Title: An internet-assisted sleep, dietary, and physical activity intervention to support weight-loss among postpartum people (Sleep GOALS): Protocol for a pilot randomized controlled trial

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Abstract

Background: Postpartum weight retention and maternal obesity are associated with short- and long-term maternal morbidity and mortality risk. Most weight-loss interventions among postpartum individuals follow evidence-based lifestyle recommendations but have produced only modest effects and had substantial heterogeneity. We developed a novel internet-assisted weight management intervention for postpartum people that integrates concepts for improving sleep health within a diet and physical activity-focused intervention. We describe the intervention protocol and discuss how the pilot study's findings will inform future development and evaluation.

Methods: We will recruit 40 postpartum individuals with overweight or obesity from Western Pennsylvania to participate in a single-blind, parallel-arm, randomized controlled trial design. Participants will be randomized at a 1:1 ratio to the Sleep GOALS (Goal-focused Online Access to Lifestyle Support) intervention or education control group. The Sleep GOALS intervention includes interactive lessons addressing sleep, diet, physical activity, behavioral self-monitoring tools, and a lifestyle coach to provide accountability, encouragement, and personalized support. The education control will receive brochures from the American Academy of Sleep Medicine (e.g., sleep hygiene, sleep in women), SNAP education connection (e.g., family-friendly activities, meal planning), and the U.S. Department of Health and Human Services (e.g., physical activity promotion during and after pregnancy). Primary study outcomes include the intervention feasibility (i.e., recruitment, enrollment, attrition rates, intervention engagement) and acceptability (i.e., participant ratings of the intervention delivery, curricula, approach to behavioral self-monitoring, action plans, intervention platform, and coaching). Secondary outcomes include weight loss and retention of pregnancy and postpartum weight gain.

Discussion: Incorporating a holistic approach that addresses sleep health alongside diet and physical activity, the Sleep GOALS intervention aims to not only facilitate weight loss but also enhance overall maternal well-being. 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.

Keywords: obesity, intervention, feasibility, acceptability, protocol, postpartum, mHealth

Background

Obesity is a global health concern that disproportionately affects birthing people of reproductive age. [1, 2] In the US, approximately two-thirds of birthing people of reproductive age have overweight or obesity. [1, 2] Postpartum weight retention (PPWR) significantly contributes to obesity development, independent of pre-pregnancy body mass index (BMI) and gestational weight gain. [3-6] In the short term, PPWR is associated with an increased risk of maternal complications like gestational diabetes and hypertensive disorders of pregnancy in subsequent pregnancies. Long-term, PPWR is associated with obesity development and increased risk for developing obesity-related cardiovascular disease (e.g., hypertension, diabetes). [6-8] Thus, the postpartum period is critical for engaging birthing individuals in weight-loss interventions to prevent PPWR and cardiovascular disease morbidity and mortality.

The US Preventive Service Task Force (USPSTF) recommends clinicians offer patients with obesity weight-management interventions that provide counseling on diet and physical activity. [9] However, results of interventions focused only on postpartum diet and physical activity have been modest. [10-12] For example, a diet and exercise intervention involving 66 postpartum women revealed that nearly half did not achieve their 5% weight loss objectives. [13] Other trials have similarly reported high variability, with many women achieving little to no weight loss. [14, 15] Person-related factors common during the postpartum period, such as sleep disturbances, likely contribute to the modest impact of these interventions. [16-18]

Epidemiological and experimental evidence links sleep to weight, weight gain, and fat metabolism in the general population. Research on the independent influence of sleep and PPWR is sparse but generally shows an inverse relationship between sleep duration and PPWR and maternal obesity. [19-22] Poor sleep health can reduce the efficacy of weight-loss interventions through behavioral (e.g., diet and physical activity) [23-36] and biological mechanisms (e.g., fat metabolism). [37] Yet, diet and

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physical activity weight management interventions rarely integrate sleep interventions. An exception is the Better Weight-Better Sleep Study, which randomized 49 participants to a diet and exercise weight loss intervention with (BWBS) or without an integrated sleep intervention. [38] Participants in the BWBS intervention lost twice as much weight as those in the control group. Although this study provides preliminary evidence that addressing sleep can enhance the effectiveness of diet and physical activity interventions on weight loss, the impact of an integrated sleep and weight management program among postpartum individuals specifically has not been evaluated.

Considering the existing research gaps, we developed Sleep GOALS (Goal-focused Online Access to Lifestyle Support), an internet-assisted sleep, diet, and physical activity weight-loss intervention for postpartum people. To develop Sleep GOALS, we used a patient-centered approach to adapt and integrate content from an existing sleep (Transdiagnostic Sleep and Circadian; TSC) and physical activity and diet weight loss intervention (GOALS). TSC is a modular intervention that addresses sleep health, rather than sleep disorder, making it broadly applicable for public health interventions. GOALS, developed by Dr. McTigue and colleagues, is an online version of the CDC-recognized Diabetes Prevention Program's Lifestyle Intervention.[39] This pilot study aims to determine the interventions' feasibility and acceptability. The secondary aim is to estimate the interventions' preliminary efficacy on postpartum weight retention and weight loss. Here, we describe the trial protocol and how findings will inform the subsequent treatment development and evaluation phase.

Methods

Study design and population:

This study uses a single-blind, parallel-arm, pilot randomized control trial (RCT) design.

We will include females between 2 and 7 months postpartum with overweight or obesity (i.e.,

BMI $\geq$25 kg/m^2). We chose this postpartum range because postpartum weight retention during

this period is associated with long-term obesity development.[5, 6] Additionally, at three months

postpartum, most infants experience increases in nocturnal sleep.[40] Thus, many of our behavioral

strategies for improving maternal sleep may be more feasible at this point rather than earlier in

the postpartum period. It is safe for most birthing people to participate in an intervention

involving physical activity during this period.[41] However, we will screen for contraindications

for physical activity using a standard questionnaire,[42] and require approval from a healthcare

provider before enrollment if contraindications are identified. We will further restrict our sample

to physically inactive people (<150 min/week) who report at least one indicator of poor sleep

health (i.e., regularity, satisfaction, alertness, timing, efficiency, and duration) based on the RU

SATED questionnaire.[43] We will enroll all women of reproductive age. We anticipate that most

participants will be between 15 and 49 years of age. Table 2 describes the additional

inclusion/exclusion criteria.

<u>Recruitment and Enrollment</u>

Our recruitment goal is to enroll 40 participants. We will attempt to recruit a diverse

sample and not exclude participants based on race or ethnicity. However, we anticipate the

sample will be predominantly black/African American and non-Hispanic white based on the

demographic characteristics of Allegheny County. The 2019 Census data reports that

approximately 80% of Allegheny County residents identify as white, and approximately 13%

identify as black/African American. Only 2.2% of Allegheny County residents identify as

Hispanic or Latino. We will attempt to oversample (>30%) black/African American women since

African Americans are disproportionately burdened by sleep-related obesity. Since Black-identifying individuals are disproportionately affected by maternal obesity and postpartum weight retention, we will attempt to over-sample in this population ($\geq$30%).[44, 45] All participants will be recruited from Allegheny County, PA, using 1) Pitt+Me, an extensive clinical research registry maintained by the University of Pittsburgh's Clinical and Translational Science Institute,[46] 2) University electronic mailings, 3) BuildClinical, an online research recruitment company, 4) Pittsburgh Brown Mama's participant services, 5) targeted postcard mailings to participant registered in the Magee Obstetric Materna and Infant database and biobank,[47] and 6) direct clinician-engagement through the Newborn Research Support Services (NuRSERy) program.[48] 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 the registry's online portal. A study team member will call interested participants to discuss the study purpose, procedures, risks, and benefits, screen for eligibility, and answer questions. Participants will be invited to our clinic to complete the consent process and begin baseline assessments.

Research Ethics and Approval

A research assistant or project coordinator will be involved in the consenting process. The study PI will be responsible for training staff and ensuring data integrity. Research data collection will not begin until after participants provide written consent. The University of Pittsburgh Institutional Review Board approved this study's protocol on April 19th, 2023 (IRB: STUDY23020169). Since this study involves minimal risk, we did not compose a data monitoring committee. This study is registered with ClinicalTrials.gov (NCT05942326).

Randomization

Participants will be randomized at a 1:1 ratio to the Sleep GOALS intervention (n=20) or

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an education control group (n=20) (Figure 1). The project coordinator will generate the randomization plan using an online tool. [49] We will use a fixed blocked size to ensure balanced intervention groups. The randomization plan results will be stored in REDCap and only accessible by the project coordinator and a trained lifestyle coach who will support participants in the intervention arm and is not directly involved with data collection. Assignment allocation will be concealed from participants until the baseline assessments are complete. Investigators will remain blinded until post-intervention data collection is complete.

Sleep GOALS:

Sleep GOALS is a 16-week online intervention that includes 1) 15 to 20-minute interactive informational videos that provide strategies to improve sleep, diet, and physical activity to achieve weight loss (see Table 3), 2) a resource section, 3) a lifestyle coach, 4) a commercial activity tracker to self-monitor sleep and physical activity, and 5) a wireless scale to monitor weight. The informational videos were based on key concepts from the Transdiagnostic Sleep and Circadian Intervention[50] and the Diabetes Prevention Program[51] (Table 3). Participants will be able to view the material at their convenience. Each new lesson will appear five days after completing the prior one to allow participants time to process the information and implement their weekly action plan. The Sleep GOALS software will send weekly automated email alerts when a new lesson is available. The resource section includes participants' handouts to support the action plans discussed in the videos, links to reputable resources (e.g., National Sleep Foundation, the American Heart Association), local events (e.g., 5K races), and other resources as needed for personalized support.

Each participant will have a lifestyle coach who will monitor their engagement (see Table 4). They will send participants weekly messages through the intervention platform to reinforce

key concepts of each lesson, respond to questions, provide personalized feedback as needed, encourage accountability, and re-engage participants who go two weeks without completing a lesson or reporting their weight, physical activity, or sleep.[52] 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.). All coaches will complete a 2-day training workshop using a similar training format as the GOALS Lifestyle intervention. [53] To ensure treatment fidelity, the PI will randomly check 10% of each coach-participant communication through the GOALS messaging portal. The PI will meet weekly with each lifestyle coach to discuss their experience and brainstorm strategies to improve participant communication and the coach's workflow.

Lastly, participants will be given a wireless scale for self-monitoring weight and an activity tracker for self-monitoring sleep (daily minutes) and physical activity (daily steps, minutes). To track dietary calories, participants will be instructed to identify an app of their choice with support from the lifestyle coach. Participants will be asked to select a day and time to weigh themselves at least once weekly and enter their weight, sleep duration, daily steps, and calories into the Sleep GOALS tracking section. [54]

<u>Education Control</u>:

We used the Pragmatical Model for Comparator Selection in health-related behavioral trials to guide our control group selection. [55] This model suggests utilizing a control group that is not likely to produce a change in the outcome of early-stage intervention development. Thus, although we considered no-treatment comparator and wait-list control conditions, we chose an education control so that participants randomized to this arm would receive a valuable, plausible condition unlikely to affect weight. Following randomization, the control condition will be emailed educational brochures from publicly available resources from the American Academy of

Sleep Medicine (sleep for overall health), the National Sleep Foundation (tips for improving sleep), the American Heart Association (tips for creating a healthy eating pattern), the US Department of Agriculture Food and Nutrition Services (building a healthy eating plan while breastfeeding), and the US Department of Health and Human Services (e.g., physical activity promotion during and after pregnancy). All materials will be delivered at one time.

Overview of Data Collection

A research assistant or project coordinator will be involved in data collection under the supervision of the PI. Data collection will include physical measurements (i.e., measured height and weight), REDCap surveys, and semi-structured interviews (Table 1). We selected previously validated interviewer-administered questionnaires relevant to the study objectives. All study data will be stored in REDCap. Hard copies, if any, will be stored in a locked filing cabinet in the PI's university office, accessible only by authorized study team members.

Primary Outcomes

The primary outcomes are the intervention's feasibility and acceptability. To systematically evaluate the feasibility and acceptability of the Sleep GOALS intervention, our study is guided by a well-established feasibility framework. This framework, adapted from the work of Bowen et al., focuses on eight domains critical to assessing health interventions: acceptability, demand, implementation, practicality, adaptation, integration, expansion, and limited-efficacy testing.[56] By applying this multidimensional approach, we aim to thoroughly assess not only the potential for implementing Sleep GOALS on a larger scale but also identify specific areas for refinement and optimization (i.e., recruitment, retention, and engagement; Table 4). To determine acceptability, we will ask participants in the intervention arm to complete a brief 3-item REDCap survey after each lesson to rate the lesson content (e.g., was it logical,

relevant, instructive) and action plan (e.g., helpful, easy to implement) on a scale of 1 to 5, where higher scores indicate higher acceptability. Lessons with an average score of <4 will be flagged for refinement.

We will then conduct 60-minute semi-structured interviews with participants at the end of the 16-week intervention. The interviews will take place in person or by video chat. We will ask participants whether the content was understandable, the action plans were achievable, and what adaptations are necessary to improve low-scoring lessons. All interviews will be audio-recorded and transcribed by trained qualitative researchers. Participants will receive $50 after completing the pre- and post-intervention assessments and a $25 honorarium after completing the semi-structured interviews.

Secondary Outcomes

Weight will be measured with a digital scale during in-person assessments with the participant wearing light clothing and no shoes at baseline and post-intervention. Postpartum weight retention will be defined as the difference in measured weight at post-intervention and self-reported pre-pregnancy weight.

Other Assessments

Self-reported demographic characteristics will include age, parity, breastfeeding status, race/ethnicity, marital status, number of adults in the home, level of education achieved, employment status, and annual household income. Since infant sleep/wake and feeding schedules are often cited for poor sleep quality in new mothers, we will assess these characteristics with the Infant Characteristics Questionnaire[57] and Infant Feeding Questionnaire. [58] Postpartum depression will be evaluated with the Edinburgh Post Natal Depression Scale. [59] The Perceived Stress Scale will be used to measure perceived stress.[60] We will use the Goals and

Relative Weights Questionnaire to assess participant treatment expectations [61] and the Medical

Outcomes Study Social Support Survey to measure social support.[62] We will use the Barkin

Index of Maternal Functioning[63] to assess overall functioning in the past two weeks in the

context of new motherhood and the American Academy of Family Physicians social

determinants of health screener to identify individual needs, including housing, food,

transportation, utilities, child care, employment, education, finances, and personal safety.[64]

Participants will be given a movement monitor (ActiGraph GT9X Link) to wear for

seven consecutive days, 24 hours per day, at pre- and post-intervention assessments. The

monitor will measure sleep and physical activity objectively. The ActiGraph GT9X Link is a

triaxial accelerometer that detects vertical accelerations along three planes of movement. The

total sum and patterns of movements are used to estimate physical activity and sleep. We will

process the raw accelerometer data using R statistical software to assess physical activity and

sleep.[65, 66] Participants will be instructed to complete a daily sleep diary during the same monitor

wear periods to help interpret the actigraphy data.[67]

Dietary intake will be assessed using two 24-hour recalls on random days within a seven-

day window at baseline and post-intervention.[68]

Statistical Analysis Plan

The primary 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. Our benchmarks for feasibility and

acceptability are similar to those used in a prior pilot trial conducted by our research team.[69] We will use a benchmark of 80% for all feasibility and acceptability measures. To evaluate the secondary outcome, we will use descriptive statistics to compare within and between group changes in weight and postpartum weight retention. While estimating changes in sleep, diet, and physical activity is not a primary or secondary outcome, we will conduct exploratory, descriptive analysis since these are the intervention's proposed mediators. We will use R to conduct all quantitative analyses.

An experienced qualitative research analyst will perform the qualitative analysis. Each interview will be audio-recorded and transcribed verbatim, removing personal identifiers. Then, the analyst will develop a comprehensive codebook based on the interviews. Next, two trained analysts will co-code a subset of transcripts to ensure coding reliability and establish intercoder reliability. Lastly, conventional content and thematic analyses will be applied to all transcripts, providing insights into the intervention's acceptability. We will use Nvivo to conduct the qualitative analyses.

Sample Size

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. While pilot trials are not typically powered to detect statistically significant effects, enrolling 40 participants can provide sufficient data to estimate effect sizes and variability. Based on the team's experience, a sample size of 40 (20 in each group), we can 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. Moreover, enrolling 40 participants balances obtaining meaningful insights and keeping within budgetary and logistical constraints.

Participant Confidentiality

The baseline and post-intervention assessments will be conducted in a private room at our research clinic. 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 remain on REDCap for as long as dictated by the reviewing IRB, Institutional policies, or sponsor requirements. Study participant research data will be stored on REDCap for purposes of statistical analysis and scientific reporting. The stored data will not include the participant's contact or identifying information. Instead, a unique study identification number will identify individual participants and their research data. The study data entry and study management systems used by research staff will be secured and password protected.

Adverse Event Reporting

The PI will determine whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the event's nature, severity, or frequency is inconsistent with the risk information previously described for the study intervention. 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 after informed consent is obtained until seven 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 visit, inquiring about the occurrence of AEs and SAEs since the previous visit and focusing 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. The PI will report AEs to the sponsor within 48 hours of the PI learning about the event.

<u>Protocol Deviation Reporting</u>

The PI and research team will 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 will be addressed in study source documents and reported to NIH. Protocol deviations will be sent to the reviewing IRB.

<u>Publication Policy</u>

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 is registered at ClinicalTrials.gov, and information on the results of 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 completing the primary endpoint by contacting the PI.

Discussion

This 16-week, single-blind pilot RCT is designed to determine the feasibility and acceptability of an internet-assisted weight loss intervention for postpartum people. Pilot testing is crucial for assessing key progression criteria to inform the feasibility and advisability of proceeding to a larger, definitive trial. These criteria encompass recruitment efficacy, participant retention, engagement levels, and preliminary changes (i.e., point estimates and measure of variability) in secondary outcomes. Our progression criteria include a set of benchmarks: successful recruitment as planned, achieving at least an 80% retention rate, high engagement with the intervention components, and indicative positive trends in secondary outcomes. These

benchmarks are designed to assess the trial's feasibility collectively, yet we acknowledge that flexibility in meeting these criteria is essential.

Our first measure of feasibility is recruitment over the planned 12-month recruitment period. We will monitor the rates and demographics of participant enrollment monthly to identify which recruitment methods yield the largest enrollment, understand potential barriers or motivators for participant enrollment, and anticipate resource allocation needs for the larger trial. If recruitment rates are below benchmarks, we will consult Clinical and Translational Science Institute (CTSI) recruitment facilitators during and after the trial to revise our recruitment protocol. When transitioning to a larger trial, these insights allow for a more streamlined and targeted recruitment process, ensuring timely participant enrollment, adequate representation, and optimal allocation of resources.

Monitoring retention rates in a pilot trial is a crucial determinant of participant engagement and the overall feasibility of the study protocol. Retention figures offer a preview of potential challenges that may arise in a full-scale trial, especially regarding participant commitment and the effectiveness of the intervention or procedure under examination. If retention rates fall below the anticipated 80% benchmark in the pilot, it signals a need to re-evaluate and adapt strategies for the larger trial. Adaptions might include enhancing participant honorarium, providing regular feedback or communication, or modifying aspects of the intervention to fit participants' needs and preferences. By addressing these challenges head-on, based on pilot trial data, researchers can refine their approach to ensure higher retention in the subsequent larger trial, thereby enhancing the study's validity and reliability.

We will monitor the number of modules completed, time spent logged into the Sleep GOALS platform, and behavior and weight tracking. If engagement is low, we will use semi-

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structured interview data to identify barriers and motivators of engagement and identify specific aspects of the intervention that may require adjustments. Likewise, we interview the lifestyle coach to discuss participant communication and obtain feedback on tools and resources, challenges, protocol fidelity, suggestions for improvement, and overall satisfaction with the program to refine the coaching protocol for the larger trial.

The secondary aim of this study is to estimate weight loss and postpartum weight retention. Exploratory aims include estimating changes in sleep, diet, and physical activity. While the study will not be sufficiently powered to detect clinically meaningful changes in weight and behavior, we will use variability estimates to inform power calculations for a larger definitive clinical trial. Likewise, the content of the intervention around physical activity and sleep will be fine-tuned based on the exploratory findings, ensuring a comprehensive, evidence-based approach that can be adaptively implemented in the subsequent trial.

Criteria for progression to full-scale RCT

While we aim to meet all progression criteria to ensure the robustness of our pilot findings, we recognize that each criterion offers unique insights into the trial's feasibility. Therefore, should one criterion be met—particularly recruitment—it may still warrant proceeding with a full RCT. In such instances, substantial intervention or study protocol modifications would be considered based on comprehensive feedback and data collected during the pilot phase. This approach ensures we make informed decisions on progressing to a full RCT, balancing between ideal benchmarks and practical insights gained.

Strengths and Limitations

This study integrates critical concepts from evidenced-based sleep, diet, and physical activity interventions, potentially filling a critical research gap by informing the development of an novel weight-loss intervention for postpartum people. Moreover, the data generated from this

study will allow us to capture essential data to inform recruitment, retention, data collection, and coaching protocols for a subsequent RCT. Despite the strengths of the study design, there are some notable limitations. First, while appropriate for a pilot study, the sample size limits generalizability or the ability to examine the feasibility and acceptability across sub-groups. Nonetheless, we will conduct an exploratory analysis of the association of demographic characteristics (e.g., parity, breastfeeding status, postpartum depression, race/ethnicity, relationship status, and employment status) on the intervention's feasibility and acceptability. However, trials with larger samples will be required to provide more definitive guidance on differential response to the intervention.

In conclusion, the results of this pilot will provide significant insights into the development of definitive trials in the future. If successful, the Sleep GOALS intervention can potentially enhance weight management strategies for postpartum individuals, ultimately improving short and long-term maternal health.

Trial Status

The trial is currently open for recruitment, which will last through July 2024.

Declarations

Ethics approval and consent to participate

The University of Pittsburgh Institutional Review Board approved this study's protocol on April 19th, 2023. All participants will be required to provide consent prior to enrollment and baseline assessments.

Consent for publication

Not Applicable

Availability of data and materials

Not Applicable

Competing interest

Over the past three years, Dr. Daniel Buysse has been a paid or unpaid consultant to Sleep Number, Idorsia, and Eisai. All consulting agreements have been for less than $5000 per year from any single entity. Dr. Daniel Buysse is an author of the Pittsburgh Sleep Quality Index, Pittsburgh Sleep Quality Index Addendum for PTSD (PSQI-A), Brief Pittsburgh Sleep Quality Index (B-PSQI), Daytime Insomnia Symptoms Scale, Pittsburgh Sleep Diary, Insomnia Symptom Questionnaire, and RU_SATED (copyrights held by the University of Pittsburgh). These instruments have been licensed to commercial entities for fees. He is also co-author of the Consensus Sleep Diary (copyright held by Ryerson University), which is licensed to commercial entities for a fee. He has received grant support from NIH, PCORI, AHRQ, and the VA. Dr. Esa Davis is a member of the United States Preventive Services Task Force (USPSTF). Dr. Judy Chang is a member of the National Academies of Science, Engineering, and Medicine (NASEM) standing committee on Reproductive Health, Equity, and Society. This article does not necessarily represent the views and policies of the USPSTF or NASEM.

Authors contributions

MSH contributed to the conception and design and drafted and revised the manuscript. EMD, KZA, KMM, DJB, JCC, and MDL contributed to the manuscript's conception and revision. MS and NK contributed to the drafting and revision of the manuscript.

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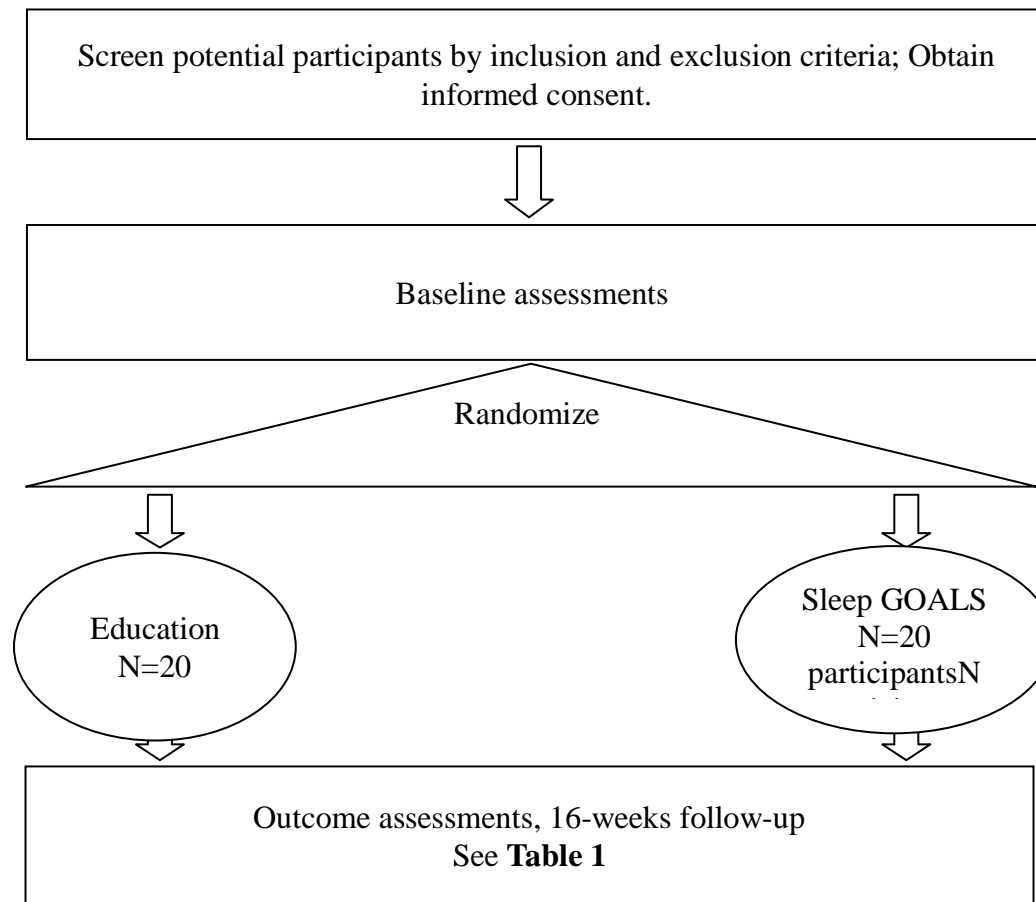
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Figure 1. Participant flow

Table 1 - Schedule of enrolment, interventions, and assessments					
	STUDY PERIOD				
	Enrollment	Allocation	Post-allocation		Outcome Assessment 16-weeks
TIMEPOINT	$-t_1$	0	t_1	t_2	t_3
ENROLLMENT:					
Eligibility screen	X				
Informed consent	X				
INTERVENTIONS:					
Sleep GOALS			●━━━━━━●		
Education			X		
ASSESSMENTS:					
Demographics	X				
Infant Feeding and Behavior	X				X
Mental Wellness	X				X
Treatment Expectations	X				
Weight Goals	X				
Social Support	X				
AAFP Social Determinants of Health Screener	X				X
Barkin maternal functioning index	X				X
Feasibility indicators	X		●━━━━━━●		
Acceptability survey			●━━━━━━●		
Semi-structured interview					X
Height and Weight	X				X
Physical activity	X				X
Sleep	X				X
Diet	X				X
AAFP – American Academy of Family Physicians					

Table 2 – Inclusion/exclusion criteria
Inclusion criteria
1. Primiparous women 2 to 7 months postpartum
2. BMI 25 to 40 kg/m^2
3. Physically inactive (<150 min/week)
4. Endorse $\geq$1 indicator of poor sleep health based on the RU_SATED questionnaire
5. Internet access (computer or phone)
Exclusion criteria
1. Currently pregnant or planning to become pregnant during the study period
2. Medications that affect weight (e.g., steroids) or sleep
3. Participating in another weight-loss intervention

Table 3 – Sleep GOALS lesson outline	
Lesson Name	Objective
Week 0: Orientation	To learn how to successfully navigate the GOALS platform to access course materials.
Week 1: Getting Started	To learn the overall program goals and the key components of the program.
Week 2: Sleep Overview	To learn the processes that regulate sleep.
Week 3: Sleep Schedule	To learn how to create a personalized wake-up and wind-down routine
Week 4: Sleep Efficiency	To learn how to maximize sleep efficiency.
Week 5: Healthy Eating	To identify and implement USDA dietary recommendations specific to pregnant and postpartum individuals.
Week 6: Sleep and Eating	To learn how to improve sleep with good eating habits and vice versa.
Week 7: Move those Muscles	To learn the health benefits of regular physical activity.
Week 8: Being active as a way of life	To implement strategies for increasing daily physical activity and managing daytime dysfunction.
Week 9: Taking Charge of What's Around You	To learn how to modify their environment to encourage healthy eating and physical activity.
Week 10: Problem Solving	To learn how to apply problem-solving techniques to overcome barriers to a healthy lifestyle.
Week 11: Talk Back to Negative Thoughts	To learn cognitive restructuring techniques to reframe negative thoughts.
Week 12: Unhealthy Sleep Beliefs	To debunk common sleep myths and apply tips for better sleep.
Week 13: The Slippery Slope of Lifestyle Change	To learn how to identify and apply strategies to regain focus on healthy lifestyle changes after setbacks.
Week 14: Jump Start Your Activity Plan	To learn how to safely increase their activity intensity based on their current level.
Week 15: Making Social Cues Work	To learn how to identify positive social cues and integrate them into their lifestyle.
Week 16: Ways to Stay Motivated	To apply motivational techniques to sustain healthy lifestyle changes over the long term.

Table 4 – Primary and secondary outcomes		
Domain	Measure, Method of Assessment	Benchmarks for Success
Feasibility (Primary Outcome)		
Recruitment/Enrollment	Total sample	3-4 participants per month 40 total 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		