Study Protocol

Official Title: Optimizing health from pregnancy through one year postpartum: A sequential multiple assignment randomized trial (SMART) of perinatal lifestyle interventions

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Scientific Background

Approximately two-thirds of American women are overweight or obese (OV/OB; BMIs > 25), and rates of obesity prior to pregnancy are increasing dramatically. For example, Kim and colleagues reported a 70% increase in the prevalence of pre-pregnancy obesity over a 10 year period. Rates of gestational diabetes mellitus (GDM), pre-pregnancy hypertension, and preeclampsia also have increased since 2000, and women who are OV/OB prior to pregnancy are at higher risk for preeclampsia, and gestational hypertension than are normal weight women. Prenatal OV/OB, along with weight gain in pregnancy, is related to difficult deliveries, an increased likelihood of macrosomia, congenital malformations, and obesity among the children born to OV/OB mothers.

Gestational weight gain (GWG) also affects maternal and child health independent of pre-pregnancy OV/OB. Excessive GWG robustly predicts the amount of postpartum weight retention, increases the risk of obstetric complications and is associated with adiposity among neonates, children, adolescents, and adults. The Institute of Medicine (IOM)reissued guidelines for GWG stratified by pre-pregnancy BMI that recommend GWG between 15 and 25 pounds for an overweight woman and 11 to 20 pounds for an obese woman. However, approximately 45% of women exceed IOM guidelines for GWG, and rates above 50% and as high as 63% have been reported. Moreover, women who begin pregnancy OV/OB are more likely to exceed IOM guidelines for GWG than are women with pregravid BMIs in the healthy weight range, and some evidence suggests that overweight women are even likelier than obese women to exceed GWG guidelines. Thus, although the causes of obesity are multi-factorial, the perinatal period is uniquely associated with women's obesity and offers a critical window for improving maternal health.

Perinatal interventions have not succeeded in decreasing GWG or affecting weight at one year postpartum.

Previous interventions to address perinatal weight have attempted either to minimize GWG or decrease postpartum weight retention. No intervention has successfully addressed 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 one year postpartum is unclear. We assert that the transition from pregnancy to postpartum offers a unique opportunity to optimize health by one year postpartum and that the optimal strategy of prenatal and postpartum interventions to effect maternal health may differ according to the amount of weight gained during pregnancy.

Interventions to address GWG have not helped OV/OB women avoid excessive GWG. A limited number of controlled studies have examined the efficacy of interventions to prevent excessive GWG. Overall efforts to moderate GWG have been unsuccessful or have been modestly successful, but only among subgroups of women. For example, Polley found intervention helped only women who were normal weight before pregnancy. Similarly, Phelan et al tested the efficacy of a lifestyle intervention to decrease the number of women with excessive GWG. In a sample of 401 women, a lifestyle intervention that addressed eating and activity and included provision of body weight scales and pedometers succeeded in minimizing GWG only with women who were normal weight prior to pregnancy. Thus, it appears interventions may succeed

in preventing excessive GWG, but not among women who begin pregnancy OV/OB.

Additionally, with the exception of a lifestyle program delivered by nurses in Finnish clinics, previous interventions to prevent excessive GWG have been limited in intensity. Interventions have been designed to offer a small number of group-based sessions, improve GWG monitoring among obstetricians, or provide dietary advice without teaching the behavioral principles necessary for longer-term behavior change. To optimize longer-term maternal weight and health for women who begin pregnancy overweight, addressing GWG alone may be insufficient, particularly through brief contacts. 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 OV/OB women.

Interventions to promote postpartum weight loss have not succeeded among lower income women. A second approach to perinatal weight management has focused on postpartum weight loss and specifically on the prevention of GWG retention. Substantial evidence indicates that changes to eating or activity postpartum pose minimal, if any, risk for OV/OB postpartum women. Studies examining the effects of diet and exercise on lactation have documented that lifestyle changes do not adversely affect breast milk composition, production or quality or infant growth and development although OV/OB women may have difficulty initiating or sustaining breast feeding. Thus, the potential risks of postpartum weight loss for OV/OB women are minimal and offset by potential benefits.

However, in contrast to interventions for GWG, postpartum weight management efforts have been modestly successful. Randomized controlled trials for postpartum weight loss have tested the efficacy of brief group sessions, mailed correspondence and group sessions coupled with individualized phone calls. For example, Ostbye assigned women to an eating and exercise intervention or a no treatment control at 6 weeks postpartum and followed women for one year. Intervention comprised 18 group classes addressing exercise and eating and 6 individualized telephone contacts. Enrollment in the program was readily accomplished and retention rates during the postpartum year were excellent, suggesting that OV/OB women are interested in postpartum weight management. However, intervention was not associated with weight loss at one year. Moreover, attendance at group classes, which predicted weight change, was very low (3.8 of 18 classes) and younger, African American and lower income women were less likely than older, white, higher income women to participate. Intervention also was delivered irrespective of GWG, and questions about the need for additional intervention for women who met or failed to meet GWG guidelines remain.

Finally, the limited efficacy of postpartum weight loss interventions may be due to timing. Most trials have initiated intervention 6- or 12-months after childbirth, and one recruited women at 6-weeks postpartum. In summary, previous postpartum weight loss efforts, and our work on health behavior change postpartum suggests that, to maximize efficacy, postpartum interventions need to engage women from lower socioeconomic groups, be delivered in a fashion that addresses postpartum stressors and capitalize on the immediate transition between pregnancy and the early postpartum period.

The proposed SMART is innovative as 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 one year 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 and health, conditions including drug use, and adult and child weight loss, but this proposal represents the first use of SMART for perinatal weight. Although pregnancy has been called a critical period for weight management, there are no data to determine if delivering a lifestyle intervention prenatally, postpartum or across the perinatal transition optimizes maternal weight and health by one year postpartum.

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 treatment sequences. 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 guideline to the strategy of no treatment postpartum for women who receive HABITpreg and met their GWG goal. Alternatively, maternal weight one year 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.

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 made adaptations to the content and modality of the lifestyle interventions described, HABITpreg and HABITpost, that address conceptually relevant and modifiable factors that affect health in either pregnancy or the postpartum period. In HABITpreg, designed to address excessive GWG, we include a focus on weight stability given that weight gain is expected. In HABITpost, we recognize the increased time demands of infant care and include a focus on postpartum sleep given the impact of sleep on mood and weight in general and postpartum weight specifically, as well as the use of telephone and home visits as in our previous postpartum work.

A final innovative aspect of the proposed research is the diversity of the proposed sample. Previous work on perinatal weight management with women from minority groups or with lower incomes has been limited. Although rates of obesity prior to pregnancy have increased among women from all backgrounds, African American women had the highest prevalence of obesity in a recent survey, and the relationship between parity and weight gain is particularly strong among African American women. Lower levels of education also are associated with greater weight retention postpartum. Given our previous perinatal health behavior research, we are uniquely situated to recruit and retain women of diverse backgrounds and to address questions about the

optimal sequence of weight-related interventions for women from minority groups and of lower socioeconomic status, who may benefit most.

Study Objectives

The purpose of this study is to determine the best combination of lifestyle intervention to improve maternal weight, health and psychological symptoms at 1 year postpartum.

Specific Aim 1: Determine the combination of prenatal and postpartum lifestyle interventions that optimizes maternal weight, cardiometabolic health, depressive symptoms and stress at 12-months postpartum.
Hypothesis 1: Women in HABITpreg who are assigned to HABITpost will have improved weight and secondary outcomes at 12-months postpartum relative to women who receive only HABITpreg or only HABITpost.
Hypothesis 2: Women who receive only HABITpost will have improved weight and secondary outcomes at 12-months postpartum compared to those who receive only HABITpreg or only TAUpost.

Specific Aim 2: Determine the optimal combination of interventions based on GWG that improves weight, cardiometabolic health, depressive symptoms and stress at 12-months postpartum.
Hypothesis 3: Among women who receive HABITpreg or TAUpreg and gain excessive GWG, those who are assigned to HABITpost will have improved weight and secondary outcomes at 12-months postpartum compared to those in TAUpost.
Hypothesis 4: Among women who receive HABITpost, women who met GWG goals will have improved weight and secondary outcomes compared to those who exceed GWG goals regardless of prenatal assignment.

Exploratory Aims: Evaluate the optimal sequence of interventions by prenatal weight. We will determine, for example, if the strategy of HABITpreg then HABITpost, regardless of GWG, optimizes outcomes for obese women, and if TAUpreg then HABITpost is helpful for overweight women only when GWG is excessive. Evaluate the effect of the sequence of interventions on infant risk for obesity.

Impact: This SMART is designed to identify the sequence of interventions most likely to improve maternal health at one year 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 and their children.

Study Design & Methods

Potential participants will be screened by study staff using a brief self-report format phone screening to make sure that they meet eligibility criteria before scheduling the first assessment where they will complete the informed consent process. Study staff will obtain verbal consent prior to asking the caller any screening questions.

If requested and preferred by potential participants, we will send them a link to complete the screening questions through webdataxpress. This link to the WDX screening form will also be available on our lab website. Individuals will have to consent to the screening process on the site before moving on to the screening questions. After answering the screening questions potential participants will be presented with different responses depending on eligibility status.
If ineligible: Thank you for your interest in the HABIT Study. Based on the answers you provided in this screener, you are ineligible to participate in our study. We will keep you in mind for any future studies. Have a great day!
If eligible: Thank you for your interest in the HABIT Study. Based on the answers you provided in this screener, you are eligible to participate! A member of our team will reach out to you within a week or so to schedule an assessment and answer any further questions you may have. Have a great day!
If we need more information to determine eligibility: Thank you for your interest in the HABIT Study. A member of our team will reach out to you within a week to discuss your potential participation and answer any further questions you may have. Have a great day!"

Assessments: All participants will complete assessments at 16 weeks of pregnancy or less (T0), Between 32 and 40 weeks (T1), at 6 months postpartum (T6) and 12 months postpartum (T12). Assessments will be conducted by research assessors. Assessments will take place at Magee-Womens Hospital and each assessment should take 1-2 hours to complete. Assessments will consist of the following: (Questionnaires and a schedule of assessments are attached and described below)

Height, weight & waist circumference. Height will be measured with a stadiometer at study enrollment (T0). Weight will be measured using a calibrated digital scale at all assessment timepoints. Women will be measured in street clothes without shoes. Prepregnancy body mass index (BMI) will be calculated as (weight in kg)/(height in m2). The use of self-reported pregravid weight is common in studies of gestational weight gain and accurate within 1-2 kg. Repeated measurements of weight will also be abstracted from medical charts during pregnancy. Waist circumference will be measured at T0, T6 and T12. This will be taken using a tape measure marked in centimeters and placed at the level of the umbilicus. The average of two consecutive measurements will be used.

Gestational weight gain and excessive gestational weight gain. Gestational weight gain (GWG) will be calculated as final weight before delivery minus prepregnancy weight. GWG will be defined as excessive according to IOM guidelines based on initial prepregnancy BMI. Both the categorical (yes/no) variable representing GWG above the IOM guideline for the woman's prepregnancy BMI, and the total amount of GWG will be used as dependent variables. Because the length of gestation is a potential confounder of GWG, we will abstract delivery date from women's medical charts and calculate gestational length.

Demographic information. Information including age, race, ethnicity, income, educational background, employment status, health insurance status and marital status will be collected at T0 and updated at T1, T6 and T12.

Self-reported mood. Women will complete the Center for Epidemiological Studies-Depression Scale (CES-D) to assess current depressive symptomatology. The CES-D was selected because it appears to be less sensitive than other depression scales to somatic symptoms that may be common postpartum. Thus, the CES-D provides a useful repeated measure during pregnancy and the postpartum period. Responses on the CES-D will be carefully reviewed, and women who endorse extreme scores will be contacted for further evaluation and referral if necessary. This questionnaire will be completed at all 4 assessments. The Edinburgh Postnatal Depression Scale (EPDS) will be given at all 4 timepoints. This measure of depression specifically looks at postnatal depression. Participants will read 10 statements and for each one choose which of four possible responses is closest to how she has been feeling during the past week. Anxiety will be measured by the State Trait Anxiety Inventory (STAI). 20 questions are rated on a 4 point scale with higher scores indicating higher anxiety. This questionnaire will be completed at all timepoints.

Sleep quality. The Pittsburgh Sleep Quality Index will be given at all timepoints to assess sleep quality.

Sleep chronotype. A modified version of the Munich ChronoType Questionnaire (MCTQ) will be used at all timepoints to assess sleep chronotype. This self report questionnaire has questions designed to collect more detailed information on sleep patterns.

Sleep health. The RU_SATED 4.0 Sleep Health Scale will assess participants' multidimensional sleep health at all timepoints (Baseline, T0, T1, T6, and T12). It is a 6-item measure that assesses sleep over the past month.

Infant sleep. The Brief Infant Sleep Questionnaire - Revised (BISQ) Short Form will be used to assess infant sleep patterns at T6 and T12. The BISQ is a parent-completed measure of infant and toddler sleep. The BISQ assesses start of the bedtime routine, bedtime, sleep onset latency, night waking frequency, night waking duration, longest stretch a child remains asleep, total nighttime sleep, nap duration, and total amount of time a child sleeps in a 24-hour period. Higher scores on the BISQ indicate better sleep.

Stress. Perceived stress will be assessed using the Perceived Stress Scale(PSS). The PSS is a 14-item scale designed to assess the degree to which an individual appraises situations as stressful. This questionnaire will be given at all assessments.

Impulsivity. The UPPS-P Impulsive Behavior Scale will be used as a general measure of impulsivity. The UPPS-P is a 59-item measure that assesses five facets related to trait impulsivity. The items comprising the measure consist of Likert scale response options. Participants will complete select subscales that have a total of 33 questions. The Barratt Impulsiveness Scale will be used to assess the personality/behavioral construct of impulsiveness. This questionnaire has 30 questions rated on a 4 point scale. Both of these questionnaires will be completed at T0, T1 and T6. Another measure of impulsivity that participants will complete at each timepoint is the Consideration of Future Consequences Scale. This is a self-report questionnaire that comprises 14-items measuring a tendency to consider future consequences of behavior.

Eating. The Eating Disorder Examination Questionnaire (EDE-Q) is a self-report version of the Eating Disorder Examination. The EDE is an interview designed to assess the complete range of psychopathology and behaviors related to disordered eating. Participants will complete the Three Factor Eating Questionnaire, which contains three empirically derived factors with good internal consistency in nonclinical samples. The restraint factor reflects conscious thoughts and purposeful behaviors to control food intake. Disinhibition reflects a tendency to relinquish control over food intake in response to environmental or emotional stimuli. The final factor is hunger. Both of these questionnaires will be completed at all timepoints. In addition, participants will also complete 2 dietary food recalls at each assessment. The study will utilize the Automated Self-Administered 24-hour (ASA24) Dietary Recall System to collect information about what participants ate in the prior 24 hours. At each timepoint participants will complete 2 separate 24 hour food recalls. The first at their in person assessment and another other one over the phone within the next couple weeks. At the end of the 12-month follow-up recalls interviewers will ask participants LOC questions (attached in question 2). The Perceptions about Eating and Weight during Pregnancy will be administered during T0 and T1 assessments. This questionnaire will measure eating and weight concerns and potential misconceptions about eating and weight specific to pregnancy. The Power of Food Scale (PFS) will be complete at each assessment timepoint. This is used to assess appetite for palatable foods and document the psychological impact of living in environments with an abundance of palatable foods. The Eating Pathology Symptoms Inventory (EPSI) will assess body image dissatisfaction and eating pathology symptoms in this study at T12 only.

Weight Bias- The Weight Bias Internalization Scale (WBIS-M) will be used at all timepoints. This measure contains 11 questions on weight bias that are rated on a 7-point Likert scale.

Physical activity- The Pregnancy Physical Activity Questionnaire (PPAQ) will be used to assess activity during each assessment. The PPAQ is a self-report measure of physical activity which evaluates the duration, frequency, and intensity of physical activity amongst pregnancy women. As an additional, objective, measure of activity, participants will be asked to wean an activity tracker for a period of time at each assessment timepoint.

Appetite and feeding. The Adult Eating Behaviour Questionnaire (AEBQ) will be used to measure the appetitive traits of our participants. The AEBQ is a self report questionnaire with 35 item rated on a 5 point scale. Participants will complete this questionnaire at each assessment. The Baby Eating Behaviour Questionnaire (BEBQ) will be used to measure the appetites of our participants' infants. Mothers will report their child's appetite by answering 18 questions rated on a 4 point scale. This questionnaire will be completed at the T6 assessment. A questionnaire about the participant's intent to breastfeed will be administered at their T1 assessment and at T6 and/or T12 they will complete a questionnaire about their experience with breastfeeding their baby. The Child Eating Behaviour Questionnaire (CEBQ) will be completed during the T12 assessment to measure the appetites of our participants' child. Participants will complete this 35 item scale reporting on their 1 year old child.

Health information. We will collect, via questionnaire, interview format and medical record review, information about use of medications, including psychiatric medications, use of other

treatments for weight, and the presence of medical conditions (e.g., gestational diabetes) at each assessment. We also will collect information about parity and current family composition (i.e., number of children and adults living in the home) as well as current and past pregnancy data via questionnaire. Information about current smoking status and history of smoking will be collected using a self-report questionnaire. The same questionnaire will also ask about past and current alcohol use. An investigator designed Cannabis Use Questionnaire will be used to evaluate current and past cannabis use. This measure will be used at all timepoints. Medical record review. Research assessors will look at participants' medical charts to extract physician measured weights, verify that they are having a singleton pregnancy, delivery date, and medical history during the pregnancy (e.g. current and preexisiting medical conditions, medications, and other treatments being pursued). We will also use participant's medical records to facilitate counseling sessions by looking up or verifying their next obstetric appointment date and time.

Mindfulness. To assess mindfulness, the Mindfulness Attention Awareness Scale (MAAS) will be used. This scale contains 15 items rated on a 6 point scale and it has been shown to be valid and reliable. Participants will completed this measure at each of the 4 timepoints.
Body Surveillance. Participants will complete a subscale of the Objectified Body Consciousness Scale (OBCS) to measure body surveillance, which closely matches self-objectification, or the "habitual monitoring of the body's outward appearance". This subscale contains 8 questions on a 7 point Likert scale. Participants will complete this measure at each of the 4 timepoints.

Food insecurity- Food insecurity will be measured using an investigator edited version of the U.S. Household Food Security Survey Module. This questionnaire will be given at all assessment visits.

Discrimination. The Major Experiences and Everyday Discrimination Scales include 19 interviewer administered questions. The Major Experiences subscale includes 9 questions about employment, housing,
and education; the Everyday Discrimination subscale includes 10 questions about interactions with others (e.g., respect, harassment). Reasons for discrimination (e.g., race, gender, religion) are assessed. This interview will be administered at all timepoints.

Adverse childhood experiences will be measured using the BRFSS Adverse Childhood Experience (ACE). The measure was edited to also include some questions of emotional and physical neglect. This questionnaire will be given at T12.

Measure of behavior change- An investigator designed measure of behavior change will be used at all timepoints. This measure contains 44 questions which were designed to evaluate topics addressed throughout HABIT treatment such as exercise, eating, sleep and social support.

Program evaluation- The program evaluation form is an investigator designed questionnaire to allow HABITpreg and HABITpost participants to give feedback on the study intervention. They are able to rate how helpful the program was, how much they enjoyed the program, and provide written feedback/suggestions. The form includes questions about their experience with the virtual format of the intervention during COVID-19. The measure will be given to pregnancy intervention participants at the T1 assessment and postpartum intervention participants at the T6

assessment.

Blood draw. Participants will be asked to provide a blood sample to measure glucose/insulin/insulin resistance and lipids/inflammation. Levels of estrogen and progesterone will also be measured. To gather this information, up to about 2-3tb of blood will be collected by a qualified individual contracted through the Magee CTRC. This will be done at all of the assessments. If women are unable to attend their assessment at Magee CTRC we will send a trained phlebotomist to their home to complete the blood draw.

Infant data: We will conduct medical chart reviews to obtain infant height, weight, and medical history during their first year of life, in accordance with the study procedures for participating women. We will also collect data on the infant gut microbiome using stool sample kits in accordance with procedures from the Center for Medicine and the Microbiome (CMM). At their 2-6 week postpartum visit, mothers will be provided with fecal sample collection kits and instructed to collect infant fecal samples, then mail them in pre-paid approved envelopes to the CMM. We will ask participants to complete 4 subscales of the Infant Behavior Questionnaire Revised (IBQ-R) at T12. This survey is designed to measure temperament in infants.

Safety alerts: We will ask participants at each follow-up (T1, T6 and & T12) about any medical events occurring between visits. Individuals enrolled in the ancillary study will also answer these questions at their T2 visit. Any medical events discussed will be logged on an interview form labeled with the participant's ID number.

COVID-19 Information: We will ask participants about any COVID-19 positive tests they had while they were in the study. Additionally, they will be asked if they received the COVID-19 vaccine. This interview form will be completed at their final assessment timepoint (12 months postpartum).

Intervention:
By study design participants will be randomized twice over the course of their participation. Once at enrollment and again at the time of their second assessment which coincides with the end of their pregnancy. After completing the baseline assessment (T0), participants will be randomized to either the HABIT intervention during pregnancy or to usual care. Usual care consists of the care that pregnant woman usually receive from their obstetric and other providers. All women in the study will continue to receive the care they usually receive. Those in usual care will not receive any extra treatment from the study team. If they are randomized to treatment they will be assigned a coach and will immediately get started with their first session. Treatment during pregnancy will consist of up to 10 in person sessions lasting approximately 20-30 minutes. These sessions will take place at their regularly scheduled OB appointments, at our research building, or a nearby location. Participants in the HABITpregnancy group will also receive texts and phone calls between sessions. HABIT will focus on weight, physical activity, eating and psychosocial issues. Intervention goals will emphasize adherence to healthy behaviors rather than absolute weight goals. Specifically, women will receive consultation about nutritional balance, dietary guidelines for pregnant women and advice to maintain an optimal rate of weight gain according to prepregnancy BMI. Women will use self-monitoring forms to identify and modify cues for unhealthy behaviors. Beliefs about body weight and eating during pregnancy

will be addressed and effects of physical activity on body weight, health, and mood will be included. Mood will be monitored by the EPDS questionnaire to help tailor individualized treatments. To help facilitate treatment, participants who need them will be provided with smart phones and Bluetooth enabled scales. Participants who are assigned to usual care will not have regular contact with study staff.
After participants complete the T1 assessment towards the end of their pregnancy they will again be randomized to either receive HABIT treatment postpartum or to receive usual care. All participants will be randomized again. Usual care consists of the care they would usually receive from their OB and other providers. All women will continue to receive this care, however, those assigned to usual care will not receive any additional treatment from the study. If participants are assigned to HABITpostpartum they complete a separate intervention of over the 24 weeks immediately following delivery. Treatment will consist of 12 biweekly sessions completed over the phone or in person. In person sessions will be done at the participant's home or another convenient location. Additionally, participants will receive calls and texts between sessions. Mood will be monitored by the EPDS questionnaire to help tailor individualized treatments. All participants will continue to receive their standard postpartum care from their medical team. Counseling sessions during pregnancy and postpartum will be conducted by research project staff that has, at least, masters level or equivalent degrees. Counselors will be trained by Dr. Levine prior to the start of the project. To help facilitate treatment, participants who need them will be provided with smart phones and Bluetooth enabled scales. Treatment materials are attached to the end of this application.
Treatment sessions will be audio taped for supervision.

All newly enrolled participants and any previously enrolled participant that has not yet delivered her baby will be invited to participate in the ancillary study. Women who agree to participate in the ancillary study will complete additional assessments at each HABIT timepoint and an additional assessment between delivery and 4 weeks postpartum. During these assessments they will complete the following:

Impulsive phenotypes. Participants will complete a battery of computer tasks to measure impulsivity. These tasks include the Go/No-Go Task- A computerized task in which stimuli are presented continuously and individuals must make a motor response for the go stimulus and withhold a motor response for the no-go stimulus. Stroop Color-Word Test- A computerized task in which individuals are required to name the color of a written color word while inhibiting the impulse to read the word itself. Delay Discounting Task- a computerized task in which individuals choose between smaller, immediate monetary rewards and larger, delayed monetary rewards. Wisconsin Card Sorting Test- a computerized task in which individuals have to match a target card with one of four category cards under changing conditions. Before completing these 4 computerized tasks, participants will complete a shortened practice round of the Go/No-Go Task and the Stroop Color-Word Test. During this practice round, participants will be encouraged to "go faster" when they are responding too slowly. In addition to these computer tasks, participants will also complete the Consideration of Future Consequences Scale which is a self-report questionnaire that comprises 14-items measuring a tendency to consider future consequences of behavior.

Eating behaviors. Participants will complete the self reported Power of Food Scale to assess

appetite for palatable foods and document the psychological impact of living in environments with an abundance of palatable foods.

All of these measures will be given at each HABIT timepoint as part of the ancillary study. In addition, participants will complete one additional visit outside of the regular HABIT timeline. This assessment will occur in the early postpartum period. In addition to the measures just described participants will be weighed, complete demographic and other questionnaires that are completed as part of HABIT (described above).

Participants will be asked to complete 3 follow up assessments. They will complete an assessment at the end of their pregnancy (T1), 6 months postpartum (T6) and at 12 months postpartum (T12). Individual components of these assessments are described in detail above.

Participants enrolled in the ancillary study will complete one additional follow-up assessment outside of the HABIT schedule. This early postpartum assessment (T2) will be completed between delivery and 4 weeks postpartum. Individual components of this assessment is described in detail above.

During the social restrictions placed due to COVID-19 we will be doing assessments remotely with already enrolled participants. The same assessments will be completed that are typically completed in our office. However, we are adding in 1 additional questionnaire (uploaded below) to assess how well the ancillary computer tasks worked for them on their device. The answers to this questionnaire will help us interpret this data that was collected in a different way.

During the COVID-19 shutdown of in person research we will consent new participants into the study remotely. In order to get a baseline weight, study staff may drop off a study scale outside a participant's home or another convenient location in order to get a baseline weight. The scales will be picked up at a later date outside of their home. Staff will have no direct contact with the participants. In addition, we will ask participants for any available self reported blood work results that match with the blood work that we typically get at baseline assessments. If recent results are available in medical records we will send the participant an additional medical release to pull that information.

Eligibility Criteria

Women will be eligible if they: (1) have a prenatal BMI ≥ 25; (2) are at or before 17 weeks and 4 days of gestation; (3) are English speaking and (4) have a singleton pregnancy. We considered an upper limit to BMI. However, given the paucity of data on weight outcomes for women with BMIs >35, we elected not to limit BMI but will randomize women in two strata according to BMI (25-29.9 vs. ≥30). Similarly, parity may impact perinatal weight, but intervention goals are similar for primagravidae and multiparous women. Thus, we will recruit women regardless of gravida and parity, and include these variables as covariates in all analyses.

With the approval of modification #20: (5) Identify as Black or Multiracial Black

Infants will be eligible for medical record and microbiome data collection if (1) mothers' are

enrolled into HABIT after MOD16020497-12 or (2) if we are able to reconsent their mothers' during the T1 or T2 timepoints.

Statistical Considerations

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. Mixed-effect models are useful for longitudinal datasets that contain missing observations, as anticipated in this study, under the assumption of missing at random (MAR). The MAR allows a relationship between missingness (e.g., drop-outs, missed assessments) and outcome through their mutual relationship to other covariates, such as treatment sequences or pre-pregnancy weight status. No residual relationship between missingness and outcome is required once covariates are taken into account. However, we also will examine patterns of missingness, and report the average effect over different missing patterns if necessary. In each mixed-effect model, we will include group, time, group by time interaction, and the stratification factor, pre-pregnancy BMI ($\geq$30 or <30) as fixed terms. Subject will be included as a random term to account for repeated measures from the same subject. Different covariance structures will be compared to determine the best model fit.

There are 8 sequences or combinations of intervention in this SMART, which we use to define group for hypothesis testing. Time also 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. For other outcomes, time will be a factor with 4 levels (baseline, end of pregnancy, and 6- and 12-months postpartum). We also will evaluate the need to control for the effects of potential confounds such as race, age, 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 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.

Finally, to fully utilize a SMART design, and to evaluate the utility of using GWG as a tailoring variable, we will explore what the optimal strategy is and for which participants. A dynamic strategy is a decision rule about which intervention is best initially and what intervention follows, depending on the response status. The proposed deisgn produces HABITpreg and TAU during pregnancy, and women who do and do not meet IOM guidelines for GWG each have HABITpost and TAU postpartum, resulting in the 8 possibilities sequences.