Sleep GOALS (Goal-focused Online Access to Lifestyle Support)

Protocol Number: SleepGOALS-01

National Clinical Trial (NCT) Identified Number: NCT05942326

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Summary of Changes from the Previous Version:

Affected Section(s)	Summary of Revisions Made	Rationale
Objectives and Endpoints	Clarified operational definitions of feasibility and acceptability outcomes and associated benchmarks.	To improve clarity and reproducibility of pilot outcomes without altering study objectives or endpoints.
Statistical Considerations	Expanded statistical analysis plan to include precision-based sample size justification and explicit definition of analysis populations.	To align analytic methods with best practices for pilot randomized controlled trials.
Study Intervention	Refined description of intervention delivery, participant engagement tracking, and compliance monitoring.	To enhance transparency of intervention implementation without changing content, dose, or duration.
Safety Monitoring	Clarified adverse event and unanticipated problem reporting and participant notification procedures.	To ensure consistency with institutional and NIH guidance for minimal-risk behavioral trials.
Assessments and Procedures	Standardized terminology related to assessment timing (e.g., baseline and post-intervention).	To improve clarity and consistency across protocol sections.
Multiple Sections	Editorial and formatting updates to improve organization and alignment with NIH-FDA protocol template.	Administrative updates only; no impact on study design or conduct.

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STATEMENT OF COMPLIANCE

The trial will adhere to International Conference on Harmonization Good Clinical Practice (ICH GCP) guidelines, and all relevant state, local, and federal regulatory requirements. Investigators and clinical trial site staff funded by the National Institutes of Health (NIH) and responsible for conducting, managing, or overseeing NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form, recruitment materials, and all participant materials were submitted to the University of Pittsburgh's Institutional Review Board (IRB) for review and approval. The protocol and consent form were approved before enrolling any participants. Any amendments to the protocol will be submitted to the IRB for review and approval prior to implementing the changes in the study. Additionally, all changes to the consent form will be reviewed and approved by the IRB; a determination will be made as to whether a new consent must be obtained from participants who provided consent using a previously approved consent form.

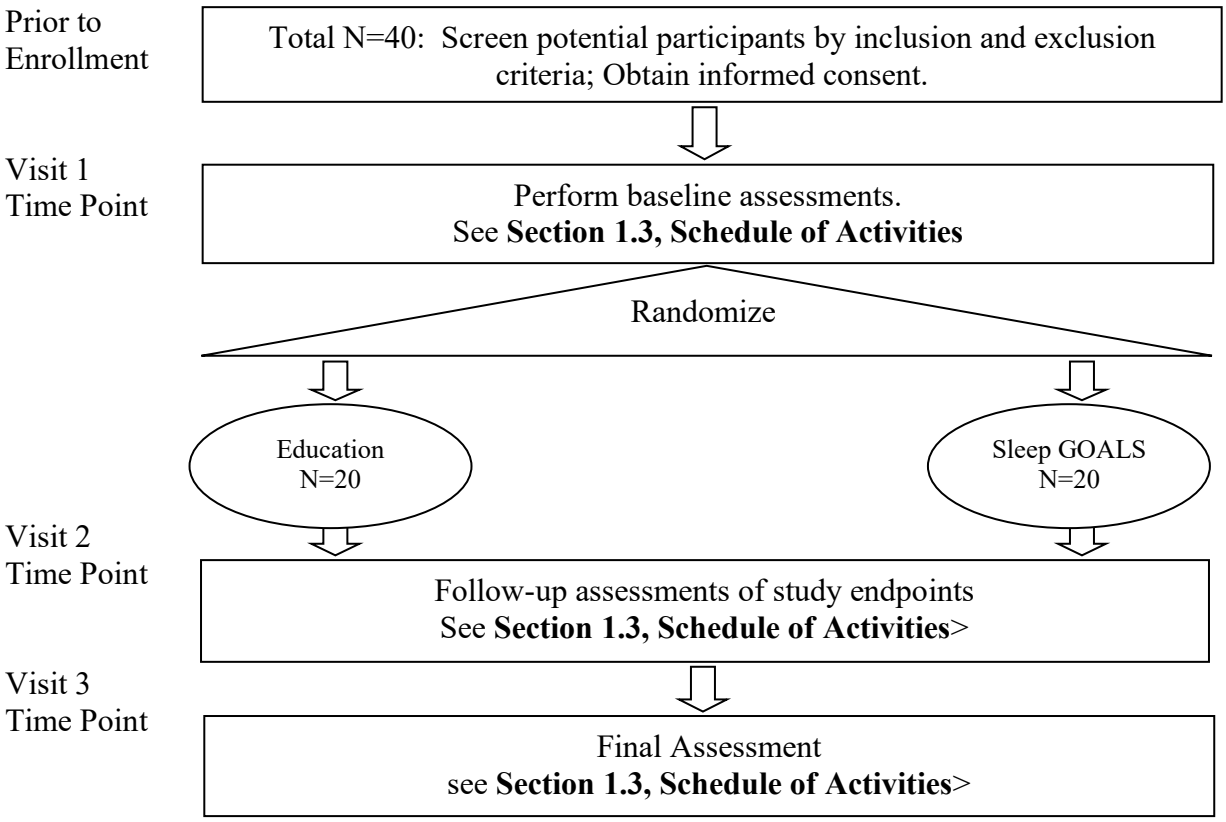
1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Sleep GOALS (Goal-focused Online Access to Lifestyle Support)
Study Description:	This study will use a single-blind, parallel-arm, randomized controlled trial design. Participants will be randomized at a 1:1 ratio to the Sleep GOALS intervention or education control group. We will measure indicators of study feasibility and acceptability to identify and refine factors related to the conduct of the planned larger trial and intervention content and estimate the change in secondary outcomes. See **Schema and Schedule of Activities, Sections 1.2 and 1.3,** respectively.
Objectives:	Primary Objective: To determine the feasibility and acceptability of Sleep GOALS Secondary Objectives: To determine the preliminary efficacy of Sleep GOALS
Endpoints:	Primary Endpoint: The intervention's feasibility (i.e., recruitment, enrollment, attrition rates, intervention engagement) and acceptability (i.e., participant ratings of the intervention delivery, curricula, action plans, intervention platform, and coaching) Secondary Endpoint: Weight loss and retention of pregnancy and postpartum weight gain
Study Population:	40 individuals from Allegheny County who are between 3±1 and 6±1 postpartum, has a body mass index ≥25 kg/m^2, self-report less than 150 minutes of moderate-to-vigorous intensity physical activity (e.g., brisk walk) per week, self-report at least one sleep disturbance, and has Internet access.
Phase:	N/A
Description of Sites/Facilities Enrolling Participants:	Baseline and post-intervention assessments will occur at the Perinatal Health Behavior (PHB) Lab on the University of Pittsburgh's campus, 100 N Bellefield Ave, Pittsburgh, PA 15213. Post-intervention semi-structured interviews will take place in the PHB lab or Zoom, at the participant's preference. Baseline assessments will occur prior to randomization (Week 0), and post-intervention assessments will occur immediately following completion of the 16-week intervention period (Week 16)

Description of Study Intervention:	16-week online intervention that includes 1) informational videos that provide strategies to improve sleep, diet, and physical activity to achieve weight loss, 2) a lifestyle coach, 3) a commercial activity tracker (e.g., Fitbit Charge 5) to monitor sleep and physical activity, and 4) wireless scale (e.g., Aria) to monitor weight.
Study Duration:	The study will last 18 months from the time it opens enrollment until the data analysis is complete.
Participant Duration:	The participants will complete all study visits in 18 to 20 weeks.

1.2 SCHEMA



1.3 SCHEDULE OF ACTIVITIES (SOA)

Procedures	Screening, Day -7 to -1	Enrollment/Baseline, Day -7 to -1	Day 1	Final Assessment, Day 112+8
Eligibility determination	X			
Informed consent		X		
Randomization		X		
Administer the intervention			X----------X	
Outcome Assessment				
Feasibility indicators		X		
Acceptability indicators			X----------X	
Height and Weight	X	X		X
Descriptive characteristics				
Demographics	X	X		
Infant Feeding and Behavior		X		X
Mental Wellness		X		X

Treatment Expectations		X		
Weight Goals		X		
Social Support		X		X
Social Determinants of Health		X		
Health Behaviors				
Physical activity	X	X		X
Diet		X		X
Sleep	X	X		X

2 INTRODUCTION

2.1 STUDY RATIONALE

Pilot testing will help us identify and refine factors related to the conduct of the planned larger, definitive trial and estimate the change in secondary outcomes.

2.2 BACKGROUND

- Postpartum weight retention and maternal obesity are associated with short- and long-term maternal morbidity and mortality risk.
- The US Preventive Services Task Force recommends that clinicians offer or refer individuals with obesity to an intensive behavioral weight-loss intervention that addresses diet and physical activity
- Most weight-loss interventions among postpartum individuals have followed these recommendations but have produced only modest effects and had substantial heterogeneity.
- Sleep is independently associated with obesity and weight gain and bi-directionally associated with diet and physical activity. However, diet and physical activity interventions are rarely integrated with sleep interventions.
- Integrating sleep interventions with diet and physical activity may enhance weight loss among postpartum individuals.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

We categorize the frequency of possible risk using the following categories: likely (occurs in >25% of people), common (occurs in 10-25% of people), infrequent (occurs in 1-10% of people), and rare (occurs in <1% of people). We will monitor the risk related to the intervention and data collection.

Intervention-Related Risk:

- The recommended physical activity may cause muscle soreness or fatigue (likely). There is the possibility that the following occurs during exercise: injury of a joint or muscle (common), broken bones (rare), falls from exercise equipment (infrequent). There is also the possibility of aggravating pre-existing problems (common), shortness of breath (common), abnormal blood pressure (common), fainting (rare), disorders of heart rhythm (rare), heart attack, stroke, or even death (rare).
- The recommended weight loss may cause constipation (common) and dizziness upon standing (common). Rapid weight loss increases the chances of developing or enlarging gallstones (rare). Other risks include hypoglycemia (infrequent), light-headedness or weakness (common), and hunger (likely).
- Wearing the wrist-worn activity monitor may cause some discomfort in the form of skin irritation (infrequent).

Data Collection Related Risk:

- The potential risks of participating in this study include discomfort (rare) from answering questions, disclosure of postpartum depression or child neglect/abuse (infrequent), and breach of confidentiality (rare).

2.3.2 KNOWN POTENTIAL BENEFITS

Participants enrolled in both intervention arms of the study may benefit from losing weight and learning strategies to improve weight-related behaviors, i.e., dietary intake, physical activity, and sleep. Participants enrolled in the Sleep GOALS intervention arm may benefit from having a lifestyle coach who can provide them with tailored information to support behavior change. Society may benefit from the study information because it will inform an intervention to improve maternal weight and health postpartum.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Postpartum weight retention (PWR) predicts weight gain and obesity development in women. PWR increases the risk of adverse maternal outcomes (e.g., preeclampsia, gestational diabetes) in subsequent pregnancies, additional weight gain, and long-term cardiovascular disease (CVD) development. The postpartum period is critical for engaging individuals in weight-loss interventions to prevent PWR and future CVD morbidity and mortality. Most weight-loss interventions among postpartum individuals have addressed diet and physical activity and have produced only modest effects. Poor sleep, common during the postpartum period, has rarely been addressed in standard weight loss interventions. Interventions that address poor sleep may enhance the efficacy of standard weight-loss interventions. The knowledge gained in this study will inform the refinement of a weight loss intervention for postpartum individuals that addresses diet, physical activity, and sleep. Iterative development of the intervention, which incorporates user feedback at various stages, is likely to increase the intervention's feasibility, acceptability, and efficacy. Participants will learn strategies for improving their sleep, diet, and physical activity and self-select the activities that fit their circumstances. Given the minimal risks of the proposed assessments, the potential benefits to the individuals and society greatly outweigh the risks of conducting the proposed research.

3 OBJECTIVES AND ENDPOINTS

Primary Outcomes: The primary outcomes are feasibility and acceptability factors relevant to conducting a subsequent efficacy trial, including the feasibility of recruitment, retention, and engagement (Table 5). To determine acceptability, we will ask participants to complete a modified Acceptability and Feasibility Questionnaire[1] post-intervention. The questionnaire asks participants to provide answers on a 5-point scale (1=*don't agree at all* to 5=*totally agree*) to 39 items about the intervention delivery (e.g., logical, understandable), curricula (e.g., was it logical, relevant, instructive), action plans (e.g., useful, easy to follow), and intervention platform (e.g., user friendly). We will also ask about the coaches' effectiveness, overall satisfaction with the intervention, and the likelihood they would recommend it to a friend. Items with an average score of <4 will be flagged for refinement.

We will then conduct 60-minute semi-structured interviews with participants and coaches. The interviews will take place in person (PHB lab) or by video chat at the participant's preference. We will ask participants whether the content was understandable, the recommendations achievable, and what adaptations are necessary to improve low-scoring items. We will ask the lifestyle coach to discuss their experience and provide suggestions for improving the delivery of the material and their workflow. All interviews will be audio-recorded and transcribed by Qual EASE for qualitative analysis. The feedback will be used to refine the intervention's content delivery, coach's workflow, and training manual. Participants will receive $50 after each assessments and intervention participants will receive a $25 honorarium for completing the post-intervention interview.

Secondary Outcomes: *Weight* will be measured with a digital scale, with the participant wearing light clothing and no shoes at baseline and post-intervention. We will estimate PWR as the difference in measured weight at post-intervention and self-reported pre-pregnancy weight.

Analysis Plan: The primary study objective is to assess the feasibility and acceptability of Sleep GOALS. We will assess the feasibility of the intervention by estimating rates of recruitment, retention, and engagement (i.e., weekly logins; modules completed; daily self-monitoring of diet, physical activity, and sleep; weekly monitoring of weight using point estimates (means or sample proportions) and 95% confidence intervals). We will assess acceptability by estimating satisfaction rates on various intervention components (≥4 Acceptability and Feasibility Questionnaire). Our benchmarks for feasibility are similar to those used in the original GOALS Lifestyle intervention. We will use a benchmark of 80% for all feasibility and acceptability measures. To assess the intervention's preliminary efficacy, we will calculate point estimates and confidence intervals for change in weight and PWR. We chose these weight measures as our secondary outcomes since they will be the primary outcome in the future R01. However, we will also explore changes in our proposed behavioral mediators, sleep, diet, and physical activity to inform power calculations for a fully powered study.

We will conduct an exploratory analysis to determine how potential covariates (e.g., parity, breastfeeding status, postpartum depression, race/ethnicity, relationship status, and employment status) impact the intervention's feasibility, acceptability, and preliminary efficacy. For example, in some studies, breastfeeding is associated with longer nocturnal sleep [2-4], but shorter nocturnal sleep in other studies.[5] Collecting data on breastfeeding and other covariates will provide preliminary data on how it impacts the intervention.

Domain	Measure, Method of Assessment	Benchmarks for Success
Feasibility (Primary Outcome)		
Recruitment/Enrollment	Total sample	40 participants in 12 months
	Demographics of sample	≥30% ethnic minority
Retention	Attrition Rates	≤20% loss to follow-up
Engagement	Modules completed	≥14 (~80%) modules completed within 16 weeks
	Weekly self-monitoring of diet, sleep, and physical activity weekly	≥14 (~80%) weeks, ≥1 day of monitoring
	Weekly weigh-ins	≥14 (~80%) weeks, ≥1 day of weigh-ins
	Total time logged in	
Acceptability (Primary Outcome)		
Acceptability	Acceptability of the intervention delivery; behavior change curricula; action plan; intervention platform	≥80% agree or totally agree with each
Preliminary efficacy (Secondary Outcome)		
Weight	Weight change	>5% weight loss
	Postpartum weight retention	<5 kg of weight retention
The primary endpoints will inform factors related to the conduct of the study (i.e., feasibility) and the intervention content and delivery (i.e., acceptability) of the planned larger definitive efficacy trial. The secondary outcomes will provide estimates of the intervention's effects on the primary outcome of the planned larger definitive efficacy trial		

4 STUDY DESIGN

4.1 OVERALL DESIGN

This study will use a single-blind, parallel-arm RCT design. Participants will be randomized at a 1:1 ratio to Sleep GOALS intervention (n=20) or an education control group (n=20).

Sleep GOALS: We anticipate Sleep GOALS will be a 16-week intervention. However, the results of Aim 1 will determine the intervention length and core content. We will use a protocol Dr. McTigue and colleagues developed to adapt TSC to an online format and integrate it with the GOALS lifestyle intervention.[6, 7] Briefly, in-person delivery of TSC has 3 components: 1) delivery of the core content, 2) providing tailored feedback, and 3) providing motivation and support. We will adapt the first component to an online format with 15-to-20-minute informational videos. The participants will view the material at their convenience, with new videos available weekly. The GOALS software will send weekly automated email reminders to review the new session materials. We will use a lifestyle coach to adapt the 2nd and 3rd components. Evaluating patient perspectives on the original GOALS lifestyle intervention found individualized lifestyle coaching, encouragement, and accountability helpful.[8] The coach will be a master's level student in a health-related program (e.g., physical activity and health promotion, nutrition and dietetics, etc.) with experience in weight-management counseling. As described in Aim 1, the coach will assist with developing Sleep GOALS to familiarize them with the intervention content. However, the coach will complete a 2-day training workshop using a similar training format as the GOALS Lifestyle intervention.[7] The coach will help participants develop an individualized sleep treatment plan based on their baseline sleep assessment. For example, coaches will encourage participants to document challenges for sleep (e.g., infant sleep, lack of partner support) and identify one treatment strategy they deem feasible to implement each week. The coach will monitor participant progress and engagement weekly to revise the sleep treatment plan, diet, and activity as needed. Coaches will provide personalized feedback and encourage accountability and re-engagement through a secure messaging system in the Sleep GOALS platform.[7] The PI will randomly check coach-participant communication weekly to ensure intervention fidelity. IF NECESSARY, the PI will meet with the coaches weekly to discuss challenges and participant communication. Lastly, participants will be given a wireless scale for self-monitoring weight and a Fitbit for self-monitoring sleep (daily minutes) and physical activity (daily steps, minutes). The Fitbit dashboard also allows participants to track dietary calories. Participants will receive instructions on how to sync the scale and Fitbit data with the Sleep GOALS platform. Participants will be asked to weigh themselves in light clothing at least once weekly.[9]

Education Control: We used the Pragmatical Model for Comparator Selection in health-related behavioral trials to guide our control group selection.[10] This model suggests utilizing a control group that is not likely to produce a change in the outcome for early-stage intervention development. We considered a no-treatment comparator and wait-list control. Given the timeline and limited resources, we decided a wait-list control is not feasible. We chose an education control because we decided the control should have some value to participants. Therefore, the control group will receive brochures from the American Academy of Sleep Medicine (e.g., sleep hygiene, sleep in women) and SNAP education connection (e.g., family-friendly activities, meal planning) after randomization is revealed.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

Pilot testing will help us identify and refine factors related to the conduct of the planned larger, definitive trial and estimate the change in secondary outcomes. Given the timeline and limited resources, we decided a wait-list control is not feasible. We chose an education control because we decided the control should have some value to participants. Therefore, the control group will receive brochures with strategies to sleep better, eat healthily, be physically active, and lose weight.

4.3 JUSTIFICATION FOR DOSE

Over the 16-week intervention, participants will have access to 16 (~20-minute) information videos, made available weekly. The intervention content will be delivered via a secure online platform. Participants can access the intervention content at their convenience, which increases the intervention's feasibility for postpartum people with small children. The intervention 16-week are similar in dose to other weight loss interventions.

4.4 END OF STUDY DEFINITION

End of study is defined as completion of post-intervention assessments, which occur immediately following the 16-week intervention period (Week 16).

5 STUDY POPULATION

We will enroll 40 primiparous adult individuals between 3±1 and 6±1 months postpartum with a body mass index ≥25 kg/m^2. We chose this postpartum range because postpartum weight retention during this period is associated with the development of long-term obesity. Additionally, at 3 months postpartum, most infants experience rapid increases in nocturnal sleep; thus, many of our behavioral strategies for improving maternal sleep may be more feasible. Evidence suggests that addressing sleep in infants between 3 and 6 months can prevent longer-lasting sleep problems. Lastly, it is safe for most postpartum individuals to participate in an intervention involving physical activity during this period.

5.1 INCLUSION CRITERIA

To be eligible to participate in this study, an individual must meet all of the following criteria:

1. Provision of signed and dated informed consent form,
2. Stated willingness to comply with all study procedures and availability for the duration of the study,
3. Primiparous, singleton pregnancy,
4. Between 3±1 and 6±1 months postpartum,
5. Has a body mass index >25 kg/m^2,
6. Physically inactive, defined as self-reporting <150 minutes/week of moderate-to-vigorous intensity physical activity,
7. Endorse >1 indicator of poor sleep health based on the RU_SATED questionnaire, and
8. Has smartphone and home Internet access

5.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

1. current use of medications that affect weight (see Appendix 1),
2. currently pregnant or plan to become pregnant during the study period (18 weeks), and
3. participating in another weight loss intervention.

5.3 LIFESTYLE CONSIDERATIONS

This study does not have any lifestyle restrictions.

5.4 STRATEGIES FOR RECRUITMENT AND RETENTION

Recruitment Strategies

All subjects will be recruited from Allegheny County using participant registries maintained by Pitt's Institute for Clinical and Translation Research (i.e., Pitt+Me, Pediatric PittNet, Women's Practice-Based Research Network). The respective registries will identify participants through:

- Postings in practice waiting rooms
- Personalizing mailing and emails about the study to women that meet eligibility criteria based upon ICD-9/10 diagnosis codes listed in their medical record (e.g., recent delivery), demographics (e.g., women aged at least 18 years)
- Personalizing mailing and emails based on stated preferences (e.g., interest in weight loss interventions)

- A custom study web page that provides a lay description of the study, the eligibility criteria, compensation, and study team biographies
- Facilitating collaborations between study staff and practicing physicians, including practices that serve a diverse sample of women
- Advertisements on Facebook and Twitter

Interested participants will be pre-screened for eligibility online or through a registry call center. Referrals to contact potentially eligible subjects will be delivered through an online portal.

A research assistant will call women who agreed to be contacted to discuss the study purpose, procedures, risks, and benefits, screen for eligibility, and obtain verbal consent. Participants will be enrolled in the study once we obtain consent.

Retention Strategies:

The lifestyle coach will implement several strategies to increase engagement with the intervention protocol and re-engage participants who have not engaged with the online platform for two consecutive weeks. These strategies include:

- Personalized reminders: Send friendly messages through the GOALS platform to participants who haven't logged in for two weeks. Personalize the reminders by addressing the participant by name and mentioning specific content they have missed or need to catch up on.
- Motivational messages: Send motivational messages that highlight the benefits of the intervention and remind them of their goals and reasons for participating in the study.
- Check-in calls: Reach out to the participant by phone to check in on their progress, address any barriers, and offer support. This personal connection can help re-engage participants and reinforce the importance of their involvement in the study.
- Address technical issues: Some participants may be disengaged due to technical problems with the platform. Reach out to them to identify any issues they may be facing and provide assistance to resolve these problems.
- Reinforce incentives: Remind participants of any incentives associated with study participation, such as financial rewards, access to additional resources, or entry into prize drawings. This can help motivate them to re-engage with the platform.
- Monitor participant progress: Keep track of each participant's progress and send personalized feedback, praise, or encouragement based on their achievements. This can help maintain motivation and create a sense of accountability.
- Revisit participant goals: Encourage participants to re-evaluate their weight loss and lifestyle goals and discuss any necessary adjustments with their lifestyle coach. This can help maintain motivation and ensure the intervention remains relevant to the participant's needs.

6 STUDY INTERVENTION

6.1 STUDY INTERVENTION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION DESCRIPTION

Sleep GOALS is a 16-week online lifestyle intervention integrating content on sleep, diet, and physical activity, supported by coaching. For the purposes of this trial and registry reporting, intervention duration is defined as 16 weeks for all participants. The Sleep GOALS intervention will include the following components:

- 16 (~20 minutes) informational videos that provide strategies to improve sleep, diet, physical activity, and weight, delivered weekly through an online platform
- Lifestyle coach to provide personalized feedback, encouragement, motivation, and accountability
- A commercial activity tracker (e.g., Fitbit) to monitor sleep, diet, and physical activity
- Wireless scale to track weight

6.1.2 DOSING AND ADMINISTRATION

The participants will view the informational videos at their convenience, with new videos available weekly. The GOALS software will send participants weekly email reminders to review the new session material and to track relevant behaviors (e.g., physical activity, sleep).

6.2 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

We will use REDCap to generate the randomization plan. We will use blocked randomization (blocks of 4) to ensure balanced intervention groups. The randomization plan results will be maintained in REDCap and only accessible by a lifestyle coach who will support participants in the intervention arm (further detailed below) but is not directly involved with data collection. Assignment allocation will be concealed from participants until after the baseline assessments. Investigators will remain blinded until post-intervention data collection is complete.

6.3 STUDY INTERVENTION COMPLIANCE

The GOALS platform contains built-in software to track compliance with intervention protocols. Specifically, the platform tracks the number of times they've logged into the system, the time spent in the system, the number of lessons viewed, workbook pages completed, self-monitoring, and communication with the lifestyle coach. The lifestyle coach will be instructed to reach out to participants if they have not logged into the system for two consecutive weeks to query challenges and provide encouragement to re-engage.

7 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION/WITHDRAWAL FROM THE STUDY INTERVENTION

Participants may withdraw voluntarily from the study at any time by submitting a formal request to the study PI. We will still use data collected before the voluntary withdrawal. The PI may discontinue a study participant if there are changes to their eligibility status, including becoming pregnant or using medications that affect weight. Any new clinically relevant finding will be reported as an adverse event (AE).

The data to be collected at the time of study intervention discontinuation will include the following:

- Reasons for discontinuation
- Timing of discontinuation
- Adverse event details (if applicable)
- Follow-up data (if applicable)
- Documentation on each participant's last available data point(s), including sleep health, diet, physical activity measurements, weight, and any other relevant outcome measures

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

An investigator may discontinue or withdraw a participant from the study for the following reasons:

- Pregnancy
- If any clinical adverse event (AE) or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant
- If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

The reason for participant discontinuation or withdrawal from the study will be recorded on the study discontinuation form. Subjects who sign the informed consent form and are randomized but do not receive the study intervention may be replaced. Subjects who sign the informed consent form, are randomized and receive the study intervention, and subsequently withdraw, or are withdrawn or discontinued from the study not be replaced.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 PRELIMINARY EFFICACY AND COVARIATE ASSESSMENTS

Assessments will be conducted at baseline (Week 0) prior to randomization and immediately after completion of the intervention (Week 16). Assessments will be conducted by a research team member in the PHB lab. Assessments should take 1-2 hours to complete. Participants will receive pre-visit instructions 3 days before their scheduled in-person visits. Assessments will consist of the following:

- Height, weight & waist circumference: Height will be measured with a stadiometer at study enrollment (T0). Weight will be measured using a calibrated digital scale. Women will be measured in street clothes without shoes.
- Demographic information: Age, race, ethnicity, income, educational background, employment status, health insurance status, marital status, family composition (e.g., number of adults and children in the household), smoking status, and current alcohol use.
- Mental wellness: Participants will complete the Edinburgh Postnatal Depression Scale to measure the frequency of depressive symptoms. The Perceived Stress Scale will be used to measure perceived stress.
- Infant sleep and eating. The Brief Infant Sleep Questionnaire - Revised (BISQ) Short Form will be used to assess infant sleep patterns. The infant feeding questionnaire to assessing infant eating patterns.
- Social determinants of health: The Barkin Index of Maternal Functioning (BIMF) is a 20-item self-report measure that was designed to assess overall functioning in the context of new motherhood. The EveryONE project social determinants of health screener to identify the social needs of participants.
- Social support: The RAND social support survey helps identify the types of support available to participants.
- Diet: The study will utilize the Automated Self-Administered 24-hour (ASA24) Dietary Recall System to collect information about what participants ate in the prior 24hours
- Physical activity and sleep: Following the in-person visit, we will give participants an Actigraph Link, which is a research-grade activity monitor, to wear on their wrist for 7

days to assess their physical activity and sleep patterns. The Actigraph will be used solely for the purposes of physical activity and sleep measurement. This study will not test the efficacy of the device. During the 7 day assessment period, participants will complete a sleep diary to help us better interpret the monitor data. After the 7 day assessment, participants will mail the Actigraph and diary back to us in a pre-paid postage envelope. Participants will also complete a modified SASS-Y and PAQ questionnaires.

8.2 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.2.1 DEFINITION OF ADVERSE EVENTS (AE)

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

8.2.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

An adverse event (AE) or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based on appropriate medical judgment, they may jeopardize the participant and require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization or the development of drug dependency or drug abuse.

8.2.3 CLASSIFICATION OF AN ADVERSE EVENT

8.2.3.1 SEVERITY OF EVENT

The following guidelines will be used to describe the severity of adverse events (AEs) not included in the protocol-defined grading system.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in low inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious."

8.2.3.2 RELATIONSHIP TO STUDY INTERVENTION

All adverse events (AEs) must have their relationship to study intervention assessed by the PI, who examines and evaluates the participant based on temporal relationship and their judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

- **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
- **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

8.2.3.3 EXPECTEDNESS

The principal investigator will determine whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

8.2.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits, community with the lifestyle coach during the intervention, and interviews. We will record all reportable events with start dates occurring any time after informed consent is obtained until 7 days (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. We will assess and document AEs and SAEs at each study visits, inquiring about the occurrence of AEs and SAEs since the last visit, with a focus on any issues related to sleep, diet, physical activity, or weight loss. We will follow up on all events for outcome information until resolution or stabilization.

8.2.5 ADVERSE EVENT REPORTING

The investigator must record nonserious adverse events and report them to the sponsor within 24-hours of the PI learning about the event.

8.2.6 SERIOUS ADVERSE EVENT REPORTING

The PI will immediately report to the sponsor any serious adverse event, whether or not considered study intervention related, including those listed in the protocol, and must include an assessment of whether there is a reasonable possibility that the study intervention caused the event. Study endpoints that are serious adverse events (e.g., all-cause mortality) must be reported in accordance with the protocol unless there is evidence suggesting a causal relationship between the study intervention and the event. In that case, the investigator must immediately report the event to the sponsor.

All serious adverse events (SAEs) will be followed until satisfactory resolution or until the site investigator deems the event to be chronic or the participant is stable. Other supporting documentation of the event may be requested by the study sponsor and should be provided as soon as possible.

8.2.7 REPORTING EVENTS TO PARTICIPANTS

We will inform participants of adverse events (AEs) that are related to the safety and welfare of the participants. To inform participants, we will take the following steps:

1. Assess the relevance and impact of the AE: Evaluate the AE to determine whether it has any direct implications for the participants' safety, welfare, or rights. If the AE is deemed relevant and important to the participants, proceed with informing them.
2. Update the informed consent document: If the AE warrants a change to the study protocol, intervention, or the risks and benefits associated with participation, revise the informed consent document accordingly. Any changes must be approved by the Institutional Review Board (IRB) before sharing the updated document with participants.
3. Prepare clear and concise communication: Develop a written or verbal communication that clearly explains the nature of the AE, its potential impact on participants, and any changes to the study protocol, procedures, or risks. Use plain language that is easily understood by the target audience and avoid jargon or technical terms.
4. Choose an appropriate communication method: Depending on the nature and urgency of the AE, select an appropriate method to inform participants. This could include individual meetings, phone calls, emails, or letters. In some cases, a combination of methods may be necessary to ensure all participants are informed promptly.
5. Provide an opportunity for questions and discussion: Allow participants the opportunity to ask questions, discuss their concerns, and seek clarification about the UP and its implications. This can be done during individual meetings, phone calls, or through written correspondence (e.g., email).
6. Re-obtain informed consent, if necessary: If the AE has led to significant changes in the study protocol or risks, you may need to re-obtain informed consent from participants. Provide them with the updated, informed consent document, discuss the changes, and obtain their signature if they agree to continue participating in the study.
7. Document the process: Keep a record of the steps taken to inform participants about the AE, including the date of communication, the method used, and any feedback or concerns raised by the participants. This documentation will be important for monitoring purposes and to demonstrate compliance with ethical guidelines and regulations.

8.3 UNANTICIPATED PROBLEMS

8.3.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.3.2 UNANTICIPATED PROBLEM REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB) and principal investigator (PI). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents a UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

UPs will be reported using the following timeline to satisfy the requirement for prompt reporting:

- UPs that are serious adverse events (SAEs) will be reported to the IRB and study sponsor within 48 hours of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB and sponsor within 5 business days of the investigator becoming aware of the problem.
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within 5 business days of the IRB's receipt of the report of the problem from the investigator.]

8.3.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

We will inform participants of unanticipated problems (UPs) that are related to the safety and welfare of the participants. To inform participants, we will take the following steps:

1. Assess the relevance and impact of the UP: Evaluate the UP to determine whether it has any direct implications for the participants' safety, welfare, or rights. If the UP is deemed relevant and important to the participants, proceed with informing them.
2. Update the informed consent document: If the UP warrants a change to the study protocol, intervention, or the risks and benefits associated with participation, revise the informed consent document accordingly. Any changes must be approved by the Institutional Review Board (IRB) before sharing the updated document with participants.
3. Prepare clear and concise communication: Develop a written or verbal communication that clearly explains the nature of the UP, its potential impact on participants, and any changes to the study protocol, procedures, or risks. Use plain language that is easily understood by the target audience and avoid jargon or technical terms.
4. Choose an appropriate communication method: Depending on the nature and urgency of the UP, select an appropriate method to inform participants. This could include individual meetings, phone calls, emails, or letters. In some cases, a combination of methods may be necessary to ensure all participants are informed promptly.
5. Provide an opportunity for questions and discussion: Allow participants the opportunity to ask questions, discuss their concerns, and seek clarification about the UP and its implications. This can be done during individual meetings, phone calls, or through written correspondence (e.g., email).
6. Re-obtain informed consent, if necessary: If the UP has led to significant changes in the study protocol or risks, you may need to re-obtain informed consent from participants. Provide them with the updated, informed consent document, discuss the changes, and obtain their signature if they agree to continue participating in the study.

7. Document the process: Keep a record of the steps taken to inform participants about the UP, including the date of communication, the method used, and any feedback or concerns raised by the participants. This documentation will be important for monitoring purposes and to demonstrate compliance with ethical guidelines and regulations.

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

The aim of this study is to assess the feasibility and acceptability of the sleep GOALS intervention to identify the necessary adaptations for a larger efficacy/implantation study. We will not perform formal hypothesis testing.

9.2 SAMPLE SIZE DETERMINATION

The primary aim of the pilot RCT is to obtain estimates of feasibility and acceptability to guide the planning of a larger efficacy trial and finalize the intervention's content and delivery. With a sample size of 40 (20 in each group), we will have the ability to estimate 95% confidence intervals with acceptable precision (i.e., confidence interval width) of 0.31 for all feasibility and acceptability benchmarks for the entire sample and 0.44 for within-group estimates. As an exploratory aim, we will obtain estimates of variability for the change in diet, physical activity, sleep, and weight to guide sample size calculations for the larger trial.

9.3 POPULATIONS FOR ANALYSES

For primary outcomes related to feasibility, we will include all randomized participants. For primary outcomes related to intervention acceptability, we will include all participants randomized to the Sleep GOALS intervention. For secondary outcomes, we will include all randomized participants (i.e., intention-to-treat)

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

We will use descriptive statistics for primary and secondary outcomes.

9.4.2 ANALYSIS OF THE PRIMARY EFFICACY ENDPOINT(S)

The primary endpoints are the feasibility and acceptability of Sleep GOALS. We will assess the feasibility of the intervention by estimating rates of recruitment, retention, and engagement (i.e., weekly logins; modules completed; daily self-monitoring of diet, physical activity, and sleep; weekly monitoring of weight using point estimates (means or sample proportions) and 95% confidence intervals). We will assess acceptability by estimating rates of satisfaction on various components of the intervention ($\geq$4 Acceptability and Feasibility Questionnaire). Our benchmarks for feasibility are similar to those used in the original GOALS Lifestyle intervention. We will use a benchmark of 80% for all feasibility and acceptability measures. To assess the intervention's preliminary efficacy, we will calculate point estimates and confidence intervals for change in weight and PWR. We chose these weight measures as our secondary outcomes since they will be the primary outcome in the future R01. However, we will also explore changes in our proposed behavioral mediators, sleep, diet, and physical activity to inform power calculations for a fully powered study.

We will conduct an exploratory analysis to determine how potential covariates (e.g., parity, breastfeeding

status, postpartum depression, race/ethnicity, relationship status, and employment status) impact the intervention's feasibility, acceptability, and preliminary efficacy. For example, in some studies, breastfeeding is associated with longer nocturnal sleep, but shorter nocturnal sleep in other studies. Collecting data on breastfeeding and other covariates will provide preliminary data on how it impacts the intervention.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

Informed consent will be obtained during an in-person meeting in the PHB label. Informed consent will be obtained before baseline assessments.

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant, and written documentation of informed consent is required prior to starting intervention/administering the study intervention.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and the participant will be asked to read and review the document. The investigator will explain the research study to the participant and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. Participants must be informed that participation is voluntary and that they may withdraw from the study at any time without prejudice. A copy of the informed consent document will be given to the participants for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form will be signed before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

10.1.2 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their interventions. This confidentiality is extended to cover baseline and post-intervention assessments. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without the prior written approval of the sponsor.

All research activities will be conducted in as private a setting as possible.

The study monitor, other authorized representatives of the sponsor, and representatives of the Institutional Review Board (IRB) may inspect all documents and records required to be maintained by the investigator.

The study participant's contact information will be securely stored on REDCap for internal use during the study. At the end of the study, all records will continue to be kept in on REDCap for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be stored on REDCap. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by research staff will be secured and password protected.

10.1.2.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

1. Data Collection Responsibilities

    a. Study Personnel: The research assistant or project coordinator will be involved in data collection under the supervision of the principal investigator.

    b. Training: The principal investigator will ensure all study personnel involved in data collection receive appropriate training on the study protocol, data collection instruments, data entry procedures, and ethical considerations (e.g., informed consent, confidentiality).

    c. Data Collection Instruments: Data collection will include physical measurements (i.e., measured height and weight), surveys and questionnaires, and semi-structured interviews. We selected previously validated interviewer-administered questionnaires relevant to the study objectives.

    d. Data Collection Procedures: Study data will be collected before randomization and post-intervention by a study team member. The study team member will provide participants a QR code or HTML link to the self-reported surveys, which can be completed on the study computer or the participant's mobile device, at their preference.

    e. Quality Control: Implement quality control measures to ensure the accuracy, completeness, and consistency of data collection, such as periodic checks, data audits, or inter-rater reliability assessments.

2. Data Management Responsibilities

    a. Data Entry: The project coordinator developed the REDCap database that will be used for data entry. Describe the procedures for entering data into the study database, including any software or platforms used, data entry formats, and procedures for verifying the accuracy of data entry.

    b. Data Storage: Study data will be stored on REDCap, an encrypted, secure server maintained by the University of Pittsburgh. Hard copies, if any, will be stored in a locked filing cabinet located in the PI's university office, accessible only by authorized study team members.

    c. Data Access: Only study team members will have full access to the study data. We will adhere to NIH's policy on dissemination of NIH-funded clinical trial information by taking the following steps:

        i. Registering the trial with ClinicalTrials.gov within 21 calendar days of enrollment of the first participant

ii. Submitting trial results to ClinicalTrials.gov no later than one year following the completion date of the study

iii. Include a statement in our informed consent document that explains that this clinical trial is registered with ClinicialTrials.gov and that the results of the study (not including any identifying information) will be reported in accordance with the NIH dissemination policy for clinical trials

iv. Working with the University of Pittsburgh's Office for ClinicalTrials.gov to ensure that all requirements within the policy are adhered to in a timely fashion

v. Create a newsletter to share findings with our study participants

vi. Submit abstracts to national scientific conferences and submit manuscripts for publication

vii. Will make de-identifiable study data available to researchers upon request after primary outcome manuscripts are published.

d. Data Monitoring: The PI will review data quality bi-monthly and ensure that there are no unexpected trends or safety issues.

e. Data Cleaning and Validation: Data will undergo range checks for each variable, logical consistency checks, and manual outlier detection. Discrepancies will be resolved by referring back to the original data source.

f. Data Analysis: See section 9.4 for details on the statistical analysis plan.

g. Data Retention and Destruction: Study data will be retained for a period of 7 years post-study completion, as per institutional guidelines. Following this period, hard copies will be shredded.

10.1.2.2 STUDY RECORDS RETENTION

Study documents should be retained for a minimum of 2 years after the last approval of a marketing application in an International Conference on Harminosation (ICH) region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study intervention. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

10.1.3 PROTOCOL DEVIATIONS

A protocol deviation is any noncompliance with the clinical trial protocol, International Conference on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the PI to use continuous vigilance to identify and report deviations within five working days of identification of the protocol deviation or within five working days of the scheduled protocol-required activity. All deviations must be addressed in study source documents and reported to NIH. Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements. Further details about handling protocol deviations will be included in the MOP.

10.1.4 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data-sharing policies and regulations:

The National Institutes of Health (NIH) Public Access Policy ensures that the public has access to the published results of NIH-funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers two years after the completion of the primary endpoint by contacting the PI, Dr. Marquis Hawkins.

10.1.5 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

10.2 ABBREVIATIONS

The list below includes abbreviations utilized in this template. However, this list should be customized for each protocol (i.e., abbreviations not used should be removed, and new abbreviations used should be added to this list).

AE	Adverse Event
CFR	Code of Federal Regulations
COC	Certificate of Confidentiality
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DHHS	Department of Health and Human Services
DRE	Disease-Related Event
EC	Ethics Committee
eCRF	Electronic Case Report Forms
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FFR	Federal Financial Report

GCP	Good Clinical Practice
GLP	Good Laboratory Practices
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICH	International Conference on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IRB	Institutional Review Board
ISM	Independent Safety Monitor
ISO	International Organization for Standardization
ITT	Intention-To-Treat
LSMEANS	Least-squares Means
MedDRA	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
MSDS	Material Safety Data Sheet
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOA	Schedule of Activities
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

10.3 PROTOCOL AMENDMENT HISTORY

The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A Summary of Changes table for the current amendment is located in the Protocol Title Page.

Protocol Version	Date	Description of Change	Brief Rationale
2	28 August 2024	Clarified and expanded descriptions of feasibility and acceptability outcomes, including operational definitions and benchmarks for engagement, recruitment, retention, and satisfaction.	To improve transparency and reproducibility of pilot feasibility outcomes without altering study objectives or endpoints.
2	28 August 2024	Expanded statistical considerations to include precision-based justification for sample size and explicit definition of analysis populations (feasibility, acceptability, intention-to-treat).	To align the statistical analysis plan with best practices for pilot randomized controlled trials and clarify analytic intent.
2	28 August 2024	Refined description of intervention delivery, compliance monitoring, and participant engagement tracking.	To provide greater clarity on intervention implementation while maintaining identical intervention content, dose, and duration.
2	28 August 2024	Clarified adverse event and unanticipated problem reporting procedures and participant notification processes.	To improve consistency with institutional and NIH guidance for minimal-risk behavioral trials.
2	28 August 2024	Standardized terminology related to assessment timing (e.g., baseline and post-intervention assessments).	To enhance clarity and consistency across protocol sections without changing study procedures or participant burden.
2	28 August 2024	Editorial updates, reorganization of sections, and formatting revisions to align with NIH-FDA protocol template.	Administrative updates only; no impact on study design, outcomes, or conduct.

11 REFERENCES

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Appendix 1 – Medication exclusion list

Adipex-p
Aldosterone
Alli
Beclomethasone
Betamethasone
Buprenorphine
Carbamazepine
Carbatrol
Chlorpromazine Hydrochloride (CPZ)
Clozapine
Clozaril
Cortisol
Cortisone Acetate
Deixtcirtucisteribe Acetate (DOCA)
Depakote
Dexamethasone
Divalproex
Equetro
Eskalith CR
Eskalith
Fludrocortisone Acetate
Gabapentin
Haldol
Haloperidol
Hydrocortisone
Insulin
Lithium
Lithobid
Lomaria
Meridia
Methadone
Methylprednisolone
Neurontin
Naloxone
Naltrexone
Olanzapine
Orlistat
Phentermine
Prednisolone
Prednisone
Quetiapine
Risperidone
Risperdal
ReVia
Seroquel

Sibutramine
Suboxone
Subutex
Tegretol XR
Tegretol
Thorazine
Topamax
Topiramate
Triamcinolone
Valproic Acid
Vivitrol
Xenical
Zyprexa