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**UNIVERSITY OF CINCINNATI  
INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES (IRB-S)  
PROTOCOL**

**TITLE:**

Healthy Introduction of Complementary Foods: An Obesity Prevention Program

**1. PURPOSE of the research project AND GENERAL INFORMATION:**

a. **PURPOSE**

The purpose of this research study is to pilot test a prevention program to promote healthy introduction of solid foods and healthy weight gain among infants. Introduction of complementary foods (i.e., foods besides formula or breast milk) represents a major dietary milestone for infants, but there are currently no empirically-derived guidelines for how parents should introduce solid foods to their infants. The current study will test the feasibility of a 3-session intervention encouraging healthy introduction of complementary foods and use of a responsive feeding approach. Feasibility of the intervention and the impact of the Healthy Start to Feeding (HSF) intervention on obesity risk factors and growth will be explored. This will be achieved through exploration of the following aims and hypotheses:

**Aim 1: Determine feasibility of the intervention and family satisfaction with the treatment.**

H1: Families assigned to the intervention condition will attend  $\geq 67\%$  of treatment sessions.

H2: Families receiving the intervention will rate the program as helpful and consistent with the families' needs and priorities.

**Aim 2: Test the impact of the HSF intervention on growth trajectories, appetite regulation, and diet at post-treatment.**

H1: Infants receiving the intervention will experience lower incidence of high weight-for-length ( $\geq 85^{\text{th}}$  percentile) compared to infants in the control condition.

H2: Infants in the treatment condition will show greater satiety responsiveness and lower food responsiveness as assessed through a well-validated parent-report measure (*Baby Eating Behavior Questionnaire* (Llewellyn, van Jaarsveld, Johnson, Carnell, & Wardle, 2010)).

H3: Infants in the treatment condition will consume a greater variety of fruits and vegetables than infants in the control condition as assessed through a food frequency questionnaire completed by parents.

b. **BACKGROUND**

1) Prior research

Pediatric obesity occurs at epidemic rates (Ogden, Carroll, Kit, & Flegal, 2014) with significant health, financial, and psychosocial consequences (Weiss & Kaufman, 2008; Williams, Wake, Hesketh, Maher, & Waters, 2005; Griffiths, Parsons, & Hill, 2010; Freedman, 2007). While many treatments for pediatric obesity exist, obesity remains intractable for many children, and most children participating in treatments do not exhibit clinically meaningful reductions in Body Mass Index. Therefore, prevention of obesity is critical, including prevention efforts within the first year of life. Children with severe obesity begin to deviate in their growth trajectories at as early as 4 months of age (Smego et al., 2017). Infants with high weight-for-length have up to a 9 times greater risk of obesity later throughout the lifespan, even until 60-70 years of age (Baird et al., 2005; Eriksson, Forsen, Osmond, & Barker, 2003). However, effective prevention programs targeting children < 2 years are limited (Blake-Lamb et al., 2016).

Interventions promoting use of responsive feeding (RF) practices have shown promise in reducing obesity-risk among young children (Savage et al., 2016). RF is characterized by parental attunement to child hunger and feeding cues and use of these cues by parents to structure and make decisions about feeding situations. Responsive parents offer foods when indicated by child hunger cues and allow children's own satiety cues to determine when a feeding is complete, rather than pressuring children to eat the amount of food pre-determined by the parent. Responsive parenting is hypothesized to reduce obesity-risk by allowing children to develop awareness and responsiveness to their own satiety cues. However, the concept of RF has rarely been applied to the key dietary transition of introduction to complementary foods. Research on the introduction of complementary foods and infant weight gain has predominantly focused on the timing of introduction with little research exploring the potential impact of weaning style or the manner in which complementary foods are introduced, including whether a RF approach to introduction of complementary foods results in reduced obesity risk. There are currently no empirically-derived recommendations for parents on how to introduce complementary foods to infants.

## 2) Significance

Early infant growth patterns and eating behaviors have been related to life-long increases in obesity-risk. However, effective interventions for preventing excess weight gain in infancy are lacking. Additionally, there are currently no empirically-derived recommendations around the critical infant dietary milestone of introduction of solid foods. This is significant given that timing and manner of introduction of solid foods has potential implications for later obesity-risk throughout childhood, adolescence, and adulthood. If the designed prevention program is effective, it will reduce early obesity-risk, improve development of infant satiety cues, and increase infant preference for food variety. Given obesity is related to poor long-term health and psychosocial outcomes, financial burden, and reduced quality of life, an early life obesity prevention program could have significant impact across multiple domains.

### c. FUNDING

#### 1) Sponsor's name and type

This study will be funded using the PI's UC start-up funding and funding from UC's University Research Council (an internal faculty grant).

#### 2) Sponsor's role

The study was developed without input of a sponsor. Study results will also be analyzed, interpreted, and disseminated without input of a sponsor.

#### 3) Location of funds

Funds will be held at UC's Psychology Department.

#### 4) Status of funding

Funding has been approved.

### d. FACILITIES

Baseline and post-treatment study visits to collect outcomes measures will occur at the Schubert Research Clinic (SRC) located in the T-building at Cincinnati Children's Hospital

Medical Center (CCHMC). Intervention sessions will occur at the PI's research lab (the Healthy Kids Lab) located in the Edwards Center on UC Main Campus. We have been approved for access to these facilities.

e. DURATION OF STUDY

The research project will take 12 months to complete.

**Timeline**

	Grant Mos: 1-2	Grant Mos: 3-4	Grant Mos: 5-6	Grant Mos: 7- 8	Grant Mos: 9-10	Grant Mos: 11-12
Recruitment (at child age 2-3 mos)						
Initial Study Visit (at child age 3 mos)						
Treatment Session 1 (at child age 4 mos)						
Treatment Session 2 (at child age 6 mos)						
Treatment Session 3 (at child age 9 mos)						
Final Study Visit (at child age 9 mos)						

Abbreviations: mos = months

f. RESEARCH TEAM

1) Research team and time commitment

Job Title / Responsibility	Time Commitment
PI	10 hr/per wk
Lead Undergraduate Research Coordinator	10 hr/per wk
Graduate Student Interventionists	10/hr per wk
Expert Consultants	< 5/hr per wk

2) Training team members in research ethics

All study team members have complete and up-to-date CITI training.

3) Training team members in research activities

(a) Training

The lead research coordinator and study interventionists will receive direct supervision from the study PI on study recruitment, the study intervention, and study data collection procedures. The lead research coordinator, study interventionists, and study PI will meet weekly for supervision.

(b) Verification

The study PI will verify appropriate use of IRB-approved forms and study procedures during weekly supervision with team members.

**2. PARTICIPANTS:**

a. RECRUITMENT

Participants will be recruited at 2-3 months of age through Pediatric Associates, PSC, a pediatrician practice that has 3 locations in northern Kentucky. If adequate enrollment cannot be achieved through Pediatric Associates, an amendment will be submitted to expand recruitment

to include daycares, Sona system (i.e., student participants can enroll if they have a child meeting study inclusion criteria), and internet and social media sites for our research lab (i.e., The Healthy Kids Lab).

1) Number of participants

The study will enroll 40 total participants. Twenty participants will be randomized to receive the study treatment and 20 participants will be randomized to the control group.

(b) Rationale

This number of participants was determined based on the number of participants feasible to enroll as part of a pilot study while still generating enough data regarding treatment feasibility.

2) Inclusion and exclusion criteria

Participants will be infants aged 3-9 months and their families ( $n = 40$ ). Infants with both normal and elevated weight-for-length will be enrolled. Inclusion criteria include 1) infant has not previously been introduced to complementary foods (i.e., any food besides formula or breastmilk), 2) infant does not have a known developmental delay, 3) infant does not have impaired fine or gross motor skills (which would impact ability for self-feeding), 4) infant does not have a condition currently impacting their feeding and eating, 5) infant born at  $\geq 38$  weeks gestation, 6) infant current weight-for-length  $\geq 10^{\text{th}}$  percentile (Infants with suboptimal growth will be excluded due to potential safety implications of modifying eating and feeding styles of infants with growth difficulties), and 7) parent is a fluent English speaker (because this is the language the intervention will be delivered in).

3) Vulnerable participants

(a) Vulnerability

All study participants will be children less than 1 year old.

(b) Rationale

The objective of the current study is to test an intervention for healthy infant feeding. Therefore, all participants are required to be infants.

(c) Confirmation

A trained research assistant or study PI will complete the informed consent process with a parent/legal guardian of each participant. During that process, the research assistant will confirm that the legal guardian is 18 years of age or older by asking parents to self-report age if they are a young adult believed to be close to 18 years of age. During the consent process, they will also inform the study PI if they have any concerns about a participant's cognitive ability to consent.

4) Risks and discomforts from participating

(a) Type and level of risk or discomfort

Risk or Discomfort	Level
Parental emotional discomfort (anxiety, nervousness) related to introducing their children to solid foods.	minimal
Child risk for choking during introduction of solid foods.	minimal

However, prior research has demonstrated that infant self-feedings are not associated with increased risk of choking (Fangupo et al., 2016).	
Child risk for growth faltering. However, prior research has demonstrated that children introduced to solid foods incorporating self-feeding are not at increased risk for growth faltering in comparison to other children (Townsend & Pitchford, 2012).	minimal

(b) Safety monitoring plan

Despite no greater than minimal risk to participants, we will still actively assess for adverse events related to growth faltering and choking. At each intervention session or study visit, study participants will report on if there were any choking episodes since the last meeting. Additionally, child weight will be measured, with any child failing to gain weight since the last session defined as an adverse event. Between sessions or meetings, parents will be advised to call 911 immediately if their child experiences a choking episode. Participants will also be informed to contact the study PI if there is any concern regarding their child's weight gain or after a choking episode occurs. Any reports of choking episodes provided either at study visits or between study visits will be recorded on the Choking Incident Form. All reported adverse events will be assessed by the study PI.

(c) Reporting

Research assistants collecting adverse event information at study visits and intervention sessions will report this information directly to the PI. Between visits and sessions, study participants will be asked to communicate to the study PI directly if they have any concerns about study participation or if their child experiences an adverse event.

(2) Notification of IRB

Serious adverse events will be reported to the IRB immediately. Other adverse events will be reported to the IRB during the study renewal period.

(3) Other notification

Although not expected, if in the unlikely event we deem participation in the intervention group to be associated with increased risk for choking or growth faltering, study participants will be made aware of this increased risk immediately.

(4) Available resources

During the consent visit, all study participants will receive safety information regarding choking and growth faltering. Study participants will also be referred to talk with their child's pediatrician if they have any concerns.

5) Direct benefits to the participant

Study participants randomized to the intervention group will receive psychoeducation and practice in treatment sessions regarding introduction of complementary foods to

their child. Study participants randomized to the control group will have no direct benefit. Given initial introduction of solid foods occurs only at one time point, a wait-list control design would be inappropriate for the current study.

6) Recruitment activities

(a) Recruitment materials

List: Study Flyer

Pediatrician Recruitment Letter

(b) Personnel

The study PI, lead research coordinator, graduate student interventionists, and expert consultants will be involved in recruitment.

(c) Recruitment activities

We will use opt-in recruitment strategies across all patients at Pediatric Associates, including having handouts for providers to give to patients, having study posters hung at the office, and posting about the study on the practice's social media and in newsletters. Physicians will then be given the option to also have an opt-out recruitment strategy used with the patients for which they are the primary medical provider. Physicians will be approached about using the opt-out strategy by Dr. Bolling, a physician at the practice who is also a collaborator on this research project. The opt-out recruitment strategy will identify children via a systematic chart review by research personnel and practice staff using a procedure from our previous research study (CCHMC 2016-1712). The pediatrician practice has a HIPAA Compliance Officer. In accordance with HIPAA policy, a waiver for review of the information in the primary care office charts and database will be placed on file with this officer. This waiver is between the pediatrician practice and researchers. A file will be kept for patients whose records were reviewed of the study personnel's access to their medical record for purposes of inviting participation into the study protocol. This procedure is consistent with HIPAA legislation (Subpart E Section 164.513, 45 CFR 164.512). A copy of the HIPAA waiver form has been uploaded to the IRB Smartform. For families of children meeting the inclusion and exclusion criteria based upon information in the chart review, the research personnel will create a recruitment letter for each identified child's pediatrician to review and sign inviting the child's guardians to learn more and participate in a screening for the study. Letters will only be sent until our enrollment target is met ( $n = 40$ ). Enclosed with the recruitment letter, families will receive a flyer describing the study and a return addressed, stamped "do not contact" postcard that a family can mail requesting not to be contacted. All families for whom a postcard is not received within 10 days of mailing will be contacted by phone by the study personnel to explain more about the study, assess the family's interest in participation in the study, and schedule an initial study visit if the family would like to participate. No patient data will be removed from the pediatrician office on children for whom a chart review was conducted or those whose families were sent letters, until 10 days after the mailing. Ten days after mailing, the names, chart review screening forms, and contact information of families who received a recruitment letter and did not return a "do not contact" postcard will be brought to Dr. Stough's lab at UC. These families will be called by study personnel to explain the study, conduct initial screening, and invite participation. All of these procedures are consistent with the recruitment procedures in our other study (CCHMC 2016-1712).

(d) Participant response

Study flyers will include the PI's contact information.

b. CONSENT PROCESS

1) Presenting information to potential participants

The informed consent process will occur individually with families at their first study visit. It will occur first thing in the visit before any study procedures. A trained research assistant or the PI will review the consent form with the parent participating with the infant and answer parent questions regarding the research study. The parent will be given adequate time to determine whether they would like to participate in the study and will then provide consent if they choose to participate on the informed consent document. Information will be presented in a manner that is understandable to the family.

2) Answering questions from potential participants

Participants will complete the informed consent process one-on-one and in-person with research staff, allowing them the opportunity to ask questions. Families will also be provided contact information for the study PI should they have questions after their initial visit.

3) Indicating consent

Participants will sign an informed consent document to indicate their consent.

4) Legally authorized representative (LAR) for minors or cognitively impaired participants  
Not applicable.

5) Verification of LAR for cognitively impaired participants  
Not applicable

6) Avoiding coercion

The research assistant or PI conducting the informed consent process will be someone who has no authority over participants. Participants will be informed that their choice to participate will have no influence on their ability to receive services at Pediatric Associates.

7) Recruitment incentives

All study participants will receive \$50 in gift cards for completion of the first study visit and \$50 in gift cards for completion of the final study visit. Participants will be given the portion of the incentive earned at the end of each completed visit (i.e., \$50 at the end of the first study visit, \$50 at the end of the final visit).

c. CONSENT DOCUMENTS (ICDs)

List: Informed Consent Document

**3. RESEARCH-RELATED ACTIVITY:**

a. SECONDARY ANALYSIS of an EXISTING DATASET

Not applicable.

b. REVIEW OF RECORDS that were collected for NON-RESEARCH PURPOSES

Not applicable.

c. RESEARCH ACTIVITIES

1) Privacy of participation

It is not necessary to keep the fact that an individual is participating private. A person participating in this study is only an indicator that they have an infant, and does not disclose anything else about the person that needs to be kept private.

2) Confidentiality of data

Data will be kept private by using a study ID number instead of the participant's name on the research forms. We will keep a master list of names and study ID numbers in a separate location from the research forms. We will limit access to research data to the research team. Participants' identities and information will be kept confidential unless the authorities have to be notified about abuse or immediate harm that may come to the participant or others (e.g., report of child abuse to Child Protective Services).

Data will be kept in Dr. Stough's research lab at UC. Paper copies of data will be kept in a locked filing cabinet in the PI's research lab at UC, and electronic data will be stored on either password protected computers or a secure network drive. Audio recording of treatment sessions will be stored electronically on the secure UC network drive. These will be stored in a separate folder from any other participant data or names. Only study staff will have access to these recordings. The document linking study ID numbers to participant names and the consent forms will be stored separately from study data. All data will be de-identified following completion of study analyses and publication with the exception of the document linking study ID numbers to participant names and the audio recordings, which cannot be deidentified based on the nature of the data. Paper copies of data, consent forms, and the document linking study ID numbers to participant names will be destroyed through secure shredding 5 years following the last publication of study results in compliance with American Psychological Association recommendations. The data from this research study may be published; but participants will not be identified in publications.

3) Research-related activities

(a) Participant cohorts

Study participants will be assigned to either the control or treatment condition at their first study visit following completion of informed consent and baseline measures. A computer-generated random number list will be used to determine condition assignment for each participant. Participants will be notified immediately at the study visit of their study condition.

(b) Activities and duration

The first study appointment will occur when the infant is 3 months of age (defined as 3 months 0 days – 3 months 30 days) at the Schubert Research Clinic (SRC) at CCHMC. The infant and at least one parent will attend the appointment. The appointment will begin with completion of the informed consent process with the study PI or trained research assistant. Next, participants will

complete study measures, including infant anthropometrics and parent-report measures of demographics, parental feeding practices and beliefs, and infant appetite. Families will also receive information about how to intervene if their child experiences a choking incident while introducing complementary foods. Following completion of study measures, families will be randomized to either the control or treatment condition using a computer-generated random number list. Participants will receive \$50 for completion of this visit. Participants in the intervention condition will be instructed to not introduce their child to complementary foods prior to their first Treatment Session at 4 months of age. All families will receive safety information regarding monitoring infant growth and choking.

Participants assigned to the treatment condition will attend 3 intervention sessions at the Healthy Kids Lab, located in the Edwards Center on UC campus. The sessions will be scheduled with individual families when the child is 4 months (+/- 30 days), 6 months (+/- 30 days), and 9 months (+/- 30 days) of age. An attendance log of whether participants attend treatment will be kept.

All participants will also complete a final study visit at the SRC at CCHMC when the child is 9 months (+/- 30 days) of age. They will complete a final study visit to complete post-treatment period measurements, which will include infant anthropometrics and parent-report of infant appetite, infant diet, and parental feeding practices and beliefs. Families receiving the intervention will also complete a measure of treatment satisfaction. Participants will receive \$50 for completion of this visit.

#### *Healthy Start to Feeding (HSF) Intervention*

The *HSF* intervention provides parent education and skills training on a responsive feeding approach to introduction of healthy foods in infancy through 3 sessions when the child is 4, 6, and 9 months. Each session content is manualized and administered by interventionists with expertise in child development and behavioral strategies for managing child eating behaviors under the supervision of a licensed clinical child psychologist and pediatric occupational therapist with expertise in infant eating behavior and oral motor skills. Sessions are conducted individually with each infant participant and at least one of their primary caregivers at PI Stough's research lab and include educational content, handouts and instructions, modeling of skills by the interventionist, caregiver practicing of skills in session, establishment of behavioral goals, and problem solving barriers to implementation of treatment content. Content will include: delaying introduction of solid foods until 6 months of age, allowing infants' own hunger and satiety cues to guide the feeding experience, introducing healthy foods (e.g., fruits, vegetables, not junk food), parental attunement to infant satiety cues, reducing choking risk, and promoting infants' own self-feeding.

All intervention sessions will be audio recorded using a portable handheld digital audio recorder for use specifically for this study. Audio recordings are being obtained in order to assess treatment fidelity and whether interventionists cover the manualized content at each session. After the sessions are recorded, they will be transferred from the audio recording device to the secure UC storage network. One-third of sessions will be coded for treatment fidelity independently by two research assistants who did not provide intervention sessions. Reliability of coding will be calculated by comparing coding of the two research assistants.

If a participant withdraws participation from the study or can no longer be reached/contacted

about study participation, all data already collected for that participant will continue to be used for the study. The alternative to participating is to not participate.

Participants may potentially be asked to participate in future studies examining the long-term outcomes of participation in our intervention. Conducting this future study, and subsequently the invitation of participants to enroll in this future study, is currently uncertain and will be determined in the future based on results of the current study and subsequent funding. Participants will be made aware of the possibility of being asked to participate in future research during the consent process. They can decline to be approached about future research by notifying the research staff member of this desire at their last study visit. Participant interest in being contacted for future research does not impact their ability to participate in the current study.

#### (c) Data collection tools

Infant Anthropometrics. Anthropometrics will be measured for pre-post analyses at both the initial and final study visit by Bionutrition Core staff at the SRC. Infant length will be measured in triplicate to the nearest 0.1 centimeter using an infant length board (O'Leary, Ellard Instrumentation, LTD). Weight will be measured in triplicate to the nearest 100 grams with the infant in a dry diaper using a Scale Tronix 4802 digital infant/pediatric scale. The average of the three measurements will be used to calculate weight for recumbent length. Percentiles for each infant's weight for recumbent length will be obtained using sex and age specific World Health Organization (WHO) growth charts. Information will be recorded on the "Anthropometrics Form".

For families in the intervention condition, infants will also have length and weight measured at each treatment session to monitor safety of growth. Measurements will be taken by study interventionists using a SECA infant length board (SECA 416) and SECA infant digital scale (SECA 374).

Infant and Family Demographics. Demographics information will be collected at the initial study visit using a form created for use in this study.

Treatment Satisfaction. Caregivers in the treatment condition will complete a survey to provide quantitative and qualitative feedback on the intervention after the final treatment session. The questionnaire includes Likert scale ratings of the appropriateness, helpfulness, and timeliness of session content as well as open-ended questions for the parent to provide qualitative feedback on ways to improve the intervention (e.g., additional content to cover).

Infant Appetite. Parents will complete a survey entitled the *Baby Eating Behaviour Questionnaire* (Llewellyn et al., 2010) at both the initial study visit and final study visit or final treatment visit to assess current infant appetite. Parents respond to 17 items on a 5-point scale. Scores for "Enjoyment of Food", "Food Responsiveness", "Slowness in Eating", and "Satiety Responsiveness" are calculated.

Block Food Frequency Questionnaire. Parents will complete the Block Food Frequency Questionnaire for Children Aged 0-2 at the initial and post-treatment study visits. This questionnaire asks reporters to identify how frequently their child has eaten a list of foods in the last week and data are analyzed by a commercial company NutritionQuest to produce scores for daily calorie, fat, and nutrient values. Additionally for the current study, we will also calculate the number of unique foods consumed by infants during the last week

as a measure of diet variety. Participants will complete a paper booklet answer questions at the study visits, and these books are sent without any identifying information to NutritionQuest for processing.

Infant Feeding Questionnaire (IFQ; Baughcum et al., 2001). Parents will complete the IFQ, which assesses maternal feeding practices and beliefs, at the initial and post-treatment study visits. The version used in the current study is adapted to assess current feeding practices and beliefs and has been used in prior research (McMeekin et al., 2013; Odar Stough et al., under review). The measure includes 20 items that assess parental beliefs: “Concern about Infant Undereating and Becoming Underweight”, “Concern About Infant Hunger”, “Concern about Infant Overeating and Becoming Overweight” and parental feeding practices: “Awareness of Infant’s Hunger and Satiety Cues”, “Feeding Infant on a Schedule”, “Using Food to Calm Infant’s Fussiness”, and “Social Interaction with the Infant During Feeding”. Parents respond to use question on a 5-point Likert scale or indicate n/a if appropriate.

List:

Anthropometrics Form  
Demographics Form  
Treatment Satisfaction Survey  
Baby Eating Behavior Questionnaire  
Block Food Frequency Questionnaire  
Infant Feeding Questionnaire  
Choking Incident Form

(d) Payments to participants: reimbursement of expenses or payment for time and effort

Participants will receive \$100 for participating. All study participants will receive \$50 in gift cards for completion of the first study visit and \$50 in gift cards for completion of the final study visit. Participants will also have the cost of parking for attending visits covered.

#### **4. DATA ANALYSIS:**

Aim 1 (Determine the feasibility of the *HSF* intervention and family satisfaction with the treatment) will be explored using descriptive analyses. We will calculate the average number of treatment sessions attended and the percentage of participants attending 2 (67%) and 3 (100%) of the sessions. Additionally, we will calculate the percentage of caregivers who either “somewhat agree” or “strongly agree” that the intervention is appropriate, timely, helpful, and satisfactory as assessed by the Treatment Satisfaction Survey. Qualitative comments on the Treatment Satisfaction Survey will also be reviewed to identify themes regarding additional information to include in the intervention, what information was most helpful, what caregivers would like to see changed about the intervention, and what they would like to see stay the same.

Aim 2 (Examine the impact of the *HSF* intervention on growth trajectories, appetite regulation, and diet at post-treatment) will be explored through group comparisons between the control and treatment groups on weight-for-length scores, subscale scores of the *BEBQ*, and number of fruits and vegetables consumed in the last week as assessed on a food frequency questionnaire. Prior to between group comparisons, potential differences between the control and treatment group on key sociodemographic and baseline variables (e.g., gender, baseline weight-for-length, household income, caregiver education level) will be explored to confirm the

effectiveness of randomization to treatment condition. A series of Analysis of Variance (ANOVA) will be computed to examine whether the control and treatment groups differ on outcome variables. If missing data are present, we will also consider an alternative analyses using a repeated measures model with maximum likelihood estimation to examine group differences on outcome variables, which will allow inclusion of all participants despite missing data.

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## **6. ADDITIONAL DOCUMENTATION:**

Not applicable.