may receive a FitBit,a scale, workout bands, and weights to aid in their weight loss journey. **Incentives**

- For the focus groups and key informant interviews (AIM 1), participants will be provided with a $25 gift card.
- For the pilot study (AIM 3), participants will be provided with a total of $75 dollars for their participation. These Participants will be followed over a period of 18 months. They will have a total of 3 follow-ups and with each follow-up they will be compensated with a $20, $25, and $30 gift card respectively.
- For the Pilot study (AIM 3), participants may be provided with a FitBit, a smart scale, a home band set, a home weight set, and a water bottle.

Study Population

- Inclusion criteria: (a) Must meet National Institutes of Health criteria to qualify for MBS for adolescents (BMI >35 kg/m^2 and at least one existing co-morbidity [e.g. elevated blood pressure, hypercholesterolemia, etc.] or a BMI>40kg/m^2). (b) Consents/assents to participate in the study.
- Exclusion criteria: (a) Does not meet National Institutes of Health (BMI >35 kg/m^2 and at least one existing co-morbidity [e.g. elevated blood pressure, hypercholesterolemia, etc.] or a BMI>40kg/m^2); and/or (b) Refuses to participate in the study or (c) has diabetes that requires mealtime insulin.
- Recruitment strategy for Pilot Study: All participants must be medically referred by a physician for bariatric surgery and have received psychological clearance for the surgery. Participants will be recruited from all Children's Health sites in the DFW area, specifically from the Children's Health Pediatric Gastroenterology Clinics and Children's Health Pediatric Endocrinology Clinics. Clinic staff will recruit patients for the study, and schedule a convenient time to administer assent and parent permission form when needed. Clinical staff will use purposeful sampling when recruiting for the study. They will target ethnic minorities only, who are the primary target population for the study and grant.
- Recruitment strategy for Focus Group and Key Informant Interviews: Severely obese adolescent participants who are 18 years old or younger and parents will be recruited by clinic staff at any of the Children's Health Hospital in the DFW area to participate in the focus group. Clinic staff (surgeons, nurse and staff) will be recruited by the research team that have received IRB approval for this study. Research staff will reach out to the clinical staff, adolescent participants and parents via phone, email or in-person to discuss the nature of the study, and if interested schedule a time to administer consent.

Study Procedures

- There will be approximately 4 Children's Health sites utilized for the study; COACH Clinic, Children's Medical Center Dallas, Children's Health Plano, and Children's Specialty Center in Dallas. All participants will be recruited at one of these 3 sites. There will be 3 follow-ups with participants in the pilot study. They will be followed over the course of 18 months. This begin 12 months before surgery. During this time the participant will have a preoperative survey and will be given the intervention. After this period they will have two post-operative surveys at 3 months and 6 months respectively. For the focus group and key informant participants they will be required to participate in only one focus group or interview lasting no more than an hour to an hour and a half. If focus groups participants are unable to attend focus group due to scheduling conflicts, time constraints or transportation issues they will have the option of participating in an in-depth phone interview, online-video interview or completing a survey. These interviews or survey will also take up to an hour to an hour and a half to complete.
- The PI will also gather medical records of each participants such as pre-surgery BMI and post-surgery BMI and obesity related co-morbidity information to determine the effectiveness of the intervention program in supporting the health outcomes post-surgery. SDOH data will also be pulled from the medical records and will be compared to a similar patient population.

  EMR data will be gathered up to 18 months post-surgery.

Study Measures

- **AIM 3. Pilot test of the MBS-supported intervention.** Based on work completed in study AIMS 1 and 2 we will conduct a 9-month pilot test of the MBS-supported intervention in AIM 3 among 20 adolescent patients meeting MBS/NIH qualifying criteria[10] (class II obesity/120% of the 95th%ile and a co-morbidity, or class III obesity/140% of the 95th%ile according to CDC's age-and sex matched growth charts). Subjects will be enrolled up to 3 months (and not < 1 month) pre-MBS and for 6 months post-MBS. We will provide a water bottle at their first clinic visit. Upon completion of the surgery participants may receive a FitBit, a smart scale, workout bands, and weights to aid in their weight loss journey. *Recruitment.* Recruitment will take place in the outpatient suites of either the COACH or MBS Clinics which are located in the Children's Ambulatory Pavilion adjacent to the Children's Health (CH) System of TX main hospital. The COACH clinic currently has a waitlist of over 200 patients for obesity treatment programs and > 50% qualify for MBS. A total of 234 patients < 18 years old have been referred to MBS from 2016 to 2019.[92]
- ***Intervention Delivery.*** After *patient/parent* consent is completed, participants will begin the pre-MBS intervention phase. *A minimum of **6** online sessions will occur pre-MBS, and **20** will occur post-MBS.* Dr. Klement, MBS coordinator and a diabetes educator in Co-I Cartwright/Qureshi's clinic will manage session delivery to adolescents/parents. All content will follow the DPP-adapted curriculum flow. After The RA will perform outreach, reminder calls, and follow-up for missed surveys or online content. Pre- and post-MBS intervention delivery (based on adapted curriculum/model) may consist of a combination of 1-on-1 and group sessions (in-person or virtually), and online support tools, dependent upon adolescent/parent qualitative feedback on delivery method preference.

- **Measures**. We are including (1) demographic (age, sex, race/ethnicity, living situation, etc.)**,** (2) anthropometric and cardiometabolic (lipids, insulin, glucose, blood pressure, HbA1c) (**Table 2**); (3) health-related quality of life (HRQOL)[93]**;** and (4) process measures (feasibility, acceptability of intervention content/delivery, guided by the RE-AIM [Reach, Efficacy, Adoption, Implementation, Maintenance] framework[94--96]) in the proposed study. We will also include standard-of-care pre-post MBS physical activity (past 7-day step counts, 24-hour diet recall assessments and the Family Assessment Device-12 item (parent and adolescent report of affective responsiveness and involvement, and problem solving within one's family); Clinical Measures. Anthropometric and cardiometabolic data will be collected at baseline and at 3- and 6-months post MBS as part of standard of care. All blood samples are documented in the Electronic Health Record. HRQOL**.** At 1 month pre- and 6-months post-MBS, we will administer the CDC's HRQOL–14 Healthy Days Measure. This survey includes 3 modules (Healthy Days Core Module = 4 questions, Activity Limitations Module = 5 questions, and the Healthy Days Symptoms Module = 5 questions). This instrument has been validated in the study age group.[97] SDOH. Literacy, social, food, driving, financial, and housing needs, and tobacc use.

- **Process Measures.** Qualitative/quantitative process measures will be collected across all intervention sessions via embedded short surveys and at 6-months post-MBS to assess: acceptability (content was appropriate, interesting, easy to use), feasibility (recruitment, retention & adherence rates), and sustainability (perceived barriers/facilitator to intervention implementation, strategies) of the lifestyle intervention. All process measures will be guided by the RE-AIM framework which is particularly appropriate for assessing the fit and relevance of interventions in real-world settings.[94-96]
  The PI has integrated RE-AIM in her past obesity work.[31,98]

- **Data Analysis Plan.** The AIM 3 dependent measure for each dependent effect will be based on the change from pre to post-MBS weight loss/cardiometabolic resolution measurements (**Table 2**). Proportions and means will be the primary scales of the dependent outcomes used to evaluate Table

Table 2. Anthropometric and Cardiometabolic Outcome Measures

Anthropometrics	Instrument
(1) Raw Weight Loss	Digital scale (to nearest 0.1 pounds) with the participants wearing light clothing, no shoes.
(**2) Body Mass Index (BMI)**	Digital scale and height (to nearest 0.5 cm, via Accustat Genentech stadiometer)
(3) Excess Weight Loss (EWL)	Pre-MBS weight - follow up weight)/(Pre-MBS weight - ideal body weight) × 100%

2 outcomes. We will use the Generalized Linear Model (GZLM) to model the impact of the intervention developed in AIM 2 for dependent effects.

(4) Body Composition	InBody570 body composition analyzer- muscle, fat and total body water measures
Comorbidity Resolution	
(1) Cardiometabolic Profile	lipids, insulin, glucose, blood pressure

Much like the General Linear Model that allows for variation in type and scale characteristics of the independent effects, the GZLM extends this versatility to include various types of dependent variables.[99] In GZLM, the relationship between the independent variables and the dependent outcomes is specified by way of a link function that defines the functional form of this relationship (e.g., when the dependent variable is a proportion, a logistic link function might be used). Through different specifications of the link and probability functions, one generalized model is used to examine the statistical relationships between the design parameters (i.e., independent variables) and the dependent variables, regardless of their scale properties. Statistical consideration is given to repeated measures (pre-, 3-, 6-month post-MBS data). Since the time component has only 2 levels (e.g., 1 pre, 2 post-MBS), there are minimal statistical complications associated with the autocorrelation structure of repeated measures. Measures taken at baseline will be included in the GZLM as covariates to ensure pretest balance and as a control on regression to the mean. Changes in weight will be analyzed by employing a generalization of the t-test, known as Hetelling's T2 test. This approach is very important in this case, since it same approach employed in the design. We shall assume a more conservative type I error of 1% to adjust for multiplicity.[100] Missing Values: GZLM models will efficiently use the longitudinal data and accommodate attrition that is ignorable (essentially, missing at random, MAR).[101] To assess sensitivity to MAR we will use approaches for the multivariate normal setting and others if normality is not reasonable.[101] This avoids the problem of eliminating subjects with incomplete repeated measurements. SAS and JMP (SAS Institute, Cary, NC) will be the primary statistical software packages. *Quality Control.* PI Messiah will coordinate the QA/QC protocol with clinical and research staff. Appropriate checks will be conducted prior to, during, and after the completion of data collection.

- **Statistical Power for AIM 3.** A single-factor, repeated measures design with a sample of 20 subjects, measured at baseline, 3-, and 6-months, achieves 80% power to detect a contrast using a multivariate T^2 test at a 0.01 significance level. We reduce the type I to a more conservative 1% to correct for multiplicity. The standard deviation across subjects at the same time point is assumed to be 1. The pattern of the covariance matrix is to have all correlations equal with a correlation of 0.25 between the first and second time point measurements.[100-103] The value of the contrast applied to the hypothesized means is 1.[97] However, since we are anticipating an attrition rate of ~10%, we will recruit 22 adolescent MBS patients.

Data and Safety Monitoring

- *Data and Safety Monitoring: All* subjects will have an assigned unique study identification number used on all data forms and instruments. Data are computer-linked to the remainder of the dataset on

each individual, and linking information between personal identifiers and study numbers is kept in a locked file cabinet in the Principal Investigator's Office. Certain program staff (e.g., principal investigator, clinical team of Barlow, Cartwright, and Qureshi, study coordinator) will have access to confidential information needed to perform their respective duties, but the rest of the research staff are not privy to confidential information.

- *Potential Adverse Events.* None of the proposed procedures involve invasive methods of data collection. Most of the proposed methods are part of, or an extension of, the standard of care to assess pre-post MBS surgery mental and physical health and are minimal risk. These studies present minimal discomforts to the patient. Should any adverse events occur during this protocol, the medical facilities at University of Texas are prepared to care for the study participants. All participants will be debriefed regarding any serious health information that might be discerned in the protocol.
- *Description of Adverse and Serious Adverse Events:* Adverse events and serious adverse events identified for study participants that will be reported during protocol are: Adverse Events
  1. Family Crises
  2. Possible Violation of Confidentiality
  3. Extreme Distress due to Assessment Procedures
  4. Extreme Embarrassment or Distress in Response to Disclosing Sensitive Personal Information

  Serious Adverse Events

  1. Suicidal Thoughts or Attempts
  2. Abuse
  3. Threat of Danger to Others
  4. Hospitalization (psychiatric, drug related)
  5. Death

- *Procedures to safeguard against adverse events:* All data collection protocols include a form on which research staff members record any problems with the data collection, concerns about the study subject or unusual occurrences during the collection. These forms allow our research staff an opportunity to quickly review and respond to any possible concerns or adverse effects. All adverse events will be monitored and supervised by the Principal Investigator.
- *Informed Consent:* All participants will be required to read and sign detailed consent/assent forms before participating in the study. Participants are advised of the voluntary nature of this program and of their right to withdraw from the study at any time and/or request that information about themselves and their family be removed from data analyses. Each participant receives a verbal and written description of the study. Experienced research staff members are available at all points of the study process to answer questions and to explain assessment procedures, uses to which the data will be put, and confidentiality of data. Because our population consists of Hispanic participants, all project documents, including the consent/assent forms, will be available in both Spanish and English, and will be administered according to the expressed preference of the participant. If a staff member

determines that a participant's reading skills are limited, all materials will be presented verbally in Spanish or in English, as indicated. Assessment questionnaires and anthropometric, cardiometabolic and biological measurements will be explained and conducted in the participant's preferred language (Spanish or English).

- *Confidentiality Safeguards:* To ensure confidentiality, all information will be coded so that it cannot be associated with any individual. A master sheet, with individual names and their respective code numbers will be kept in a locked file that can be accessed only under supervision of the Principal Investigator. All data entered into the computerized database will be identifiable by subject code number only. No one other than the Principal Investigator and the study coordinating team (TBA coordinator) will have access to records identifying subjects' names at any time. However, the facilitators will not have access to the data collected as part of the assessment. The information gathered will be used only for scientific, educational, or instructional purposes.
- *Mandatory Reporting Safeguards:* Procedures to prevent the violation of confidentiality in accordance with reporting requirements are limited by the mandatory nature of these requirements. Subjects are informed in the consent document that staff must report to authorities 1) physical injury caused by other than accidental means, as required by ORS 419B.005 through 419B.040; and 2) information from a study participant which leads staff to believe a person is in imminent danger of physical harm.
- *Staff Training Safeguards:* Every personnel on the study will be required to complete the CITI-Core course, an extensive, training/testing program which focuses on good clinical practice, to be certified by the IRB at the University of Texas. Study personnel will also have to be re-certified on a biannual basis by completing the CITI-CE course.
- Research staff receive training specific to each assessment/measurement tool until they meet criteria for each assessment administration procedure. All project staff will meet on a weekly basis for ongoing training, monitoring of protocol, and problem solving. Questions regarding data collection will be promptly referred to the PI.
- Research staff as well as facilitators will be trained to identify events that would fall under mandatory reporting guidelines. These include physical injury to any study subject caused by other than accidental circumstances or information from a study participant that leads staff to believe a person is in imminent danger of physical harm.
- *Data Safeguards:* Identifying information is kept separately from the electronic or hard copy data sets at all times. During the analysis of the data, only the subject identification number is kept with the data. No information about the identities of study participants will be published or presented at conferences.
- *Discomfort or Embarrassment Due to Assessment Procedures Safeguards:* During the course of participation in the research, a participant may have questions about the assessment and measurement procedures. A project staff member will be available to answer questions. Should a participant feel embarrassed or uncomfortable asking questions to a project staff member, the PIs will be available to answer questions or to handle problems encountered as a result of this project.
- To prevent discomfort or embarrassment, all staff are trained in rapport building, skillful interviewing, and obtaining accurate measurements while minimizing the potential for stigmatization. Participants

are informed prior to the assessment that they may choose to skip any question or procedure they find uncomfortable. If any individual becomes overly distressed or distraught during the assessment and/or clinical measures, the assessment will be stopped immediately and a staff clinician will talk privately with the affected individual(s). Appropriate referrals will be made as needed.

- *Discomfort with Disclosure Safeguards:* During initial training, staff members will be coached by Dr. Messiah, to respond to embarrassment, discomfort, or distress in an appropriate and compassionate manner. If a participant experiences any other adverse reaction to the assessment, Drs. Barlow and Cartwright will be available to assess and refer the participant to appropriate services. Participants will receive specific written (in the form of a project description and PIs' contact business card) and verbal instructions during the project consent procedures about how to contact a PI or project staff if necessary.
- *Dissatisfaction Safeguards*: Participants will be encouraged to discuss with the project PIs or facilitators any possible dissatisfaction with the assessment/measurement activities. Referrals to alternative community services will be made at the study subject's request or when it appears to be appropriate.

Response procedures for adverse events

Mandatory Reporting
Staff must report two kinds of events that are potentially harmful to participants or others: adverse events and serious adverse events.

Adverse Events

Adverse events are those events that create distress for participants, such as (1) family crises; (2) possible violations of confidentiality; (3) extreme distress caused by assessment procedures; and extreme embarrassment or distress in response to disclosing sensitive personal information. Adverse events that are not serious will be logged into the project's adverse events folder and noted in the participant's study file. Serious adverse events will be logged and notated, and they will be reported to the PI immediately. A Serious Adverse Event form will be completed and sent to the Institutional Review Board of the University of Texas as well as the NIH project officer within 2 business days.

1. Family crises

Family crises involve a range of situations that threaten the ability of parents to provide essential support for their children and also include domestic violence or marital crisis, symptoms of mental illness in parents (e.g., depression and mania), and family environmental changes (e.g. homelessness).

Assessment staff: Project staff will be trained by Co-I Klement and PI Messiah to recognize signs of family crises and to consult with the PI. Together they will determine the best response to the patient's needs, including referral, if so indicated. Project staff will be trained to recognize symptoms of severe problem

behavior, extreme family disagreements, domestic violence, marital crisis, and mental illness. Participants in the project will have emergency numbers to call if there is a crisis situation involving the parent's use of the curriculum tools that may have resulted in a problem situation that escalates, such as violence to others in the household.

2. Possible Violations of Confidentiality

When any staff member becomes aware that participant confidentiality has been violated, the staff member is required to report this to the PI. The PI will then meet with the staff member who violated confidentiality, will review the information and determine next steps. If the suspected staff member is found to have violated participant confidentiality, the staff member will be terminated. The incident will be reported to the University of Texas IRB and to the NIH project officer within 5 business days.

3. Extreme Distress Caused by Assessment Procedures

In cases where a participant reports or displays extreme distress in response to assessment/measurement procedures/battery, the assessment will be discontinued immediately. Staff will be trained to identify and handle signs of participant distress and will contact the project facilitator(s) and /or PI who will assess the participant's distress level and will refer her/him to counseling if necessary. In cases of extreme distress caused by assessment procedures, a notation will be made in the participant's study file.

4. Extreme Embarrassment or Distress in Response to Disclosing Sensitive Personal Information

If a participant reports or displays extreme embarrassment or distress in response to requests for sensitive personal information (e.g. eating behavior, other psychopathology), the assessor will discontinue the assessment and will refer the participant to counseling if necessary. In cases of extreme embarrassment or distress caused by disclosing sensitive personal information, a notation will be made in the participant's study file and the study coordinator will be notified.

<u>Serious Adverse Events</u>

Serious adverse events refer to events that place participants or others in imminent danger. Such events include suicidal ideations or intentions, instances of physical abuse, neglect or threat of physical harm among participants to themselves or others. Other serious adverse events, in which harm to participants or others has already occurred, must also be reported. Such events include hospitalization or death. To anticipate these concerns, the project has established procedures and guidelines to respond to risk disclosures and crisis situations among subject families. Assessment staff will be trained to recognize risks or crises that require immediate reporting response. Five types of situations require special procedures:

1. Suicidal Thoughts or Attempts

Two types of risks will be addressed in the project: (a) ideation or the presentation of thoughts or interest in suicide, and (b) action, which includes both thoughts of suicide as well as the presence of a plan and means to accomplish a suicide act.

The participants will complete all self-report measures in conjunction with direct entry onto a laptop. The research coordinator will be required to review identified instruments and items for response values that indicate suicidal ideation or plans for action. Based on the response, the coordinator will be required to review disclosure information with the PI and, if deemed necessary, conduct follow-up inquiry with the participant to further determine level of risk. If the participant is determined to present immediate risk of suicidal action, one of the staff facilitators, will develop a safety plan with the client and make indicated referrals. In the most extreme cases of risk, the staff facilitator assumes follow-up responsibility for the plan of action with the family.

2. Abuse

Child/adolescent or spousal/partner abuse concerns may arise from any or a combination of the following sources: (a) the participant verbally indicates that abuse has occurred or is occurring, or (b) the participant is observed with bodily injury (e.g. bruises, burns, black-eyes) whose origin appears to differ from the explanation given of the injury. Abuse is considered a serious adverse event because it represents an imminent danger to the person.

At any time during the assessments, if any of the above information leads staff to suspect abuse or neglect, steps are outlined for staff to obtain additional information, document the information in the participant's study file and contact the study coordinator. Based on the information, the coordinator will advise the PIs and follow-up regarding communication to the family, appropriate further inquiry, follow-up, and reporting. The PI will be notified to review the information and determine next steps. If abuse is

indicated, the project coordinator will report abuse to protective services on behalf of the participant.

3. Threat of Danger to Others

The threat of danger to others includes disclosure of potential physical harm by a participant to others, including members of the participant's family or other individuals in the community.

At any time during the assessment, if any information derived lead staff to suspect a participant poses a threat of harm to others, steps are outlined for staff to obtain additional information, document the information and contact the PI.

4. Hospitalization

Participants' hospitalization (both for physical and psychiatric conditions) will be documented and reported (see reporting procedures for serious adverse events below).

5. Death

If a project staff member is advised of the death of a participant, the project staff member will document the death in the participant's study file and report the death to the PI.

Reporting procedures for adverse events

An Adverse Events and Serious Adverse Events form will be used to record any events.

The anticipated potential adversity inherent in assessment is limited to those situations described above and is addressed by the timely intervention of a licensed project facilitator skilled in risk assessment and mandatory reporting requirements.

The prevalence of adverse events described above will be reported both to our IRB and to NIH through annual progress reports. We will also report adverse events to others, as directed by our IRB or NIH Program Official.

Reporting Procedure for Serious Unanticipated Adverse Events
In the event of an unanticipated serious adverse event, the project PI will ensure that these events are reported to the NIH Program Official and the University of Texas IRB within 24 hours by phone, fax, and/or email and will submit a written report to the Program Official within two days. The project staff will utilize the following reporting procedures:

1. When the project staff and/or PI become aware of a serious adverse event, reporting requirements must be implemented in a timely manner.
2. PI completes a Serious Adverse Event Reporting Form and submit the form to the University of Texas IRB within two days. Serious adverse events include any hospitalizations or other life-threatening conditions (see serious adverse events above). All serious adverse events will be examined for the need for appropriate referral, an assessment of relatedness to the project, the need for any additional documentation and/or follow-up, and modification of the Informed Consent and notification of existing participants. All adverse events that are ongoing will be followed until they stabilize or resolve. Dr. Messiah will resolve each adverse events or serious adverse event and will consult with the IRB, as necessary.
3. The PI will review the study protocol and determine what further action to take based on the best interests of the participants and of the research and submit to the IRB for approval.

Oversight: Dr. Messiah, the Principal Investigator, will administer the Data Safety Monitoring Plan for this project and report all results of the yearly reviews to University of Texas IRB and the NIH Project Officer. Events specifically examined will include (but are not limited to) psychiatric hospitalization, suicidal attempts, and abuse. No planned interim statistical analyses will be performed, though the occurrence of events by condition will be examined in tabular form. Should trends become apparent

that indicate the potential for significant imbalance by condition, a special board will be convened to review the data and make a recommendation as to the disposition of the trial. Any action that results in the temporary or permanent suspension of the project will be undertaken with consultation with the study's NIH project officer and the University of Texas IRB.

The University of Texas is responsible for the general oversight for all grants. Each study is reviewed yearly by the IRB during the regular continuing review process, outlining the following points:

- Reassessment of the risks and benefits to study participants
- Participant recruitment, accrual, and retention
- Confidentiality
- Consideration of external scientific or therapeutic developments with impact on the safety of participants
- Review of adverse events The PI will update the general DSMP procedures as needed.

Statistics

- This study was designed around the maximum sample size possible given the logistical limitations of the study (time, expense). For a total sample size of 25 subjects (Aim 3, the power associated with any of the independent effects in any of the proposed statistical models will be approximately 80% (P value cutoff = .01) as long as the effect accounts for 3% of the total variance relative to the model specific error term (i.e., $R^2 = .03$). This will be true for any effect that is included in any of the statistical models either pre or postoperative and includes both main effects and possible interactions. The power will change slightly due to the complexity of the model and the number of independent effects included, but overall, considering the tradeoff between increased efficiency and lose of error degrees of freedom in more complex models, the power will remain at approximately 80% when 3% of the variance is explained. This axiom also holds no matter the scale of measurement (i.e., continuous or discrete). An R^2 of .03 equates to a "d" statistic (i.e. Cohen's d) of approximately .35. According to Cohen's taxonomy for the social sciences, this is a small to medium effect size. Effects accounting for less than 3% of the total variance are most likely of limited clinical significance. As previously stated in the statistical methods, considering the observational nature of the investigation, we have chosen to use a more conservative P value cutoff. More importantly this conservative standard also increases the chances of reproducibility and helps to account for the amount of statistical modeling/testing that increases the likelihood of irreproducible results.

Ethics

- For all study participants the initial consent process will take place during recruitment process by clinical staff and research staff. However, if a willing participant does not have time to learn about, and sign all consent forms, study staff will schedule a follow up time with them to consent. If needed participants will be allowed to take consent home to review before speaking to research staff or clinical staff administer consent.

Data handling and record keeping

- *Quality control and assurance.* Data storage and management will be accomplished via FileMaker Pro, a cross-platform object-oriented relational database application. Our database manager will be responsible for the development, security, backups, audit logs, and managing database user access. Regarding data/records confidentiality, we have an established set of procedures designed to ensure the protection of confidentiality. All records on active participants will be stored in locked file cabinets in the office of the Principal Investigator, who will maintain strict control over these records. As in our other studies, we will use a record system in which all participant records are filed numerically by case number, with no names attached to the database. Access to the database and data files is strictly controlled by the Principal Investigator. Passwords are used to restrict entry into the database. Project staff is specifically trained on issues of confidentiality. Facilitators will also be trained on issues of confidentiality.

- *Filemaker Data Management Platform.* The database manager will develop a web-based relational database using FileMaker Pro, a secure cross-platform object-oriented relational database application for electronic collection and management of research and clinical study data. The database design will replicate the proposed data collection forms and will be developed in accordance with necessary security, compliance, and study requirements, with oversight from the study's PI. The data collection team will be able to enter data into the database through a secure website. Access to and user privileges within the database will be managed using the UT single sign-on(SSO).

Quality control and assurance

- *Quality Assurance: Accuracy and Completeness of the Data during Data Collection, Entry, Transmission and Analysis.* The project lead coordinator will be entrusted with scanning spot check 10% of the data after entry to ensure accuracy and check questionnaires for completeness as they care collected. Field team staff will follow-up with study participants and concerning questions that are skipped. Participants are allowed to decline to answer, but data checking is in place to ensure that data is not missing due to unintended circumstances.

- *Data Integrity:* To maintain data integrity, fields within the FileMaker application will have data type validation, simple ranges, and/or constraints. Data type validation will check that the entered data fits into the field type (e.g. a date field only accepts data entered in a date format). Simple ranges ensure that the data entered fits within the minimum and maximum values. Constraints check for invalid characters or values. Additionally more advanced checks can be done, such as cross-reference and structured validations. Additionally, ad-hoc reports can be generated to check for data accuracy during the data collection process. Access to this feature will be restricted to required users using user privileges.

- *Data Export for Analysis:* Data can be exported out from FileMaker in various ways and in various formats. Data may be exported as a CSV (comma-delimited) file from a report or as a PDF file from the data entry page when viewing a particular record. Additionally, all collected data can be exported to CSV, XML, DBF, or Microsoft Excel file types. Other database management systems and/or statistical software, such as SAS or SPSS can interface via open database connectivity (ODBC). This interface allows for direct data importing, running SQL queries, generating ad-hoc reports, and accessing the data in real time. Access to these features will be restricted to authorized users using user privileges.

- *Data confidentiality, Storage and Preservation:* At the completion of the data collection process, access to the database by the data collection team will be disabled. Study coordinators and the PI will continue to have access for any required data cleaning. At the completion of the proposed study, access to database will be removed for all nonessential team members and further data modification will be disabled. All data will then be transferred from the database server into a 256- bit AES encrypted archive file and will only be accessible to the PI and a secondary co-custodian. All participants will be assigned a unique code number by PI Messiah. This ID number will be used on all response forms, spreadsheets and data files to ensure participant confidentiality. Participant name, address, telephone, and any other means of identification will be destroyed following the completion of data collection using methods described by the IRB. All study personnel are equipped with password protected personal computer access and password protected access to a network drive accessible only from project staff computers. All computers and network drives are maintained by UT Health's Information Technology Department (IT).
- **Data Security.** For added security and reliability, the FileMaker environment is separated into two servers, a web server and a database server. Data entry is done through the web server only and users do not have direct access to the database server. All transmitted data is encrypted using HTTPS and Secure Socket Layer (SSL) encryption, to maintain secure communication from the user to the web server. All incoming data is then sanitized and stored using AES-256 encryption on the database server. Both servers will be managed by UT Health's Information Technology and are physically located at its data center and covered by its security policies. Which include continuous network scans, penetration testing, daily patches, off-site tape backups, and other enterprise-level data management procedures. Additional security is implemented at the application level. FileMaker maintains a built-in audit trail that logs all events, user access, and data creation and modifications. Log files can be exported for analysis and reporting purposes. All collected data is backed up hourly with redundant nightly backups stored to a separate server going back 6 months. Database consistency checks for errors and server maintenance also occur daily.
- Finally, a Data Safety Board will monitor all adverse events. Possible adverse events include those cases identified above as well as emotional distress associated with assessment or study participation. Adverse events will be reported to the chair of the committee as soon as possible and no later than 24 hours after they occur. Appropriate measures will be taken to ensure the participant's safety including referrals to primary care physician or supportive counseling provided by intervention staff. A summary of all adverse events will be sent to the chair of the Data Safety

Board every month. At least monthly, the Data Safety Board will review all adverse incidents via a face-to-face meeting. This committee will have the power to suspend recruitment to the study or discontinue the study entirely if they have concerns about the safety of the participants or the study itself.

Publication Plan

 Results from this study will be published in leading peer-reviewed journals. The PI anticipates a minimum of 6 final published manuscripts. These aggregate results will be available to research subjects and they will be made aware of their existence.

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Attachments

1. NIH Grant submission application