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A randomized controlled trial to prevent excessive gestational weight gain and promote postpartum weight loss in overweight and obese women: Health In Pregnancy and Postpartum (HIPP)

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Abstract

Background—Interventions to prevent excessive gestational weight gain and promote postpartum weight loss have yielded modest results, particularly in overweight and obese women.

Objectives—To examine the impact of a theory-based lifestyle intervention on gestational weight gain, postpartum weight loss, and related maternal and child outcomes and to examine race differences in these outcomes.

Design—A randomized controlled trial (target N=400; 200 intervention, 200 standard care; 200 African American, 200 white).

Methods—Overweight and obese African American and white women ≤16 weeks gestation are recruited from obstetrics and gynecology clinics in South Carolina. Intervention participants receive two in-depth counseling sessions (early pregnancy and postpartum), telephone counseling, behavioral podcasts, and social media support that target weight self-monitoring and increasing

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physical activity and healthy dietary behavior practices, guided by Social Cognitive Theory. Standard care participants receive monthly mailings and a matched number of podcasts on non-weight related topics. All intervention activities last from ≤18 weeks gestation to 6 months after delivery. Gestational weight gain is the primary outcome. Secondary outcomes are meeting gestational weight gain guidelines (inadequate, adequate, excessive), weekly rate of gestational weight gain, postpartum weight retention, physical activity and dietary behaviors, health-related quality of life, and offspring adiposity. Participants are assessed at baseline (≤16 weeks gestation), 32 weeks gestation, and 6 and 12 months postpartum, and offspring are assessed at 6 and 12 months.

Summary—HIPP is an innovative study that addresses significant gaps in the literature. Primary outcome results are expected in 2019.

Keywords

Pregnancy outcome; obesity; maternal health; physical activity; diet; weight loss

1. Introduction

Excessive gestational weight gain (GWG) is a significant clinical and public health problem due to its high prevalence and deleterious effects on maternal and offspring health [1]. Estimates from the United States are that nearly half (47.2%) of all pregnant women exceed the Institute of Medicine (IOM) GWG guidelines [2, 3]. Women who enter pregnancy overweight or obese are at even greater risk for excessive GWG with nearly two-thirds exceeding recommendations [2]. These numbers are important when considering the majority of women in the United States aged 20–39 years are overweight or obese, and the prevalence is notably higher among African American women [4, 5].

Excessive GWG is a consistent risk factor for postpartum weight retention [6–9], even up to 15 and 21 years postpartum [7]. Furthermore, excessive GWG increases a woman's risk for gestational diabetes [10], pregnancy-associated hypertension [11], and adverse birth outcomes such as cesarean delivery and large for gestational age infants [1, 11]. Accumulating observational studies also show that higher GWG is associated with higher offspring weight and obesity [6, 12, 13].

Although pregnancy and postpartum are high-risk periods for the development of overweight and obesity [14, 15], they are also times that afford unique opportunities for lifestyle behavior change due to women's frequent contact with health care providers and concern for their offspring's health. Behavioral interventions can increase the chance of achieving a healthy weight over the life course of both mother and child. Indeed, a recent Cochrane review concluded that diet, exercise, or combined interventions reduce the risk of excessive GWG and may reduce the risk of caesarean delivery, macrosomia, and neonatal respiratory morbidity [16]. Despite this positive review, notable gaps exist in the literature. Relatively few studies target GWG in overweight and obese pregnant women, and results are inconsistent [17–19]. Few intervention studies span both pregnancy and postpartum and include measures of offspring [20–22]. Evidence-based behavior change strategies are often not used. Few studies are adequately powered to test intervention effects within racial and

ethnic minorities or to examine differences in outcomes [23, 24]. Finally, mean GWG differences between intervention and control groups tend to show relatively modest differences, ranging from around 1.0 kg [25, 26] to 2.0 kg [19, 27]. These differences may not translate into meeting IOM GWG recommendations [20].

In response to the gaps in literature, the Health In Pregnancy and Postpartum (HIPP) study is a randomized controlled trial designed to examine the efficacy of a behavioral lifestyle intervention to reduce excessive GWG and promote postpartum weight loss among women who enter pregnancy overweight or obese as compared to a standard care intervention. The primary study outcome is GWG and the secondary outcomes are postpartum weight retention, physical activity (PA), dietary intake, health-related quality of life, and offspring adiposity. This paper provides an overview of the study design, theoretical framework, intervention protocol, outcome evaluation, program evaluation, and statistical considerations for the HIPP study.

2. Methods

This study was funded by the National Institutes of Health (R01HD078407) and is registered in clinicaltrials.gov (NCT02260518). Institutional Review Boards at Palmetto Health, the University of South Carolina, Lexington Medical Center, and the Medical University of South Carolina approved the study protocol. CONSORT reporting guidelines were followed [28].

2.1. Study aims

The HIPP study has four specific aims: (1) examine the impact of a lifestyle intervention on GWG and postpartum weight loss in overweight and obese women, (2) examine the impact of the intervention on PA, dietary intake, and health-related quality of life, (3) examine race differences in total GWG, PA, dietary intake, and health-related quality of life; and (4) examine the impact of the intervention on offspring adiposity.

2.2. Setting and recruitment

This study is being conducted in South Carolina, a state known for its poor maternal and child health indicators, high prevalence of obesity, high proportion of African Americans, and racial disparities in health [29–32]. Based on data from the 2009 SC Pregnancy Risk Assessment Monitoring Surveillance (PRAMS), 46.5% of South Carolinian mothers gained excessive weight during pregnancy (48.9% of white women, 44.0% of African American women) [33].

Participants are recruited primarily through obstetrics and gynecology (OB/GYN) clinics, although self-referrals also occur in response to community-wide and social media advertisements. A total of 13 OB/GYN clinics were targeted for recruitment, 9 in the greater Columbia, SC area, 2 in Sumter, SC, 1 in Winnsboro, SC, and 1 in Charleston, SC. In these OB/GYN clinics, study advertisements are posted in waiting rooms and other highly-trafficked areas and trained research assistants, nursing staff, or reception staff ask participants to complete a one-page, 7-item screening form that assesses initial eligibility and provides permission for study staff to contact the participant. Initial eligibility criteria

are that the participant is 18–44 years of age, is white or Black/African American, can read and speak English, has no plan to move outside of the geographic area in next 18 months, is within first 16 weeks of pregnancy, and has a prepregnancy body mass index (BMI)≥25 kg/m^2 and a prepregnancy weight≤370 pounds. In addition to OB/GYN clinics, flyers are posted in other locations in the greater Columbia, SC area, including a large pediatric clinic, university bulletin boards, local grocery stores, childcare centers, Women, Infants, and Children (WIC) offices, Healthy Start offices, and other businesses commonly frequented by pregnant women. Study advertisements are also distributed through Craig's list, social media sites, such as Facebook, local parenting magazines, some of the participating clinics' websites, and some local events that are mainly targeting pregnant women or mothers with young infants. Interested women can complete the screening form on the study website or by telephone with study staff.

Study staff attempt to contact all women who are initially eligible, based on the initial screening form responses, for a more comprehensive telephone screening. The main purpose of the telephone screening is to identify and exclude women with contraindications to exercise [34, 35] and women who have substantial barriers that would preclude participation in the trial. Medical exclusions include uncontrolled blood pressure (>160 systolic or > 100 diastolic), use of insulin for diabetes, uncontrolled or untreated thyroid disease, hospitalization for a mental health or substance-abuse disorder in the past 6 months, multiple gestation, persistent bleeding in first trimester, history of more than 3 miscarriages, history of eating disorder or malnutrition, history of incompetent cervix, physical disabilities that prevent exercise, and physician advice to not exercise during pregnancy. Intervention-related exclusions are irregular or inconsistent access to a telephone and unwillingness to take part in weekly telephone calls.

Modeled after Goldberg and Kiernan [36], women who remain eligible based on the telephone screening are also guided through an interview in which they explore the pros and cons of the two study arms, barriers to participation in each study arm, and potential solutions to barriers regarding participating in the two study arms of the trial. The purposes of this interview, based on principles of motivational interviewing, are to ensure that participants are fully informed about the two study arms and what they entail, have an opportunity to think through challenges they may experience related to participation, determine whether these challenges can be overcome, and explore any ambivalence they might have about participating. Women who remain eligible and interested after the telephone screening and motivational interview are scheduled for a baseline visit.

The study enrolls women relatively early in pregnancy, and their health and pregnancy status may change as the pregnancy progresses. Therefore, at each measurement visit (two during pregnancy and two during postpartum), all participants are systematically screened for new symptoms or conditions since starting the program or since the participant's last study visit. In addition, if participants (irrespective of randomization group assignment) report a change in their health status at any other contacts besides measurement visits (e.g., phone calls, emails, letter to the study), a symptoms questionnaire is administered. Participants are withdrawn from the study if any of the following conditions occur: miscarriage, fetal loss, still birth, discovery of pregnancy with multiples after randomization, sudden death of

newborn, or delivery before 32 weeks gestation. With approval of the principal investigators (PI), participants who develop a condition that necessitates bedrest or limiting of PA during pregnancy but can safely participate in postpartum intervention activities are able to remain in the study. Examples of such conditions include uncontrolled pregnancy-induced hypertension (>160 SBP or >100 DBP); diagnoses of preeclampsia or eclampsia, placenta previa, incompetent cervix, or postpartum cardiomyopathy; severe mental disorder that requires hospitalization; heart attack; surgical procedures; injuries that prohibit exercise; and evidence of intrauterine growth restriction. For participants in the intervention group who develop a contraindication to exercise, no PA content is included in intervention contacts during pregnancy, but nutrition content is delivered as appropriate. In addition, the participant continues with all postpartum intervention-related activities if her conditions are resolved and it is safe to resume moderate-intensity PA. Similarly, if a woman becomes pregnant again within the first year of her index pregnancy, she continues in the study but her data will not be included for any outcome where her pregnancy status may influence the measure (e.g., postpartum weight).

All recruitment, enrollment, and retention data, including number of clinic screening forms completed, number of telephone screenings conducted, number of women eligible to participate, reasons for ineligibility, study visit completion rates (at each time point), and study withdrawals (by participant and by study), will be tracked in order to create a study flowchart consistent with CONSORT reporting guidelines [28].

2.3. Randomization

A stratified randomization procedure with blocking is used to balance randomization within four intended delivery hospitals (two hospitals in Columbia, one hospital in Charleston, one hospital in Sumter) and two racial groups, which resulted in eight subsamples of eligible participants. If the intended delivery hospital is outside of these hospitals, the hospital that is geographically closest is selected. For every four participants within each subsample, two are randomized to the behavioral lifestyle intervention group and two to the standard care group. The study statistician conducted this randomization with a SAS program that generated an assignment list for each subsample noted above. The assignment lists are stored electronically, and the Program Manager selects the first available number sequentially on the list when randomizing a new participant.

The participant ID, allocation assignment, and date of randomization are recorded. These lists can only be seen by the program manager, the study PIs, and the study statistician. Clinic staff, physicians, and measurement staff are blind to participant randomization. Randomization is done after the participant successfully completes all baseline measurement activities including the 2nd dietary recall and wearing the activity monitor according to protocol.

2.4 Behavioral Lifestyle Intervention

2.4.1 Intervention goals and theoretical framework—Consistent with guidelines for pregnant women, [35, 37, 38] participants randomized to the behavioral lifestyle intervention are encouraged to accumulate 150 minutes a week of moderate intensity PA

(e.g., brisk walking) and to eat a diet high in fruits, vegetables, and whole grains and low in saturated and trans fats, while also balancing caloric intake to match but not exceed dietary needs for pregnancy and lactation. The *MyPlate Daily Checklist for Moms* (formerly *Daily Food Plan for Moms)* [39] is used to help participants select a balanced diet that incorporates the higher needs for some vitamins and minerals [38]. Customized calorie goals are provided. GWG goals are consistent with the 2009 IOM recommendations: 15–25 lbs for overweight and 11–20 lbs for obese women [3]. During the postpartum period, participants are encouraged to lose 1–3 lbs/wk. They also receive feedback regarding achieving a healthy BMI, although even modest weight loss affords health benefits [40].

Intervention contacts begin prior to 18 weeks gestation and continue through 6 months postpartum. Many interventions for non-pregnant populations start with frequent contacts that lessen over time. In pregnancy, barriers to lifestyle change may increase over time; thus, intervention contacts occur weekly or biweekly. All intervention components are grounded in Social Cognitive Theory [41] but are tailored to the unique needs, interests, and barriers of pregnant and postpartum women. Formative work [42, 43] as well as the published body of literature in this area [44] guided our tailoring. The intervention helps participants learn to use behavioral skills and knowledge; self-regulate (set goals, self-monitor, problem solve, and use reinforcement); employ stimulus control strategies to prompt healthier choices; seek out social support; increase self-efficacy through setting and reaching progressive and attainable goals; identify high-risk situations and coping strategies; and prepare for and cope with setbacks. These strategies, while shown to be effective in changing PA and dietary intake in adults in general [45], have rarely been employed in combination in studies of pregnant and postpartum women, which could explain the modest weight outcomes in the literature [19, 27]. Frequent self-monitoring of PA, diet, and weight is strongly encouraged, as self-monitoring is positively associated with behavioral adherence [45–48]. Self-monitoring behavior is promoted through the use of bathroom scales (provided to participants) with GWG and postpartum weight loss tracking graphs, pedometers, and weekly paper logs. The paper logs include space for participants to record two behavioral goals for healthy eating and PA, and to indicate for each day (across seven days), whether that goal was met, not met, or partially met. The paper logs also ask participants to record their pedometer steps, minutes of exercise, and weight each day.

2.4.2 Intervention components—The intervention is comprised of two in-depth counseling sessions (one each in early pregnancy and early postpartum), weekly or biweekly telephone counseling, behavioral podcasts with accompanying educational handouts, and a private Facebook group.

2.4.2.1 In-depth counseling sessions: Most of the in-depth pregnancy counseling sessions take place in-person, although telephone sessions are provided for those participants who live too far away from the study office. The counseling session is the first intervention contact during pregnancy, typically lasts one hour, and occurs prior to 18 weeks gestation (and typically substantially earlier). The study interventionist provides feedback regarding the participant's dietary intake and PA (based on baseline dietary recalls and SenseWear armbands, described later). *MyPlate Daily Checklist for Moms* is used to support nutrition

content, including calorie and food goals. Supertracker, a tool on the choosemyplate website, provides caloric needs based on the participant's age, sex, level of physical activity, height, pre-pregnancy weight, and due date. Each participant receives a personalized dietary report (includes participant data along with dietary guidelines), a personalized PA report (e.g., daily and average steps, minutes of PA, sleep, and sedentary time), and a personalized weight gain tracking graph. The weight gain tracking graph contains upper and lower recommended weight gain lines drawn over time so that participants can plot their weight each week and see how it compares to their target weight gain. The interventionist helps the participant set an initial dietary and PA goal based on an area in which current behavior is not in line with study goals and clinical recommendations. Participants receive a binder of study handouts referenced in the podcasts and discussed during pregnancy calls 1 to 10, a pedometer for tracking PA, and a bathroom scale for regular self-monitoring of weight.

In postpartum, many of the in-depth counseling sessions occur in the participants' homes, but they are also provided in the study office or by telephone to accommodate participant preferences. This session takes place 6 to 8 weeks postpartum and lasts approximately one hour. The session focuses on setting goals for gradually resuming PA, meeting nutritional needs during postpartum, the benefits of breastfeeding for weight reduction, how nutritional needs are affected by breastfeeding, calorie targets for weight loss based on postpartum weight, and strategies for losing 1–3 lbs/wk. *MyPlate Daily Checklist for Moms* is used to support nutrition content. Supertracker, as described earlier, provides caloric needs based on the participant's age, sex, level of physical activity, height, postpartum weight, breastfeeding status, and the goal of promoting healthy weight loss. Similar to the GWG graph, all participants receive a personalized weight loss tracking graph that includes the upper (3 lbs/wk) and lower (1 lb/wk) bounds of recommended weight loss over time for six months. If this postpartum counseling session is conducted in the participant's home, the interventionist offers to do a kitchen tour and provides advice regarding food choices.

2.4.2.2. Telephone counseling: Our formative work [43] indicated that women desired group intervention sessions. Initially, the study included 10 weekly group sessions that began immediately following the in-person counseling session. However, due to the challenges in recruiting an adequate number of women at one time to form a group and the less-than-ideal attendance at sessions, a protocol change was made very early in the study to replace these 10 group sessions with 10 individual telephone counseling calls, allowing for rolling recruitment. When the protocol was changed from group sessions to telephone counseling, all of the content was retained; just the mode of delivery changed. Only one intervention group was conducted (n=6).

Each of the first 10 pregnancy telephone counseling calls lasts approximately 20 minutes. If a call is missed, the interventionist completes a makeup call where the content from two calls is combined in a longer call. Each call begins with a "weigh- in" where the participant reports her weight using the study-provided scale. She is encouraged to graph her weight on the weight gain tracking graph provided during the in-depth counseling session. The interventionist also plots the current weight on the HIPP copy of the weight gain graph. A discussion of where the participant's weight gain stands relative to the IOM GWG recommendations takes place. In the first call, detailed information regarding exercise safety

and warning signs during pregnancy is provided. In each subsequent call, participants are asked about any changes in their pregnancy and/or health status. Responses are documented and one of the study PIs is notified of any potential increased health risk. The medical monitor is consulted as needed. Each call then includes didactic information and discussion, and the interventionist refers to handouts in the participant's binder that correspond with the content (these handouts are also emailed to the participant each week). The call content is also complementary to the content in the podcast (described in a later section). Participants earn a small incentive (e.g., cookbook, baby products) each week if they complete the counseling call and listen to the podcast. Each call emphasizes at least one key behavioral strategy (e.g., goal setting) that is applied to PA and healthy eating. Calls are interactive, supportive, and engaging. Table 1 presents the call topics and behavioral strategies for each of the 10 weeks.

When the first 10 pregnancy calls end, participants receive shorter weekly or biweekly counseling calls (depending on their preference) throughout their pregnancy. The calls include a "weigh- in," assessment of changes in their pregnancy and/or health status, discussion of progress toward PA and healthy eating goals set in the previous call, problem-solving regarding barriers to reaching goals when needed, and PA and healthy eating goal setting for the next week. More frequent calls or the provision of additional resources can be provided for participants who are having difficulty reaching study goals.

After a participant delivers her baby, the interventionist calls the participant weekly for very brief check-in calls; weight, PA, and healthy eating topics are not discussed. After the participant's postpartum counseling session (at 6–8 weeks postpartum) and through 6 months postpartum, biweekly counseling calls are initiated to focus on postpartum weight loss. The structure of the calls is the same as the brief pregnancy counseling calls.

Each telephone call is audio-recorded (after consent of the participant in writing at the time of study consent, and verbally before each call start) to aid in supervision and monitoring of quality assurance.

2.4.2.3 Behavioral podcasts: Participants receive 10 behavioral podcasts during pregnancy and 16 during postpartum. Prior to each of the first 10 pregnancy calls, the participant is emailed (or sent via text message) a link to the corresponding podcast, and is also emailed the handouts for that week's call (also included in her binder). The email includes a summary sheet that lists each handout, anything that should be done prior to the call, a place to record questions for the interventionist, and a reminder of the incentive for completing the call and listening to the podcast for that week.

The pregnancy podcasts, which parallel the content of the first 10 in-depth telephone counseling calls, provide information on recommended weight gain in pregnancy, healthy eating, and PA through intervention dialog and an audio blog of two pregnant women attempting healthy weight gain. One voice is of an African American woman and the other of a white woman. Podcasts average 21 minutes in duration (range: 16–28) and contain an introduction and review of the previous week's topic, an audio blog, nutrition and PA information, inclusion of a behavioral strategy, and goal setting. The structure of these

podcasts was based on previous work that found podcasts effective for producing weight loss in non-pregnant adults [49, 50].

Beginning at 4 weeks postpartum, 16 weekly podcasts are delivered to participants. These podcasts follow the 16 core Diabetes Prevention Program sessions [40]. The content was tailored, as necessary, to take into account the unique barriers and motivators for postpartum women (e.g., fatigue, childcare needs, breastfeeding). These podcasts emphasize gradual weight loss (1–3 lbs/wk), achieving 150 minutes/wk of PA, and eating a healthy diet within energy intake limits. An audio blog of two new moms attempting weight loss is used. The women in the postpartum podcasts are different than those in the pregnancy podcasts, although one voice is still of an African American woman and the other of a white woman. Podcasts average 20 minutes in duration (range: 15–27) and contain an introduction and review of the previous week's topic, audio blog, nutrition and exercise information, a behavioral strategy, and goal setting.

For both pregnancy and postpartum podcasts, the participant is required to enter an ID and personal initials to download the podcast from a private website, which allows the study to track whether the participant clicked on that week's podcast. Midway through the week, reminder emails and texts are sent to participants who have not yet accessed the weekly podcast. Podcast links remain valid for the duration of the study, but participants are advised to listen to the podcasts in order of delivery as the storylines build throughout the episodes. Participants who are unable to listen to podcasts on a computer or a smartphone are mailed a copy of the audio podcast on a CD each week. Boomerang for Gmail (https://www.boomeranggmail.com/) was used to schedule weekly delivery of podcast emails and reminders.

2.4.2.4 Private Facebook group: Participants are encouraged to join a private HIPP Facebook group for pregnant participants during the in-depth pregnancy counseling session, and a private HIPP Facebook group for postpartum participants during the in-depth postpartum counseling session. During the postpartum in-depth counseling session (6–8 weeks postpartum), participants are removed from the HIPP pregnancy group and transitioned to the HIPP postpartum Facebook group. The private postpartum Facebook group continues through 6 months postpartum. The Facebook groups allow study participants to provide support to and receive support from other pregnant/postpartum women, and they are another vehicle for delivering messages and resources that reinforce intervention content. Intervention staff post one message per day (Monday through Friday) that reinforces behavioral skills, weight regulation (pregnancy), modest weight loss (postpartum), PA, and/or diet. Intervention staff view Facebook daily to ensure posts by participants are appropriate. Staff also respond to participant posts to encourage posting behavior.

There are five categories of posts (corresponding to each day of the week): (1) recipes, meal suggestions, or local sales; (2) pregnancy or postpartum health and safety; (3) tips or suggestions (e.g., baby care, parenting, exercise, nutrition); (4) links to exercise videos; and (5) victory related to health goal (not focused on weight). These categories were selected

based on previous work that used Facebook to engage participants during weight loss interventions [51, 52].

Facebook content for both pregnancy and postpartum is posted on a continuous cycle, but there is enough content to prevent it from being repeated for any given participant. Because the study uses rolling enrollment (and not cohorts), the content is not matched to gestational age or weeks postpartum. The posts were designed to be appropriate regardless of gestational age (for the pregnancy Facebook group) or postpartum weeks (for the postpartum Facebook group). Posts are prescheduled using Hootsuite (https://hootsuite.com/).

2.5 Standard care

Participants in the standard care group attend regularly scheduled clinic visits with their prenatal care providers, which typically occur monthly until 28 weeks gestation, biweekly from 28–36 weeks gestation, weekly from 36 weeks gestation until delivery, and at 6 weeks postpartum. Participants receive standard nutrition counseling provided by physicians, nurses, nutritionists, and counselors from the WIC program (if applicable). This counseling typically emphasizes a well-balanced diet and advice to take a multivitamin/iron supplement. Participants are weighed by nurses at each clinic visit but weight graphs are not provided as part of the standard care materials.

To enhance retention and keep participants engaged in the study, the standard care group receives study mailings and podcasts. Study mailings, six each in pregnancy and postpartum, are sent monthly. Each mailing includes a cover letter and a commercially available educational material. During pregnancy, the mailings begin two weeks after randomization and focus on tips for a healthy pregnancy and on fetal development. During postpartum, mailings begin four weeks after delivery and focus on infant development. None of the mailings at either period include discussions of weight, PA, or diet (except for foods to avoid in pregnancy for safety reasons).

Parallel to the intervention participants, standard care participants also receive 10 weekly podcasts during pregnancy and 16 weekly podcasts during postpartum that are similar in duration (pregnancy podcasts average 28 minutes, range: 17–39 minutes; postpartum podcasts average 22 minutes, range: 14–33 minutes) and identical in frequency and timing to the intervention group (see section 2.4.2.3). All podcasts are commercially available, do not include discussions of weight, PA, or diet (except for food safety issues), and focus on having a healthy pregnancy, fetal and infant development, and parenting. Participants who listen to at least 9 of the 10 podcasts receive a small incentive (e.g., baby wipes and bibs).

2.6 Outcome evaluation

All participants are assessed at baseline (≤16 weeks gestation), 32 weeks gestation, and 6 and 12 months postpartum. By default, all measurement visits occur at the university unless the participant expresses difficulty coming to the university and prefers to complete the visit in her home or at the prenatal clinic she attends. At each assessment, research staff obtains physical measurements (maternal weight, height, and blood pressure) and conducts interviewer-administrated questionnaires. Participants complete one dietary recall at the visit and complete the second dietary call on a random day after her visit within a week.

Participants receive a SenseWear armband that assesses PA to wear for eight consecutive days after the visit. At the 6- and 12-month postpartum visits, several anthropometric measures are also taken with the infants. A description of the primary outcome, secondary outcomes, and potential mediating variable measures and citations for validity and reliability are presented in Table 2. Small monetary incentives in the form of gift cards are provided following the completion of each study visit, with the value increasing slightly over time (range: $20 to $50 per visit; total if complete all visits: $140).

2.6.1 Primary outcome – total gestational weight gain—Total GWG is calculated as the difference between the weight recorded at delivery and self-reported pre-pregnancy weight on the initial screening questionnaire. Self-reported pre-pregnancy weight is highly correlated with measured weights (≥0.95), and the correlation is higher if collected in early pregnancy [53, 54]. Weight at delivery is abstracted from medical records after delivery. Because participants consent to a medical record review when they sign the informed consent form, we expect nearly complete study data for weight at delivery. Weight at last prenatal care visit will be used if delivery weight is not available.

2.6.2 Secondary outcomes—Unless otherwise noted, all secondary outcomes are assessed at baseline (≤16 weeks gestation), 32 weeks gestation, and 6 and 12 months postpartum. All intervention activities end at 6 months postpartum. Thus, 6-month postpartum outcomes (such as weight, diet, and physical activity) are used to evaluate our intervention's effectiveness, while 12-month postpartum outcomes are used to examine the maintenance of changes over time.

2.6.2.1 Weekly rate of weight gain and meeting IOM gestational weight guidelines: The weekly rate of weight gain in the second and third trimesters will be calculated by computing the change in weight from the baseline visit to delivery (or last available weight), and then dividing this number by the number of gestational weeks between the two time points (i.e., continuous outcome). Further, using the 2009 IOM recommended range of the weekly rate of weight gain for overweight or obese women, each participant will be classified as above (excessive), below (inadequate), or within (adequate) the IOM recommendation for weekly GWG (i.e., categorical outcome). Weight is measured with a Seca scale by trained research staff at the baseline measurement session. Prenatal clinic weights, weight at last prenatal care visit or at delivery, and gestational age estimates will be abstracted from medical records.

2.6.2.2 Postpartum weight retention: Postpartum weight retention is defined as 6- and 12-month postpartum weight, measured at study visits, minus self-reported pre-pregnancy weight at screening.

2.6.2.3 Pregnancy and postpartum physical activity: Both sensor-measured and self-reported PA are assessed. More emphasis will be placed in analyses on the sensor-measured PA because it is a more objective measure and not prone to recall biases. The self-report PA measure will offer additional information about the type of PA performed in our sample.

The SenseWear Armband contains a 2-axis accelerometer and four sensors to assess PA (including steps), energy expenditure, sleep, and total wear time. It has been validated, including in pregnant women [55–57]. Steps per day and minutes per week spent in moderate- to vigorous-intensity PA (MVPA) will be the main indicators of PA. Participants are instructed to wear the armband on their upper left arm over the triceps muscle for eight consecutive days (24 hours/day) and to only remove it for showers/baths, water activities, and monitor cleaning. They are instructed to record in a log when they remove or put on the monitor each day. Study staff call participants on the 2nd and 5th day to remind them to wear the device, answer any questions they have, and remind them to mail back the armbands. After the 8-day wearing period is over, the participants mail back the device and its accessories in a pre-paid envelope. In order to be enrolled (baseline) and receive the full study incentive (subsequent visits), the participant must wear the armband continuously for at least 5 days, including at least one weekend day, and the monitor must be worn on those 5 days for at least 21 hours/day. Participants are given the opportunity to rewear the monitor if they do not comply with the protocol or if there is an equipment issue.

The short form of the International Physical Activity Questionnaire (IPAQ) is used to assess hours per week of MVPA, walking, and sitting over the previous 7 days [58]. The short form was chosen to reduce participant burden, and has shown to have acceptable reliability [58, 59] and criterion validity [60] among adults. This questionnaire has also been validated with pregnant women [61–64].

2.6.2.4 Pregnancy and postpartum dietary intake: Twenty-four hour dietary recalls are conducted to assess dietary intake. Each participant completes two unannounced dietary recalls using the validated Automated Self-Administered 24-hour dietary recall (ASA24) [65, 66]. One recall is conducted for a weekday and one for a weekend (defined as Friday, Saturday, or Sunday). The first dietary recall is completed at the measurement visit where participants receive a brief training on how to complete the dietary recall (how to log on, how to enter food, etc.). Participants are notified to complete the second dietary recall via text, email, and telephone reminder. If a participant is unable to complete the second dietary recall on their own or does not have access to a computer or the internet, the second dietary recall is completed over the telephone with measurement staff.

Because GWG is our primary outcome, we focus on energy intake. Additional exploratory outcomes include fruit and vegetable intake; % calories from fat, saturated fat, and trans fat; servings per day of whole grains; servings/day of sugar sweetened beverages; grams/day of fiber; and diet quality (Healthy Eating Index [67]).

2.6.2.5 Health-related quality of life: Health-related quality of life is measured with the 12 item Short Form (SF-12), a widely used and validated instrument [68]. Health-related quality of life is assessed in eight areas: physical functioning, role physical (limitations due to physical problems), bodily pain, general health perceptions, vitality, social functioning, role emotional (limitations due to emotional problems), and mental health. Participants rate how often physical and emotional symptoms or experiences occurred over the past four weeks. Items are summed and yield both a physical and a mental component summary scale.

2.6.2.6 Offspring adiposity: Offspring's central and peripheral adiposity are assessed at 6 and 12 months postpartum. WHO's Child Growth Standards are used to determine infant's central and peripheral adiposity [69–71]. Specifically, we calculate sex- and age-specific percentiles and z-scores for the following indicators: weight-for-age, length-for-age, weight-for-recumbent length (WFL), BMI-for-age, head circumference-for-age, upper-arm length-for age, mid-upper arm circumference- for -age, triceps skinfold- for-age, and subscapular skinfold- for-age [69]. The sum of subscapular and triceps skinfold thickness and the ratio of subscapular to triceps skinfolds will also be used to measure adiposity. Trained research staff measure the weight, length, head circumference, mid-upper arm circumference, upper arm length, mid-upper arm circumference of infants according to the standard protocols used in NHANES [72] and the National Fetal Growth Study. Infant's subscapular and triceps skinfold thickness are measured using a Lange caliper. Three readings for each anthropometric measurement are taken at each site.

2.6.3 Mediating variables—All mediating variables are assessed at baseline (early pregnancy), 32 weeks pregnancy, and 6 and 12 months postpartum. These variables were selected because they have been shown to be mediators of behavior change in general adult populations [73] and/or important variables in predicting GWG in pregnancy [74], and they are consistent with the underlying theoretical model guiding the intervention.

2.6.3.1 Social support: Social support for exercise is assessed with the 13 items from the validated Friend Support for Exercise Habits Scale and the Family Support for Exercise Habits Scale [75] plus 3 additional pregnancy specific questions developed for this study ("Took over chores so I had more time to exercise," "Told me it is unsafe for me to exercise during pregnancy." "Told me I could harm my baby if I exercise too much during pregnancy."). For each item, participants rated separately how frequently family and friends did each activity in the past month on a scale of 1 (none) to 5 (very often).

Social Support for diet is assessed with the 10 items from the validated Friend Support for Diet Scale and the Family Support for Diet [75] plus 2 additional pregnancy specific questions developed for this study ("Told me I should eat more because I'm 'eating for two.'" "Commented that I have not gained enough weight in my pregnancy and I should eat more."). For each item, participants rated separately how frequently family and friends did each activity in the past month on a scale of 1 (none) to 5 (very often).

2.6.3.2 Self-efficacy: Self-efficacy for overcoming common barriers to exercise is assessed with Marcus and colleague's validated 5-item questionnaire [76]. Participants rate their confidence to overcome common barriers to exercise on a scale from 1 (not at all confident) to 7 (very confident).

Self-efficacy for overcoming common barriers to eating a healthy diet is assessed with the validated 10-item Self-Efficacy for Diet Questionnaire [77]. Participants rate their confidence to eat a healthy diet over the next month in situations that are challenging from 1 (not at all confident) to 4 (very confident).

2.6.3.3 Self-regulation: Self-regulation for exercise is assessed using the validated 10-item Exercise Goal-Setting Scale (EGS) and the 10-item Exercise Planning and Scheduling Scale [78]. Participants rate the extent to which each item describes them from (1) does not describe, (3) describes moderately, to (5) describes completely.

Self-regulation for diet was assessed using a 22-item scale from the HealthStyles survey [79]. Participants rated whether they used each of 21 strategies to control their weight in the past month (yes or no). They also reported how frequently they weigh themselves (ranging from never to every day).

2.6.4 Other variables

2.6.4.1 Sociodemographic, health, and pregnancy-related characteristics: A comprehensive history is obtained from each participant. Examples of sociodemographic characteristics assessed include age, education, income, race, marital status, household characteristics, health insurance status, WIC enrollment, and employment status. Health-related characteristics include participant's menstrual history, health behaviors (smoking, alcohol use, sleep). Pregnancy-related characteristics include gestational age, prenatal history, pregnancy intentions, breastfeeding intentions/behavior, breastfeeding beliefs, previous pregnancy history, infant details at postpartum (e.g., health concerns, feeding practices, childcare details, support received for child and house care, time spent in seated activities).

2.6.4.2 Satisfaction with body function and appearance: Body satisfaction is assessed at all study visits with a previously developed scale validated in a non-pregnant sample [80] where participants were asked to rate their satisfaction over the past 4 weeks with nine aspects of body appearance and function. This measure includes two subscales, satisfaction with body function (6 items) and satisfaction with body appearance (3 items). For each item, participants rate their satisfaction ranging from −3 (very dissatisfied) to +3 (very satisfied).

2.6.4.3 Perceived stress: Perceived stress is assessed at all study visits with the validated 4-item Perceived Stress Scale [81]. Participants rate how often in the past month they experienced the described thoughts or feelings, from 0 (never) to 4 (very often).

2.6.4.4 Depressive symptoms: Depressive symptoms (prenatal and postpartum) in the past seven days are assessed at all study visits with the widely used and validated 10-item Edinburgh Postnatal Depression Scale [82, 83].

2.6.4.5 General social support: General social support is assessed at all study visits with the validated 8-item modified Medical Outcomes Study Social Support Survey [84, 85]. Participants rate how often each type of support described in the item is available, ranging from 1 (none of the time) to 5 (all of the time).

2.6.4.6 Physical activity environment: The PA environment is assessed at baseline only with 11 items from the Physical Activity Neighborhood Environment Scale (PANES), also known as the IPS/IPAQ Environment Survey Module [86]. Six items were omitted due to

non-applicability in our population (3 on cycling, 1 on transit, 1 on four-way intersection, 1 on type of housing).

2.6.4.7 Food environment: Four aspects of the food environment are assessed at baseline: perceived accessibility (3 items) [87], perceived neighborhood food availability (4 items) [88], perceived in-store availability (4 items) [87], and perceived in-store affordability (4 items modified from the in-store availability items [87]). Participant rate their agreement with each item, ranging from (0) strongly agree to (4) strongly disagree.

2.6.4.8 Food insecurity: Food insecurity is assessed at all study visits with the 6-item short form of the Household Food Security Scale [89]. These are the same items used in the U.S. Household Food Security Survey Module: Six-Item Short Form created by the USDA [90].

2.6.4.9 Fast food consumption: Fast food consumption is assessed at all study visits with one item from the Early Childhood Longitudinal Study [91]. Participants rate how often in the past 7 days they ate a meal or snack from a fast food place (examples provided) on a scale ranging from 0 (I did not eat food from a fast food restaurant during the past 7 days) to 6 (4 or more times per day).

2.7 Process evaluation

The process evaluation: (a) examines the extent to which the intervention takes place and in a timely manner; (b) examines whether intervention activities are consistent with the theory and logistics underlying the theoretical model (Social Cognitive Theory); (c) provides guidance concerning necessary adjustments to the intervention; and (d) monitors intervention fidelity.

A Microsoft Access database was developed to track the delivery of all intervention activities to each participant (see Section 2.4). Thus, activities are tracked at the individual level, and type of data captured include not only the delivery of the activity, but where applicable, the duration of the activity (e.g., telephone call), information reported by the participant (e.g., weight, major barriers), and progress notes from the interventionist.

All intervention counseling calls are audio-recorded. These audio recordings are used to review the quality of delivery, provide feedback to interventionists, and train new interventionists. A subsample of calls will be selected for review to ensure the inclusion of essential elements.

For both the pregnancy and postpartum Facebook groups, we will capture the number of “likes,” responses to polls, and participant posts. If staffing allows, the nature of these posts (e.g., type of support provided) will also be coded.

For both the intervention and standard care groups, the date each podcast was sent and whether the participant logged on to private website and downloaded each podcast is tracked. For standard care participants, the date each mailing was sent is tracked.

Intervention and standard care participants complete a process evaluation survey at the 32-week gestation visit and at the 6-month postpartum visit. Structured and open-ended

questions assess most/least liked aspects of the intervention, recommendations for intervention modification, perceived usefulness of components of the intervention, and factors helped and hindered behavior change.

2.8 Safety monitoring

The risks of participating in this study are low. We are promoting healthy eating, active living, and appropriate weight gain that are endorsed and recommended by groups such as the American College of Obstetrics and Gynecology [35, 37, 38]. In our feasibility study, no participants reported adverse outcomes associated with participation [43].

Potential participants are closely screened and those with health conditions that would be contraindicated for participation in our intervention activities in general or specific to pregnancy are excluded from the study. These exclusion criteria are based on the Physical Activity Readiness Questionnaire for pregnancy and ACOG guidelines [34, 35].

Intervention contacts emphasize the safety of participants by promoting the idea of “going at one’s own pace” and “starting low and going slow.” Participants receive information about exercise safety and warning symptoms. Participants who are breastfeeding are given special attention to ensure that they are obtaining adequate caloric and nutrient intake. Intervention staff consult with the medical director in instances where there is concern for the participant’s safety. Referrals are made to the federal (e.g., WIC) or other local food assistance programs if participants experience food insecurity, and those with elevated levels of pregnancy or postpartum depression receive feedback on their elevated score, encouragement to consult with their health care provider regarding their symptoms, and crisis referral numbers.

All participants (irrespective of randomization group assignment) complete a questionnaire of symptoms and significant medical conditions that the participants experienced *since joining HIPP study or since their last visit*. This form is completed at the 32-week visit and at the 6- and 12-month postpartum visits. It is also completed if a significant health issue is raised during an intervention or standard care contact outside of the measurement visit. Adverse events forms are completed and reviewed by the medical director in instances where the participant reports any of the following: heart attack, broken bone, torn ligament, fall requiring medical attention, any hospitalization, doctor-ordered bedrest, miscarriage, or still birth. Adverse events that are unexpected (nature, severity, or frequency) and related or possibly related to participation in the research are reported to the Institutional Review Boards.

2.9 Sample size justification

The primary study outcome is total GWG (lbs). Effect size estimates and standard deviations for the proposed study came from the 2009 SC birth certificates for overweight/obese African American and overweight/obese white women after adjustment for pre-pregnancy BMI. Because weight at delivery is determined by medical record abstraction, we anticipate nearly complete data for the primary outcome. With the planned sample size of 400 women, and assuming a two-sided α=0.05, we have greater than 80% power to detect a 4.5 lbs difference in total GWG between intervention and standard care participants, corresponding

to a small effect size of 0.28. We anticipate that the power will be greater (or the detectable difference smaller at 80% power) because of reduced variability when controlling for other factors.

Assuming 90%, 80%, and 70% completion of measurements at 32 weeks, and 6 and 12 months postpartum, with our planned sample size, we have 80% power to detect an odds ratio of 0.60 for exceeding the IOM recommendation, that is, if 52% of standard care women exceed the IOM recommendation (SC 2009 birth certificate data), we would expect only 39% of women in the intervention to exceed the recommendation. We also have at least 80% power to detect small to medium effect sizes (d = 0.28 to d = 0.34) [92, 93] for each of the other continuous secondary outcomes.

For examining race differences in our primary and secondary outcomes, we have to take into account expected means in each of the four groups (African American standard care, African American intervention, White standard care, White intervention). We estimate that effects will be twice as favorable in Whites as compared to African Americans. A sample size of 400 would provide 64% power to detect a small effect size for our primary outcome of interest (GWG). For the other study outcomes, there is 52% to 75% power to detect small to medium effect sizes. Data for power and effect size calculations come from the 2009 SC birth certificates data (weight gain), our feasibility data (PA and caloric intake), and other literature for weight retention, black/white differences, postpartum depression scores, and WFL z-score [15, 54, 94, 95].

2.10 Statistical analyses

Intent-to-treat analyses will be used to examine differences in all outcomes for the intervention and standard care groups.

2.10.1 Primary outcome—We plan to conduct analyses of variance (ANOVA) for total weight gain (primary outcome), with total weight gain (continuous outcome) as the dependent variable and group membership plus potential confounding variables as independent variables. Race will be considered as a potential confounder if there is differential attrition by race.

2.10.2 Secondary outcomes—We will examine the categorical outcome of meeting the IOM recommendation for weight gain during pregnancy (secondary outcome) using logistic regression (exceeds recommendation versus does not exceed, basis of power calculation) and multinomial logistic regression (inadequate, adequate, excessive) with adequate weight gain as the reference group. For the remaining continuous secondary outcomes (rate of weekly weight gain, postpartum weight retention, PA, energy intake, QOL, WFL z-scores, and skinfold thickness), separate ANOVA models will be estimated with each secondary outcome as the dependent variable and intervention and other corresponding covariates as independent variables. Race will be considered as a potential confounder for all the analyses except those addressing our third aim (focused on examining race differences), and included where needed. Because many covariates are measured at multiple time points, the covariates used as independent variables are either those prior to or concurrent with the respective outcome variable.

For 6-month postpartum weight retention, we will first conduct analyses with available data. We will then use a conservative approach of carrying forward the last measurement (e.g., weight at delivery) in instances of missing data, thus assuming no change in the outcome of interest. We also will explore patterns of weight gain and weight retention by considering multiple weight measures from pre-pregnancy or baseline, to postpartum measures.

To examine our third aim, which focuses on racial differences for the various outcomes, we will first examine the interaction between race and group assignment. If the interaction term is statistically significant at the 0.05 level, we will consider the four intervention/racial groups as a single variable. Otherwise, no race-stratified results will be presented. Given the lower power of the study to detect the interaction term, a higher p-value (e.g., <0.20) might be used.

2.10.3 Mediation analyses of primary and secondary outcomes—Mediation analyses will be conducted to examine whether key constructs in Social Cognitive Theory (social support, self-efficacy, and self-regulation for PA and diet) mediate the relationship between group assignment and the primary (GWG) and selected secondary outcomes (rate of weekly GWG, postpartum weight retention, PA, and energy intake). MacKinnon et al.'s [96, 97] product of coefficients approach will be used to test for the indirect effects of each hypothesized mediator (noted earlier and described in section 2.6.3) on these primary and selected secondary outcomes. To assess the magnitude of the effect for each potential mediator, asymmetric confidence limits based on the distribution of the product (α and β coefficients) will be constructed using the PRODCLIN program [97]. This method considers the non-normal distribution of the mediated effect by constructing upper and lower confidence limits based on the distribution of the product of two normal random variables. This approach has been shown to be more powerful than other analytic approaches in simulation studies [96, 98].

3. Discussion

Half of all women of childbearing age are overweight or obese [4, 99]. Obesity and excessive GWG put women and their offspring at risk, both in pregnancy and in later life [1, 7, 12, 100, 101]. The resultant health services costs for pregnant women and their offspring are considerable [102, 103]. Thus, the rising prevalence of maternal overweight/obesity and excessive GWG poses a serious public health concern. Preventing excessive GWG to optimize maternal, fetal, and infant well-being is of great importance.

The HIPP study is significant because of its focus on evaluating the effectiveness of a behavioral lifestyle intervention program on reducing excessive weight gain during pregnancy and promoting postpartum weight loss among overweight/obese women. There are a number of unique and innovative aspects of this trial. First, it is theoretically-grounded and based on formative work [42, 43], using evidence-based behavior change strategies [45] delivered through traditional intervention channels (i.e., in-person and telephone-based) along with more innovative intervention channels (i.e., podcasts and social media support). Intervention messages are thus tailored to women from a southeastern state with poor maternal and child health indicators [32]. Second, the intervention fully targets PA in

addition to healthy eating. Third, it includes state-of-the-art measures including staff-assessed weight at multiple points during pregnancy and during the first year after delivery, objectively measured PA, 24-hour dietary recalls, and rich data on psychosocial factors, biomedical and environmental factors related to weight gain and behavioral lifestyles. This rich source of data will be useful to evaluate the impacts of our trial on primary and secondary outcomes as well as to identify possible pathways. Fourth, our study population is unique in that we include racially diverse women who are overweight or obese. Prior studies are modestly effective in helping this high-risk group to decrease total weight gain during pregnancy [19, 25, 27], limiting our ability to translate interventions to reduce the proportion of women gaining above IOM's recommended amount. To our knowledge, no studies have paid attention to the possible differential effectiveness of the trial in white and African American women. Fifth, the HIPP study spans from early pregnancy to one year postpartum. Pregnancy is a critical time when women are open for health messages and willing to adopt healthy behaviors. Yet women in this life stage also have barriers for them to effectively adopt healthy lifestyles. Thus, by emphasizing the maintenance of healthy behaviors and weight management skills after delivery, this study has the potential to improve long-term health outcomes for these high-risk women, which can be translated to better health outcomes for their offspring and the family as a whole. Finally, by including offspring measures of weight and adiposity, we can further examine the intervention's effect on offspring's adiposity, an important contribution as much of the research examining maternal weight in relation to offspring adiposity to date is based on observational studies [13].

There are limitations in the research design that should be noted. First, based on our formative work, women expressed a preference for a group-based intervention delivery. Thus, the original intervention included two in-person sessions, 10 group sessions, telephone counseling, podcasts, and Facebook support. Due to the hardship of forming a group of about 10 women in a timely fashion, the need to start weight gain monitoring in early pregnancy, and prospective participant and enrolled participants' unwillingness to come to the group session, we had to replace the 10 group sessions with individual telephone sessions (content remained the same). Second, due to the somewhat intensive nature of the intervention and long follow-up duration, we may not enroll women representative of the population of pregnant women. Instead, we may be biased toward enrolling more educated women with fewer barriers, such as transportation. Third, and related, we are enrolling from several towns and cities in South Carolina, and our recruitment is limited to African American and white women. Thus, our findings may not generalize to other regions of the United States (and beyond) and to other racial and ethnic groups.

In spite of these limitations, the HIPP study is innovative and the findings from the study will be helpful to examine the effectiveness of a behavioral intervention in a racially diverse sample of pregnant women. Given that the intervention is theory-based, targets both diet and PA, offers weight gain graphs, provides individualized plans, and is tailored for the unique needs and barriers to behavioral changes for pregnant and postpartum women living in South Carolina, our behavioral lifestyle intervention program provides an important opportunity to evaluate the effectiveness of such an intervention on preventing excessive weight gain during pregnancy, promoting weight loss after delivery, and advancing positive physical health for the mothers and their offspring.

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Table 1

Topics Covered on the First 10 Pregnancy Telephone Counseling Calls

Call #	General content	Behavioral strategy	Dietary skill /topic	Exercise skill /topic
1	• Study and call overview	• Benefits (outcome expectations)	• Healthy eating during pregnancy • Benefits of healthy eating during pregnancy • Rate your plate (RYP)	• Benefits of exercise during pregnancy • Exercise safety
2		• Setting goals • Self-monitoring	• Fruits & veggies	• Using a pedometer
3		• Problem • solving	• Myths & realities of diet during pregnancy • Whole grains	• Myths & realities of exercise during pregnancy
4	• Breastfeeding			
5		• Enlisting social support	• Meal planning • Choosing healthy protein	
6		• Dealing with emotions	• Shopping on a budget • Grocery shopping with families	• Exercise intensity
7		• Stress management		• Yoga
8		• Time management	• Label reading • Calcium / Vitamin D	
9		• Relapse prevention	• · - Eating out / fast food tips	
10	• Review of skills /topics that were most useful	• Setting goals (postpartum) • Planning /relapse prevention (postpartum)	• Healthy snacking & beverages	• Exercise options with baby • Keeping it fun

Table 2

Primary and Secondary Outcomes and Mediating Variables

Variable	Description	Assessment Method	Assessment Time*	Reference
Primary Outcome				
Total gestational weight gain	Difference between the delivery weight and pre-pregnancy weight (lbs). Weight at last prenatal care visit is used if delivery weight is not available.	• Delivery weight: medical record abstraction • Pre-pregnancy weight: self-reported at initial screening	S, Chart	Validity of self-report measure: • Oken et al [53] • Phelan et al [54]
Secondary Outcomes				
Meeting IOM GWG guidelines and weekly rate of GWG	Difference between delivery weight or weight at last prenatal care visit and measured baseline weight divided by number of gestational weeks; compared to 2009 IOM recommended weekly rate of weight gain (excessive, adequate, or inadequate)	• Delivery weight: medical record abstraction • Study starting weight: staff assessed with Seca scale	B, Chart	IOM Guidelines [3]
Postpartum weight retention	• Difference between weight at 6 months and pre-pregnancy weight (lbs) • Difference between weight at 12 months and pre-pregnancy weight (lbs)	• 6 and 12 months: staff assessed • Pre-pregnancy: self- reported	S, 6M, 12M	
Pregnancy and postpartum physical activity	Steps/day and minutes/ week spend in moderate- to vigorous- intensity physical activity	• SenseWear Armband worn continuously for at least 5-days wearing (≥1 weekend day) and having at least 21 hours/day of on- body time (main focus) • Self-reported via the International Physical Activity Questionnaire	B, 32W, 6M, 12M	• Johannsen et al. [55] • Smith et al [56] • Berntsen et al [57] • Craig et al [58]

Variable	Description	Assessment Method	Assessment Time*	Reference
		(secondary focus)		
Pregnancy and postpartum dietary intake	Main variable (averaged over two days): caloric intake per day. Exploratory variables (averaged over two days): fruit and vegetable cups per day; % calories from total fat, saturated fat, and transfat; servings per day of whole grains; servings per day of sugar sweetened beverages; grams/day of fiber; diet quality (HEI)	• 2 24-hour unannounced dietary recalls (one weekday and one weekend day) assessed via the Automated Self-Administered 24- hour Recall (ASA24)	B, 32W, 6M, 12M	ASA24: • Kirkpatrick et al [65] • Subar et al [66] HEI: • Guenther et al [104]
Health- related quality of life	Health-related quality of life in eight areas used to create two scores: physical component summary score (PCS) and mental component summary score (MCS).	• Interview-administered self- report measure: The Short Form health survey (SF-12) • 12 items • The raw scores of each item are coded, weighted, and summed to create the two composite scores	B, 32W, 6M, 12M	Ware et al [68]
Offspring adiposity	Measures of offspring adiposity are weight, weight-for-recumbent length (WFL), BMI, mid- upper arm circumference, triceps skinfold, and subscapular skinfold	• All staff assessed • Weight assessed with digital baby scale (Tanita Model 1584) • Recumbent length assessed with Infantometer (SECA 417) • Head circumference and mid-upper arm circumference assessed by infant head tape measure • Upper arm length and mid-upper arm length measured with woven tape measure (ADC item 396)	6M, 12M	• WHO Child Growth Standards [69, 71] • NHANES Anthropometry Procedures Manual [72] • Grummer-Strawn et al [70]

Variable	Description	Assessment Method	Assessment Time*	Reference
		• Triceps and subscapular skinfolds measured with a Lange caliper • Using WHO's Child Growth Standards, sex- and age-specific percentiles and z-scores are computed for each measure		
Mediating variables				
Social support for exercise	Frequency with which friends and family are supportive of the participant's exercise	• Interview-administered self- report measure: Friend Support for Exercise Habits Scale and Family Support for Exercise Habits Scale plus 3 additional items created for pregnancy • 16 items, rated for both family and friends • Each item rated for frequency on 5-point Likert scale and averaged across items	B, 32W, 6M, 12M	Sallis et al [75]
Social support for healthy eating	Frequency with which friends and family are supportive of the participant's healthy eating	• Interview-administered self- report measure: Friend Support for Diet Scale and the Family Support for Diet plus 2 additional items created for pregnancy • 12 items, rated for both family and friends • Each item rated on a 4-	B, 32W, 6M, 12M	Sallis et al [75]

Variable	Description	Assessment Method	Assessment Time*	Reference
		point Likert scale and averaged across items		
Exercise self- efficacy	Confidence for overcoming common barriers to exercise	• Interview-administered self- report measure • 5 items • Each item rated on a 7-point Likert scale and averaged across items	B, 32W, 6M, 12M	Marcus et al [76]
Diet self- efficacy	Confidence for overcoming common barriers to eating a healthy diet	• Interview-administered self- report measure: Self-Efficacy for Diet Questionnaire • 10 items • Each item rated on a 4-point Likert scale and averaged across items	B, 32W, 6M, 12M	Sallis et al [77]
Exercise self- regulation	The extent to which self-regulation (setting goals and planning/ scheduling) skills are used for physical activity	• Interview-administered self- report measures: Exercise Goal- Setting Scale and Exercise Planning and - Scheduling Scale • 10 items per scale • Each item rated on a 5-point Likert scale and averaged across items	B, 32W, 6M, 12M	Rovniak et al [78]
Diet self- regulation	The use of weight control strategies and frequency of weighing	• Interview-administered self- report measure: Scale from the HealthStyles survey • 22 items • Participants report (yes/no)	B, 32W, 6M, 12M	Kruger et al [79]

Variable	Description	Assessment Method	Assessment Time*	Reference
		whether they used each of 21 strategies to control weight. Also rate frequency they weight themselves (range: never to every day)		

*B = baseline visit (≤16 wks of gestation); Chart = medical chart review after delivery; S = screening; 32W = 32-wk visit (32–34 wk of gestation); 6M = 6-month postpartum visit; and 12M = 12-month postpartum visit.