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Trial design and methodology for a non-restricted sequential multiple assignment randomized trial to evaluate combinations of perinatal interventions to optimize women's health

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ABSTRACT

Pre-pregnancy overweight/obesity and excessive gestational weight gain (GWG) independently predict negative maternal and child health outcomes. To date, however, interventions that target GWG have not produced lasting improvements in maternal weight or health at 12-months postpartum. Given that interventions solely aimed at addressing GWG may not equip women with the skills needed for postpartum weight management, interventions that address health behaviors over the perinatal period might maximize maternal health in the first postpartum year. Thus, the current study leveraged a sequential multiple assignment randomized trial (SMART) design to evaluate sequences of prenatal (i.e., during pregnancy) and postpartum lifestyle interventions that optimize maternal weight, cardiometabolic health, and psychosocial outcomes at 12-months postpartum. Pregnant women ($N = 300$; ≤ 16 weeks pregnant) with overweight/obesity (BMI $\geq 25\ kg/m^2$) are being recruited. Women are randomized to intervention or treatment as usual on two occasions: (1) early in pregnancy, and (2) prior to delivery, resulting in four intervention sequences. Intervention during pregnancy is designed to moderate GWG and introduce skills for management of weight as a chronic condition, while intervention in the postpartum period addresses weight loss. The primary outcome is weight at 12-months postpartum and secondary outcomes include variables of cardiometabolic health and psychosocial well-being. Analyses will evaluate the combination of prenatal and postpartum lifestyle interventions that optimizes maternal weight and secondary outcomes at 12-months postpartum. Optimizing the sequence of behavioral interventions to address specific needs during pregnancy and the first postpartum year can maximize intervention potency and mitigate longer-term cardiometabolic health risks for women.

1. Introduction

The perinatal period, from pregnancy through the first postpartum year, has important implications for maternal weight management and long-term health. Rates of obesity prior to pregnancy are increasing [1,2] and most pregnant women exceed Institute of Medicine (IOM) guidelines established for gestational weight gain (GWG) [3], which, in turn, robustly predicts postpartum weight up to 15 years later [4,5]. Given that pre-pregnancy obesity and excessive GWG independently predict negative maternal and child health outcomes [6–10], helping women manage GWG and mitigate the health risks associated with weight gain during the perinatal period can have substantial public health benefits.

To date, perinatal interventions have not produced lasting improvements in maternal weight or health at 12-months postpartum. Interventions to minimize excessive GWG [11] and prevent postpartum weight retention [12,13] have been only modestly successful. Compliance with weight change interventions in women is difficult in general [14,15], and the perinatal period presents additional psychosocial challenges. Depressive symptoms [16,17] and increased stress [18,19] are common and can affect women's appetite, self-regulation efforts, and weight. Moreover, women who begin pregnancy with overweight/obesity, gain a recommended amount of gestational weight, and successfully lose their gestational weight postpartum will, nonetheless, continue to have overweight/obesity at 12-months postpartum. Therefore, intervening only to prevent excessive GWG is

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unlikely to equip women with the skills needed for effective postpartum weight management.

Lifestyle interventions that address weight management and health behaviors over the perinatal period might maximize maternal health in the first postpartum year. However, the optimal timing of intervention delivery may vary for some women. The sequence of interventions that can optimize maternal health may depend on the efficacy of intervention during pregnancy, whether a woman meets or fails to meet IOM GWG targets, and the efficacy of intervention during postpartum. Thus, the current study utilizes a sequential multiple assignment randomized trial (SMART) to evaluate combinations of interventions during pregnancy and postpartum to optimize women's health at 12-months postpartum. This SMART [20–22] is designed to identify optimal intervention sequences [23] and is uniquely-suited to address questions about when to deliver intervention during the perinatal period. The current trial is a non-restricted SMART, meaning the second randomization is not influenced by participants meeting specified criteria, and all women are re-randomized prior to delivery. Women with overweight/obesity before pregnancy remain at health risk postpartum, regardless of GWG, and understanding the sequence of prenatal and postpartum interventions that improves longer-term maternal weight and health for women with varying GWG is critical. For example, some women may lose weight postpartum only if a comprehensive weight management intervention delivered during pregnancy is continued postpartum, whereas other women may find intervention delivered only during postpartum sufficient. Accordingly, the trial described below uses a multiple stage randomized design to address questions related to sequencing intervention during the perinatal period to optimize women's weight and health outcomes at 12-months postpartum.

2. Study design and methods

2.1. Overview of study design

The goal of this ongoing investigation is to determine the sequence of prenatal and postpartum lifestyle interventions that optimizes maternal weight, cardiometabolic health, and psychosocial outcomes at 12-months postpartum. Pregnant women, stratified by prenatal weight (overweight or obese), are enrolled at the beginning of prenatal care and randomly assigned to an intervention that addresses the unique challenges of weight and self-regulation of health behaviors during pregnancy (Health and Behaviors in Transition [HABITpreg]) or a comparison condition involving treatment as usual (TAUpreg). Prior to delivery, all women, regardless of gestational weight gain, again are randomized to intervention that addresses postpartum weight and self-regulation (HABITpost) or TAUpost, thereby creating four sequences: HABITpreg + TAUpost, TAUpreg + HABITpost, HABITpreg + HABITpost or TAUpreg + TAUpost (see Fig. 1). Women complete assessments of weight (primary outcome) as well as cardiometabolic health, depressive symptoms, and stress (secondary outcomes) at baseline (≤16-weeks pregnant), end of pregnancy (~36-weeks pregnant), and 6- and 12-months postpartum (see Fig. 2). This study was registered on ClinicalTrials.gov (identifier: NCT03069690) and is approved by the University of Pittsburgh Institutional Review Board.

2.2. Recruitment and eligiblity screening

Pregnant women are recruited to participate at prenatal care visits from obstetric clinics and local midwifery services affiliated with a large, local women's hospital, which has over 10,500 deliveries annually. Women also are recruited through University of Pittsburgh research registries (e.g., Pitt + Me), online postings (e.g., Read Green), brochures and fliers posted in local doctors' offices, and word of mouth. Recruitment began in December 2016 and is expected to last until 300 eligible women are enrolled.

Women are screened for eligibility by phone. Women are eligible if they: (1) have a pre-pregnancy body mass index (BMI) ≥ 25 kg/m^2; (2) are ≤16 weeks of gestation; (3) are English speaking; and (4) have a singleton pregnancy. Additional screening is conducted when women report BMI ≥ 24 due to the potential for underestimating self-reported pre-pregnancy BMI [24,25]. Given the paucity of data on weight outcomes for women with BMI > 35 kg/m^2, we elected to randomize women in two strata according to BMI (25–29.9 vs. ≥30 kg/m^2) rather than limiting BMI. Similarly, although parity may impact perinatal weight, the intervention goals are similar for primagravidae and multiparous women. Thus, we do not exclude women based on parity. In addition, women are excluded for: (1) multiple gestations; (2) pre-existing diabetes; (3) previous bariatric surgery within the past three years; or (4) use of medications known to affect weight (e.g., second generation antipsychotic medications, regular steroid use). Women who endorse acute psychiatric symptoms that warrant immediate treatment (e.g., suicidality) are excluded and referred for care.

2.3. Sample size estimation

Sample size is based on the power to detect differences in maternal weight at 12-months postpartum, the primary outcome. Using means and standard deviations reported at baseline and 12-months postpartum in a previous trial [12], we estimate the effect size of a perinatal weight management intervention to be 0.50 using the formula provided in Morris [26]. This medium-sized effect is consistent with the range of results in other trials comparing intervention to treatment as usual at 12-months postpartum [13,25]. We also estimate the effect of HABITpreg + HABITpost vs. only HABITpreg or only HABITpost to be 0.50 and, based on our previous perinatal trial [27], project a 15% attrition rate at 12-months postpartum. Thus, we will recruit 300 women. We further expect that between 45% and 63% of women will exceed GWG guidelines [28,29] and used 50% as the rate of women exceeding GWG guidelines to estimate the number of participants per sequence. We will have power of 0.90 to detect the difference between women who receive HABITpreg followed by HABITpost (an estimated 63 women after attrition) and those who receive only HABITpreg or only HABITpost (an estimated 126 in total), using a two-sample *t*-test at 0.05 level. Similarly, we will have power of 0.90 to detect the difference between women who receive the sequence of TAUpreg followed by HABITpost (63 women) compared to the TAUpreg then TAUpost or the HABITpreg then TAUpost sequences (126 women). The above power calculation was obtained from the power calculator, PS [30].

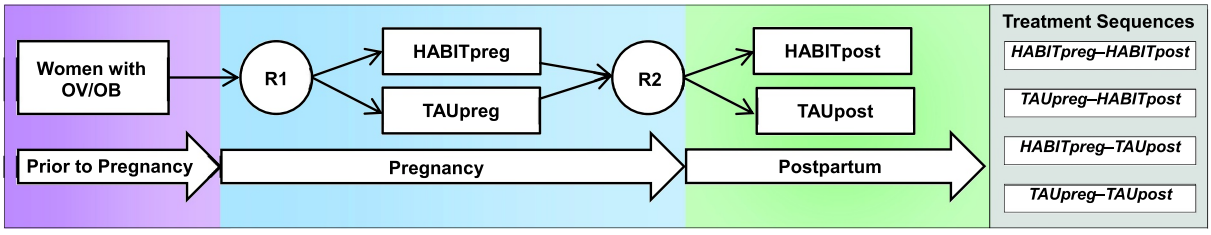

Fig. 1. Non-restricted SMART design. OV/OB = overweight/obese; R1, R2 = randomization time point 1 (< 16-week pregnant), randomization time point 2 (~36 weeks pregnant), respectively; TAU = treatment as usual.

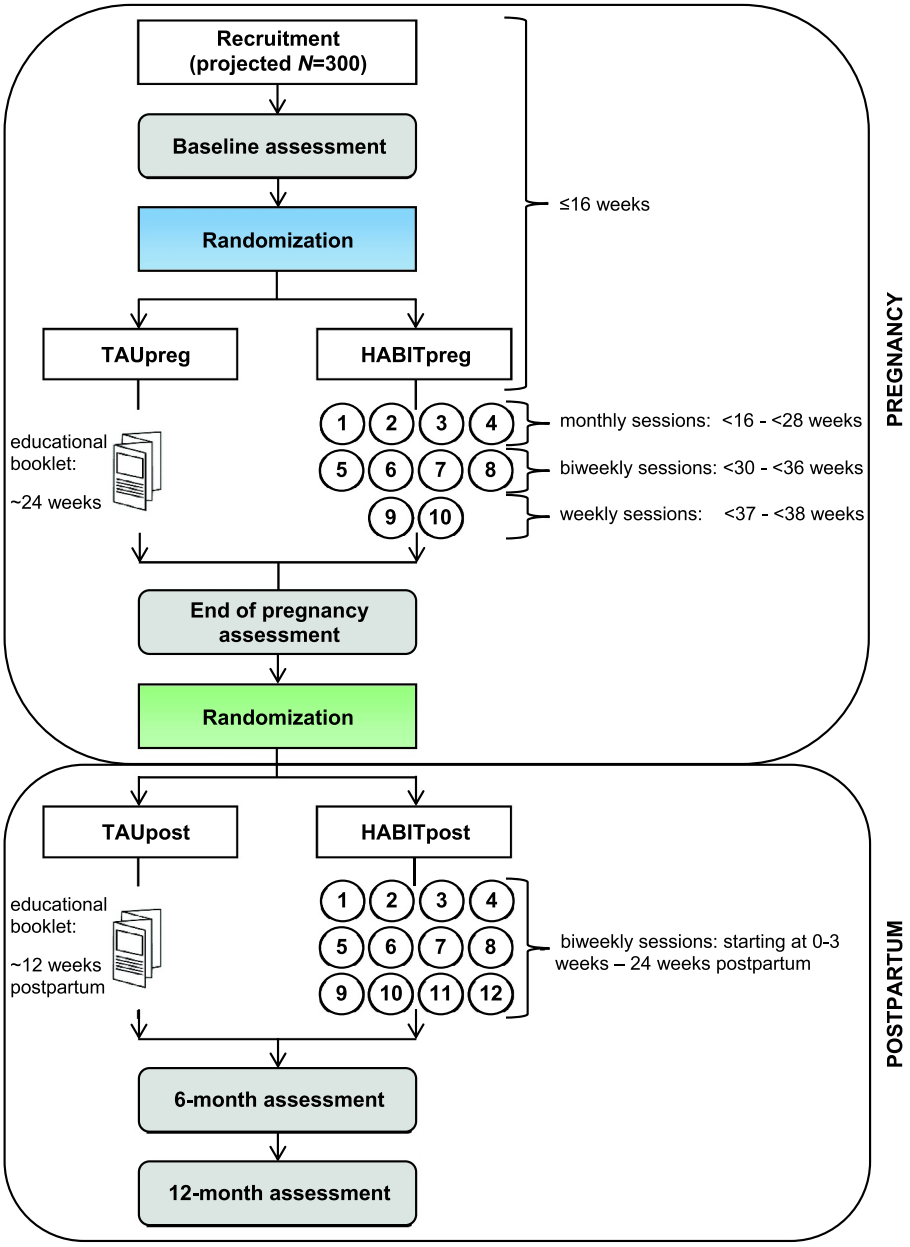

Fig. 2. Overview of study procedures.

2.4. Randomization

There are two randomization points in this SMART: (1) At study entry (≤16-weeks gestation) women are randomized to HABITpreg or TAUpreg; and (2) Prior to delivery (~36-weeks gestation) women are randomized to HABITpost or TAUpost (see Fig. 1). At both randomization points, separate randomization schedules are used for women with a pre-pregnancy BMI of 25–29.9 kg/m^2 (overweight) and for women with a BMI ≥ 30 kg/m^2 (obese). Randomization schedules were generated by a statistician at the start of the study. Three hundred women will be randomized with equal probability to one of the two initial interventions, HABITpreg or TAUpreg, stratified by their pre-pregnancy weight status (overweight or obese). Since this is a non-restrictive SMART, women are then randomized with equal probability to one of the two postpartum lifestyle interventions, HABITpost or TAUpost, regardless of whether they have met their GWG goals. Procedurally, we created a randomization list of the four treatment sequences, stratified by initial weight status.

Without attrition, one-quarter of women are expected to follow each one of the four treatment sequences. However, attrition is common and a particular treatment sequence may relate to disproportionately higher attrition than other treatment sequences. In particular, disproportionate attrition after the second randomization cannot be avoided. Dropouts at this stage, however, will be informative. Specifically, dropout after the second randomization for women randomized to the TAUpreg + TAUpost treatment sequence will suggest that TAUpost is associated with higher attrition, whereas HABITpreg may help to keep women in the postpartum phase of the study even after women are randomized to TAUpost (i.e., HABITpreg + TAUpost randomization sequence). When attrition occurs before the second randomization, we use two separate randomization lists, one for each phase, which helps mitigate potential imbalance in treatment sequences.

A related implication of the two-stage randomization design relates to intent-to-treat analysis. If a woman is assigned to a treatment sequence upfront, she is included in the analysis for that treatment sequence regardless of her completion status. Alternatively, if a woman is

first assigned to an initial intervention, such as TAUpreg, and drops-out during the pregnancy phase of the study, she will not be further randomized. Under the intent-to-treat principal, this woman will be associated with both treatment sequences related to her initial randomization (i.e., TAUpreg + TAUpost and TAUpreg + HABITpost). Proper weighting will be used to distinguish this woman from those who complete TAUpreg and are further randomized to TAUpost or HABITpost, as the latter is only representative of either TAUpreg + TAUpost or TAUpreg + HABITpost.

2.5. Study interventions

Both HABITpreg and HABITpost interventions utilize evidence-based cognitive behavioral treatment, the cornerstone of effective weight management intervention [31,32], incorporate strategies from third-wave cognitive and behavioral therapies [33–38], and focus on weight, physical activity, eating, sleep, and psychosocial issues associated with the perinatal period (see Table 1 for intervention overview and Table 2 for intervention content and schedule of sessions).

Self-monitoring is key to effective behavioral weight control [39] and important for perinatal weight loss [40]. Accordingly, women are taught to self-monitor food intake and weight in both interventions, although the targets of monitoring and the order in which they are introduced differ in HABITpreg and HABITpost. To facilitate adherence to self-monitoring, Bluetooth-enabled scales and simplified food intake tracking methods are used. Women are also taught to use self-monitoring information as feedback on efforts to adopt more effective health behaviors. Interventionists assist women in setting behavioral goals, evaluating progress, and finding ways to reinforce themselves for small changes. HABITpreg and HABITpost are both delivered using a combination of in-person sessions, telephone calls, and text messages, methods that we have used successfully in our previous work with perinatal women [26]. Given that many/most women of child-bearing age are young, diverse, and technologically-savvy, we have incorporated a mobile texting-based system to enhance the delivery of treatment across pregnancy and postpartum. Women receive a series of automated text messages following the treatment schedule to reinforce concepts discussed during sessions, including weighing oneself and monitoring food intake, physical activity, mood, and sleep (see Table 3 for details on text messages).

To alter weight trajectories from pregnancy through the postpartum period successfully, lifestyle interventions need to address the specific and distinct weight management challenges that each phase of the perinatal period presents. Thus, the strategies and content of both interventions have been adapted to the unique needs of and demands on women during pregnancy and the postpartum period. As in other manual-based interventions, the topics and skills of the HABITpreg and HABITpost interventions are presented in a standardized fashion. However, treatment is individualized by focusing each session on the participant's unique goals and interests. Differences between the HABITpreg and HABITpost conditions are reviewed below and outlined in Tables 2 and 3.

2.6. HABITpreg

Pregnancy is an ideal period to learn the principles of energy balance and nutrition that are related to lifelong health behaviors given that weight loss is not encouraged and appropriate GWG is expected. Thus, the prenatal period provides a natural opportunity to learn health habits without a strict focus on weight loss. Specifically, the strategies associated with successful weight loss maintenance, stability skills [41,42], are applicable to pregnancy weight management and are emphasized during HABITpreg. There are five stability skills: (1) being savvy, (2) enjoying lifestyle habits, (3) making peace with the scale, (4) fine-tuning habits, and (5) navigating disruptions confidently. Women are instructed to observe weekly weight changes, experience how to interpret weekly weight fluctuations nonjudgmentally, practice small adjustments to eating and physical activity to keep rate of weight gain steady, learn to self-nurture inexpensively, explore negative thoughts related to weighing oneself and body image, engage in active problem-solving to meet health-related goals, reflect on navigating successful disruptions, and other skills. These concepts dovetail nicely with mindfulness and acceptance-based approaches [37,43] to reduce stress and improve mood.

Table 1
Overview of HABITpreg and HABITpost interventions.

	HABITpreg	HABITpost
Goal	- Appropriate GWG - Appropriate intrauterine environment	- Lose GWG (birth to 4 months) - Promote further weight loss
Intervention targets	- Appropriate GWG - Optimize nutrition and decrease sedentary behaviors - Pregnancy-specific education	- Optimal nutrition and physical activity - Maternal weight loss to achieve a healthier weight range (5–10% loss from pre-pregnancy)
Characteristics		
Location	- In conjunction with OB visits	- In home, via phone, and in convenient community settings
Intervention contact	- Monthly sessions with increased frequency throughout pregnancy (10 visits total*) - Weekly phone check-ins when week of no in-person session - Additional texts	- Biweekly sessions (12 calls and visits total) - Weekly phone check-ins when week of no in-person or phone sessions - Additional texts
Self-monitoring	- Small changes in intake - GWG graph at HABIT sessions	- Sustained change in intake - Self-weighing
Equipment provided	- Bluetooth-ready scales - Smartphone (if needed)	- Bluetooth-ready scales - Smartphone (if needed)
Conceptual focus		
Weight	- Appropriate rate of GWG	- Loss of GWG - Promotion of additional weight loss
Activity	- Activity guidelines/safety	- Timing of initiation - Safety (short bouts)
Eating	- Prenatal nutrition (small changes) - Mindful eating	- Women's nutrition - Lactation support - Mindful eating
Psychosocial	- Stability skills - Social support - Mood and stress - Sleep	- Mindfulness skills - Social support - Mood and stress - Sleep

Note. GWG = gestational weight gain; OB = obstetric. *interventionists aim for ≥8 sessions.

Table 2
HABIT intervention outline.

Session	Session-specific content	Monitoring target	Week
HABITpreg			
1	- Introduce interventionist and treatment - Weekly weighing and weight goals during pregnancy, stoplight eating - Self-monitoring	- Daily eating/drinking	< 16 weeks pregnancy
2	- Review monitoring and stoplight eating; introduce nutrition label reading	- RED/GREEN foods, activity	< 20 weeks pregnancy
3	- Activity during pregnancy, reducing sedentary behaviors, increasing lifestyle behaviors, stress management	- RED/GREEN foods, activity, mood	< 24 weeks pregnancy
4	- Introduce mindfulness: review "Taking hold of your Mind" and 3-min breathing exercise	- RED/GREEN foods, activity, mood, sleep	< 28 weeks pregnancy
5	- Sleep patterns and sleep hygiene - Social support	- RED/GREEN foods, activity, sleep	< 30 weeks pregnancy
6	- Connection between thoughts, emotions, and behaviors - Negative thoughts, thought restructuring	- RED/GREEN foods, activity, negative thoughts	< 32 weeks pregnancy
7	- Achieving balance, participating in rewarding activities/"wants" and the importance of self-care	- RED/GREEN foods, activity	< 34 weeks pregnancy
8	- Stability skills/transitioning to post-pregnancy sustaining healthy changes	- RED/GREEN foods, activity	< 36 weeks pregnancy
9	- Review stability skills/transitioning to post-pregnancy - Review nutrition label reading	- RED/GREEN foods, activity	< 37 weeks pregnancy
10	- Review stability skills/transitioning to post-pregnancy	- RED/GREEN foods, activity	< 38 weeks pregnancy
HABITpost			
1	- Introduce interventionist and treatment - Weekly self-monitoring, weighing, and postpartum weight goals	- Daily meals/snacks eaten, mood	0–3 weeks postpartum[a]
2	- Postpartum mood fluctuation, emotion regulation - Monitoring mood and thoughts/mood diary - Introduction to energy balance	- Daily meals/snacks eaten, mood	4 weeks postpartum[b]
3	- Finding balance between acceptance and change - Introduce mindfulness skills, mindful eating	- Daily meals/snacks eaten, mood	6 weeks postpartum[a]
4	- Energy balance - Stoplight eating/nutrition, reading nutrition labels	- RED/GREEN foods	8 weeks postpartum[a]
5	- Reducing sedentary behaviors, increasing lifestyle behaviors - Using activity to manage stress	- RED/GREEN foods	10 weeks postpartum[b]
6	- Physical activity, activity goals - Monitoring physical activity	- RED/GREEN foods, daily activity	12 weeks postpartum[b]
7	- Healthy eating at restaurants, asking for what you want/choices to align with health-related goals - Mindful eating review	- RED/GREEN foods, daily activity	14 weeks postpartum[a]
8	- Review nutrition label reading, portion control - Stimulus control/changing one's environment	- RED/GREEN foods, daily activity	16 weeks postpartum[b]
9	- Connection between thoughts, emotions, and behaviors - Negative thoughts, thought restructuring	- RED/GREEN foods, daily activity, thoughts/emotions/behaviors	18 weeks postpartum[a]
10	- Social support - Working to achieve health-related goals - Sleep patterns and hygiene	- RED/GREEN foods, daily activity	20 weeks postpartum[b]
11	- Sustaining healthy changes - Getting back on track after having a "slip" - Achieving balance	- Individualized	22 weeks postpartum[b]
12	- Overall review, sustaining healthy changes - Thoughts/feelings/suggestions about intervention	- Individualized	24 weeks postpartum[a]

[a] In-person session
[b] Phone session.

In HABITpreg, women are assigned a trained interventionist and work with this interventionist for the duration of prenatal intervention. Women receive consultation from their interventionist about nutritional balance and dietary guidelines for pregnancy. Women are advised to follow IOM guidelines for rate of weight gain according to their pre-pregnancy BMI [44]. These guidelines suggest GWG between 15 and 25 pounds for a woman with pre-pregnancy overweight and between 11 and 20 pounds for a woman with pre-pregnancy obesity. To facilitate recommended GWG, women receive a Bluetooth-enabled scale and a Bluetooth-enabled cell phone unless women prefer to use their own Bluetooth-enabled cell phone. Weight is synced weekly from the Bluetooth-enabled scale to women's smartphones through a mobile application, and women manually send weights from the smartphone application to their HABIT interventionist. These weekly weights are graphed against desired IOM-suggested weight gain and reviewed with the participant at in-person sessions. The effects of physical activity on body weight, health, and mood also are reviewed, and women discuss decreasing sedentary behaviors.

Given the often limited nutrition knowledge of young perinatal women, we have adopted monitoring strategies from the stoplight eating approach, which has been applied successfully in individuals with limited nutrition knowledge as it does not require calorie counting or adherence to complicated eating plans [45]. The stoplight approach categorizes food as GREEN (low energy density, low calorie–eat often), YELLOW (medium energy density, medium calorie–eat in moderation), or RED (high energy density, high calorie–limit intake), to guide eating behavior. Further, to promote changes in diet, we implement a small change approach and use the stoplight eating approach to optimize nutrition and appropriate weight gain [46], with continuous reinforcement of self-monitoring in an effort to simplify the monitoring of dietary intake. All women receive education on GREEN, YELLOW, and RED foods, though focus is placed on decreasing RED foods (e.g., soda, chips, cake) and increasing GREEN foods (fruits, vegetables). Finally, women discuss strategies like using mindfulness to enhance satiety and slow the act of eating, behaving assertively in social interactions, utilizing social support to aid in initiating and maintaining health behaviors, and engaging in effective sleep hygiene habits.

In HABITpreg, women complete up to 10 in-person sessions

Table 3
HABITpreg and HABITpost texting schedule.

Content	Prompt	Frequency	Initiation
HABITpreg			
Weight	- Remember to weigh yourself today and use the weight app to email your weight to habit@upmc.edu or send it to your coach	Weekly	Session 1
Food	- Did you track your RED and GREEN foods yesterday from 12 AM–11:59 PM? Please reply with a Yes or No.	Daily	Session 2
	- How many RED foods did you eat yesterday from 12 AM–11:59 PM?		
	- How many GREEN foods did you eat yesterday from 12 AM–11:59 PM?		
Physical activity	- Of these past 7 days, how many days did you do physical activity?	Weekly	Session 2
	- How many minutes of physical activity did you do on average each day?		
Sleep	- For the past 7 days, how many hours did you sleep (on average) each night?	Weekly	Session 4
HABITpost			
Weight	- Remember to weigh yourself today and use the weight app to email your weight to habit@upmc.edu or send it to your coach	Weekly	Session 1
Eating/mood	- Just a reminder to keep on monitoring what meals and snacks you are eating this week in addition to your mood.	Weekly	Start: Session 1 End: Session 4
Food	- Did you track your RED and GREEN foods yesterday from 12 AM–11:59 PM? Please reply with a Yes or No.	Daily	Session 4
	- How many RED foods did you eat yesterday from 12 AM–11:59 PM?		
	- How many GREEN foods did you eat yesterday from 12 AM–11:59 PM?		
Physical activity	- Of these past 7 days, how many days did you do physical activity?	Weekly	Session 5
	- How many minutes of physical activity did you do on average each day?		
Sleep	- For the past 7 days, how many hours did you sleep (on average) each night?	Weekly	Session 9

Note. In HABITpreg and HABITpost, clinicians are referred to as "coaches."

(interventionists aim for a minimum of eight completed sessions, and additional sessions depend on delivery timing), starting at ≤16-weeks of pregnancy. Table 2 includes information on treatment session timing and content. The schedule of sessions is designed to be conducted in conjunction with routine obstetrical care. Sessions are initially held every four weeks, increase in frequency to every two weeks, and are then held weekly at the end of pregnancy. Each week during which an in-person session is not scheduled, women engage in a 10- to 15-min phone call with their interventionist to review recent health-related goals and problem-solve any challenges in health-related goals that may have arisen since the prior session.

2.7. HABITpost

The postpartum intervention, HABITpost, begins within the first 3-weeks after delivery, and continues through 6-months postpartum. HABITpost is treated as a separate intervention from HABITpreg, and regardless of GWG, the goal of the HABITpost intervention is to promote a loss of an additional 5–10% from women's pre-pregnancy weight. Interventionists are assigned randomly for HABITpost and women in the HABITpreg + HABITpost sequence do not have the same clinician for both interventions.

In HABITpost, women complete up to 12 sessions, starting as soon as possible after delivery. Intervention visits are held every other week, alternating in-person sessions with phone sessions until 6-months postpartum (see Table 2 for intervention timing and content). Given the demands of caring for a newborn, interventionists meet women in their homes or, if the woman prefers, at convenient locations in the community, such as libraries, cafes, and doctor's offices. Phone sessions are used to additionally accommodate demands on mother's time and allow for continued intervention. Similar to HABITpreg, HABITpost involves weekly phone calls during weeks when in-person or phone sessions are not held. Phone calls consist of a 10- to 15-min phone call with the interventionist to review health-related goals and problem-solve related challenges that may have arisen since the prior session.

Women in HABITpost receive Bluetooth-enabled scales to encourage regular self-weighing, which has been linked to weight control [46], and to enable the transmission of weight data to the study team. Women also receive nutritional consultation and education about calorie goals related to a 0.5–2.0 pounds per week weight loss. Self-monitoring of intake is continually reinforced. As in HABITpreg, the stoplight eating approach is implemented to simplify self-monitoring, providing an easy-to-use system that can be implemented while women are facing the increased demands of the postpartum period. Women are initially advised to reduce calorie intake and given instruction on setting goals to reduce RED food consumption (e.g., by replacing RED foods with GREEN foods) and monitor total calorie intake. Education is provided regarding how many calories to decrease in order to approximate the level of weight loss to achieve 5–10% reduction from women's pre-pregnancy weight. Women are encouraged to reduce calories by up to 500 kcal/day starting at week 8 postpartum. Similarly, women are advised to set gradually increasing physical activity goals, in step-wise increments, based on current activity levels and physician advice. In addition, decreasing sedentary behaviors like watching television, which has been specifically associated with postpartum weight retention [47,48], is encouraged and strategies to address barriers to physical activity such as the use of 10-min bouts of activity [49] are included. Strategies to increase cues for physical activity (e.g., location of baby carrier), reduce cues for sedentary activities that are unrelated to baby care (e.g., setting a timer for computer use), and increase lifestyle exercise (e.g., taking the stairs) are discussed.

As in HABITpreg, women in HABITpost discuss strategies for mindful eating to enhance satiety during eating episodes. Additionally, in recognition of the increased stress associated with newborn care, strategies such as mindfulness and acceptance-based approaches [37,43] to reduce stress and improve postpartum mood are used in HABITpost. Women discuss the behavioral management of maternal and infant sleep, given their relevance to mood, eating, and weight. Finally, efforts to behave assertively in social interactions involving eating, exercise, and childcare, as well as strategies to enhance social support for health behaviors postpartum are discussed and women role-play the management of difficult interpersonal situations.

2.8. TAUpreg and TAUpost

During both pregnancy and postpartum, the comparison condition represents a standardized and enhanced version of treatment as usual (TAU). These control conditions were selected to reduce overlap between conditions, minimize the chance of underestimating the true effect associated with a childbearing-specific lifestyle intervention [50–52], and evaluate the sequence of interventions relative to that provided as standard of care.

During pregnancy, women randomized to treatment as usual (TAUpreg) receive brief educational materials about the amount and rate of GWG distributed by mail at approximately 24-weeks of pregnancy. Separate booklets are sent to women with pre-pregnancy overweight and obesity, given the different GWG recommendations. Similarly, women randomized to treatment as usual in the postpartum

period (TAUpost) receive a booklet of materials on postpartum resources and health, including information on energy balance, at 3-months postpartum. Women in TAU complete assessments on the same schedule as those in HABITpreg and HABITpost.

2.9. Interventionist training and fidelity assessment

Interventionists are masters- and doctoral-level clinicians, formally trained prior to the start of the study. Interventionists receive general training in cognitive-behavioral approaches to health behavior change, are provided with both a HABITpreg and HABITpost treatment manual, and attend a training that includes didactic materials, role-play, and feedback. In addition, clinicians shadow an experienced clinician who provides individual supervision on their first case. To further ensure fidelity, interventionists participate in ongoing weekly group supervision. Given that in-person sessions are designed to occur in locations convenient to pregnant and postpartum women, issues related to the presence of others during intervention, distraction from children or media (e.g., radio, televisions) in the home while meeting, and concerns about clinician and participant relationships are discussed regularly during supervision meetings.

3. Study assessments

As shown in Fig. 2, women complete assessments at the end of the first trimester (≤16-weeks), end of pregnancy (~36-weeks), and 6- and 12-months postpartum. All women receive incentives to complete assessments, and we have found that a schedule of increasing compensation improves compliance with assessments. Thus, women receive $60 for completing the prenatal assessment, $40 at the end of pregnancy, and $50 and $100 for the 6- and 12-month postpartum assessments, respectively. In addition, assessment of both primary and secondary outcomes is completed separately from the intervention and conducted by a member of the study team not involved in providing intervention. Assessments include both self-report and biochemical measures, as described below.

3.1. Primary outcome

The primary outcome of the trial is postpartum weight at 12-months. Weight is measured in-person at each assessment using a calibrated digital scale while women are in street clothes without shoes. Height is measured with a stadiometer at the first assessment. Women self-report their pre-pregnancy weight during the phone screen. The use of self-reported pre-pregnancy weight is common in studies of GWG [53–55] and accurate within 1–2 kg [54].

3.2. Secondary outcomes

We expect that the intervention will affect psychosocial functioning and cardiometabolic health. Women complete the Center for Epidemiological Studies-Depression Scale (CES-D) [56] and the Edinburgh Postnatal Depression Scale (EPDS) [30] to assess current depressive symptomatology at all assessments. The CES-D is less sensitive than other depression scales to somatic symptoms that may be common in pregnancy and postpartum [57], and thus provides a useful repeated measure throughout the perinatal period. The EPDS is repeatedly administered as well as to identify women who endorse suicidality. Women with elevated scores on either the CES-D or EPDS or who endorse suicidality on the EPDS are contacted for further evaluation and referral as indicated. Women also complete the Perceived Stress Scale (PSS) [58], a 14-item scale with adequate reliability designed to assess the degree to which an individual appraises situations as stressful. Finally, the Pittsburgh Sleep Quality Index (PSQI) [59], a widely-used 19-item self-report measure of sleep quality is administered. Dietary intake is also assessed using the Nutrition Data System for Research (NDSR), a 24-h dietary recall interview. Additionally, we collect objective and self-reported assessments of physical activity. As an objective measure of physical activity, women wear an Actigraph wGT3X-BT for a 1-week period at enrollment, end of pregnancy, and at 6- and 12-months postpartum. As a subjective measure of physical activity we use the Pregnancy Physical Activity Questionnaire (PPAQ), a validated tool to assess household, caregiving, and lifestyle activities [60]. Finally, at each assessment cardiometabolic health indicators, including insulin resistance, lipids, and markers of inflammation, are collected via blood samples.

3.3. Covariates

Demographic variables that have been previously related to weight, cardiometabolic health, depressive symptoms, and stress during the perinatal period are collected. Specifically, age, race, ethnicity, income, educational background, employment status, health insurance status, and marital status are collected at baseline. We also collect information about whether pregnancy was intentional, parity, and family composition (i.e., number of children and adults living in the home). We inquire about the use of medications, medical conditions (e.g., gestational diabetes that may have been diagnosed after study entry), and additional interventions that might affect weight. Women also are queried about smoking using timeline follow-back methodology [61]. Birth control status, breastfeeding status, and other reproductive information (e.g., subsequent pregnancy timing) are collected postpartum only. These variables will be evaluated for statistically significant relationships with the primary outcome of interest, 12-month postpartum weight, to determine inclusion of covariates.

In addition, we plan to examine the utility of using GWG as a tailoring variable for perinatal intervention. Repeated gestational weights are extracted from medical charts and GWG is calculated as the final weight before delivery minus self-reported pre-pregnancy weight. GWG is defined as excessive according to IOM guidelines [44] based on initial pre-pregnancy BMI. Because the length of gestation is a potential confounder of GWG, we will use delivery date to calculate gestational length, which will be included in analyses of GWG. GWG will be considered in analyses to evaluate its utility as a future tailoring variable.

3.4. Planned statistical analyses

First, we will use descriptive statistics and graphic displays to identify outliers, missing data, and patterns of attrition, and to guide decisions about the use of transformations to satisfy the normality assumption. Next, demographic variables and baseline measures will be compared between HABITpreg and TAUpreg and between HABITpost and TAUpost using two-sample *t*- or Wilcoxon rank sum tests for continuous variables and chi-square or Fisher's exact tests for categorical variables. Data from women who have become pregnant again or for whom pregnancy did not result in a live birth will be excluded.

To utilize the longitudinal data collected, linear mixed-effect models will be the primary analytic tool. In each mixed-effect model, we will include treatment group, time, group by time interaction, and the stratification factor (pre-pregnancy BMI $<$ 30 or ≥30), as fixed terms. Participant will be included as a random term to account for repeated measures from the same participant. Different covariance structures will be compared to determine the best model fit.

Primary analyses will determine the combination of prenatal and postpartum lifestyle interventions that optimizes maternal weight, cardiometabolic health, depressive symptoms, and stress at 12-months postpartum. First, we will test whether women in HABITpreg + HABITpost have improved weight and secondary outcomes at 12-months postpartum relative to women who receive only HABITpreg or only HABITpost. We will then test whether women who receive only HABITpost have improved weight and secondary outcomes at 12-months postpartum compared to those who receive only HABITpreg or

only TAUpost.

Secondary analyses will incorporate GWG as a tailoring variable. These analyses will determine the optimal combination of interventions based on GWG that improves weight, cardiometabolic health, depressive symptoms, and stress at 12-months postpartum. We will examine if, among women who receive HABITpreg or TAUpreg and gain excessive GWG, those who are assigned to HABITpost have improved weight and secondary outcomes at 12-months postpartum compared to those in TAUpost. Additionally, we will test if, among women who receive HABITpost, women who meet GWG goals will have improved weight and secondary outcomes compared to those who exceed GWG goals, regardless of prenatal assignment.

In the mixed-effect models, time is a generic factor, and the number of levels will depend on the outcome being modeled. For example, for weight, mood, and stress, time will be a linear term beginning at baseline, and a quadratic term will be added to the model if necessary. However, for the outcomes of sleep, lipids, insulin resistance, and inflammatory measures, time will be a factor with 4 levels (baseline, end of pregnancy, and 6- and 12-months postpartum). We also will examine and, if indicated, control for the effects of potential confounds such as race, ethnicity, age, and socioeconomic status (fixed covariates) as well as breastfeeding, smoking status, and physical activity (time-varying covariates). If the coefficients for groups or group by time interactions are significant, planned contrasts will evaluate the effect of groups on weight and related outcomes at 6- and 12-months postpartum. Additionally, we will create a binary variable for 5% weight loss and use generalized mixed-effect models with the logit link to compare groups on proportions with 5% loss at 6- and 12-months postpartum.

4. Discussion

Approximately two-thirds of American women have overweight/obesity [62] and rates of obesity prior to pregnancy are increasing dramatically [1,2]. The increasing prevalence of obesity in women is problematic given that women with overweight/obesity prior to pregnancy are at higher risk for preeclampsia [6,53,63–65], gestational diabetes mellitus [6,53,63,65], and gestational hypertension than are women with normal weight [8,63]. Additionally, weight gained during gestation affects maternal and child health independent of pre-pregnancy overweight/obesity. Excessive GWG robustly predicts the amount of postpartum weight retention [4,5], increases the risk of obstetric complications [10,66] and is associated with adiposity among neonates [67], children [68,69], and adolescents and adults [9]. Approximately 45% of women exceed guidelines established by the IOM [44] for GWG [70–73], and rates above 50% [74] and as high as 63% [75] have been reported. Moreover, women who begin pregnancy with overweight/obesity are more likely to exceed IOM guidelines for GWG than are women with pre-pregnancy BMIs in the normal weight range [74,76]. Thus, although the etiology of obesity is multifactorial, the perinatal period is uniquely associated with women's obesity and offers a critical window for improving maternal health.

Unfortunately, effective interventions that address weight across the perinatal period, from pregnancy and through the postpartum period, are lacking. A limited number of controlled studies have examined the efficacy of interventions delivered during pregnancy to prevent excessive GWG. Overall these efforts to moderate GWG have been unsuccessful [1,11,77,78] or have been modestly successful, but only among women with normal weight before pregnancy [28,29]. Additionally, with the exception of a lifestyle program delivered by nurses in Finnish clinics [78], previous interventions to prevent excessive GWG have been limited in intensity. Interventions have been designed to offer a small number of group-based sessions [1], improve GWG monitoring among obstetricians [70], or provide dietary advice without teaching the behavioral principles necessary for longer-term behavior change [77,79]. Moreover, to optimize longer-term maternal weight and health for women who begin pregnancy with overweight, addressing GWG alone may be insufficient. Additional components, intensified interventions, or an approach to weight over the perinatal period may be necessary to alter longer-term obesity-related risks, particularly among women with pre-pregnancy overweight/obesity.

A second approach to perinatal weight management has focused on the postpartum period and specifically on the prevention of GWG retention. The efficacy of interventions aimed at postpartum weight management have been modestly successful. Randomized controlled trials for postpartum weight loss have tested the efficacy of brief group sessions [12], mailed correspondence [38], and group sessions coupled with individualized phone calls [13], with interventions failing to predict weight loss at 12-months [13] or indicating weight loss, but among extremely small samples (e.g., $n = 13$) [12]. Leermakers et al. [40] found significant weight loss following postpartum weight loss intervention, but only followed women to 6-months postpartum. Thus, previous postpartum weight loss efforts, suggest that, to maximize efficacy, postpartum interventions need to be delivered in a fashion that addresses postpartum stressors and capitalize on the immediate transition between pregnancy and the early postpartum period. Finally, given the robust relationships among prenatal weight, GWG, and postpartum weight retention [80–85], understanding when and for whom interventions can be sequenced for optimal weight and health is critical, particularly for women who begin pregnancy with overweight/obesity. The present study addresses these critical gaps in the literature with several innovative features.

First, the present investigation is the first effort to evaluate different combinations, or sequences, of intervention across pregnancy and the postpartum period to decrease maternal weight and improve health by 12-months postpartum. Previous interventions to address perinatal weight have attempted either to minimize GWG or decrease postpartum weight retention without successfully addressing the psychosocial and circumstantial changes that relate to maternal self-regulation across the transition from pregnancy through the postpartum year. Thus, the sequence of interventions that promotes behavior change from pregnancy through the postpartum period to improve weight at 12-months postpartum is unclear. We assert that the transition from pregnancy to postpartum offers a unique opportunity to optimize health by 12-months postpartum. Use of a SMART design provides the opportunity to test the efficacy of different sequences of intervention during pregnancy, postpartum or both, and to collect data on the benefit of adapting this sequence according to GWG. SMART and other dynamic treatment approaches have been applied to psychiatric [86–88] and health [89] conditions including drug use [90] and adult and child weight loss [91,92], but the present study represents the first use of SMART for perinatal weight.

Moreover, the transition from pregnancy to postpartum provides an ideal period to evaluate the utility of GWG as a potential tailoring variable. GWG is routinely documented and easily measured in all women. As such, GWG would be a pragmatic variable on which to tailor perinatal interventions. However, there are no data on the efficacy of GWG as a tailoring variable for perinatal weight interventions. The proposed SMART design enables us to evaluate the optimal sequence and to test the efficacy of different strategies, or combinations of sequences, for women who do and do not meet GWG goals. For example, we will compare the strategy of starting with HABITpreg and continuing with HABITpost only when GWG exceeds IOM guidelines to the strategy of no treatment postpartum for women who receive HABITpreg and meet their GWG goal. Alternatively, maternal weight at 12-months postpartum may be decreased most by starting with TAU and receiving HABITpost only if GWG is high. Finally, by stratifying women according to pregravid BMI, we will be in a unique position to explore whether a different decision rule is more efficacious for a particular weight group.

Lastly, there is substantial innovation in using interventions to address the different situational and psychosocial needs of women during pregnancy and the postpartum year. To date, no interventions have successfully addressed the unique sequential challenges presented by

the perinatal period. We have adapted the content and modality of HABITpreg and HABITpost to address conceptually-relevant and modifiable factors that affect health in either pregnancy or the postpartum period. Specifically, in HABITpreg we focus on weight stability [42,93] given that weight gain is expected. In HABITpost we focus on weight loss and recognize the physical and emotional changes that women experience after delivery as well as the increased time demands of infant care by meeting with women in locations that are easily and readily accessible (e.g., homes, libraries). HABITpost also focuses on the importance of postpartum sleep given the impact of sleep on mood and weight in general [94,95] and on postpartum weight specifically [96,97].

5. Conclusions

In conclusion, the perinatal period has important implications for weight management and health, especially for women who begin pregnancy with overweight/obesity. Results of this trial will inform the sequence of interventions most likely to improve maternal health at 12-months postpartum and will evaluate the efficacy of GWG as a tailoring variable for perinatal weight. Optimizing the sequence of behavioral interventions to address specific needs during pregnancy and the first postpartum year can maximize intervention potency and mitigate longer-term cardiometabolic health and psychosocial risks for women.

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