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Protocol for Human Subject Research

Protocol Title:

Healthy Mom Zone: Control Systems Engineering for Optimizing a Prenatal Weight Gain Intervention Study 2
Short title: Healthy Mom Zone Study 2

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Version Date:

October 28, 2015; December 18, 2015; February 26, 2016; March 29, 2016; April 27, 2016, June 9, 2016, September 1, 2016; October 24, 2016; March 30, 2017; April 4, 2017, May 8, 2017; June 29, 2017; July 25, 2018

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Table of Contents

1.0 Objectives

1.1 Study Objectives

Purpose: The proposed overall research aims to establish feasibility of delivering an individually-tailored, behavioral intervention to manage gestational weight gain [GWG] that adapts to the unique needs and challenges of overweight/obese pregnant women [OW/OBPW] and will utilize control systems engineering to optimize this intervention; in other words, make this intervention manage GWG in OW/OBPW as effectively and efficiently as possible.

Aim 1: This application is to conduct the second study of the research plan (Study 2) to (a) test an individually-tailored behavioral intervention (including components of physical activity, healthy eating, goal-setting, self-monitoring, and GWG management) with decision rules for when and how to adapt dosages for an individual and (b) the randomization, participant retention, and data collection procedures with an intervention (treatment) and control groups in a cohort of OW/OBPW from approximately ~6-35 weeks gestation; with follow-ups through delivery to 6-weeks postpartum. We hypothesize that women in the intervention group will have more positive eating and activity behaviors and psychosocial and behavioral outcomes as well as manage their GWG better compared to controls.

Aim 2: R56: To prospectively characterize the effects of the intrauterine environment on fetal growth and infant birth weight. Detailed, prospective data collection on Healthy Mom Zone participants offers the novel opportunity to (a) assess how the intrauterine eating and physical activity environment impacts fetal growth and (b) explore the effects of our GWG intervention on fetal growth and infant weight. We hypothesize that by changing the maternal prenatal eating/physical activity environment, a critical time in the lifecycle, we will observe differences between intervention and control mother-infant dyads on in utero markers of fetal growth and

infant birth weight. R56: In addition, we will explore how individual differences in maternal sleep duration, hydration, and stress impact fetal growth and development and infant birth weight.

Aim 3: To use data collected from Aim 1 and control systems engineering to build a model that characterizes the effects of energy balance and planned/self-regulatory behaviors on GWG over time and use this model to develop an optimized intervention. We will also use the data collected in Aim 1 and 2 to build and validate dynamical systems models that characterize fetal growth and infant birth weight as well as how fetal weight respond to changes in maternal sleep duration and stress.

1.2 Primary Study Endpoints

Gestational Weight Gain [GWG] – amount of weight gained over the course of the total pregnancy as well as in smaller time points such as weekly, monthly, and in the pregnancy trimesters and weight behaviors

1.3 Secondary Study Endpoints

Healthy eating [HE] and physical activity [PA] behaviors
Self-regulation behaviors
Sleep behaviors
Adult temperament
Psychological well-being (body image satisfaction, depressive symptoms, anxiety, perceived and actual stress)
Motivational determinants of HE and PA (attitude, social norm, perceived control, self-efficacy, intention)
Social-demographic and health correlates (e.g., age, pregnancy history, etc.)
Fetal growth, weight, height, birth weight, postnatal weight
Mobile resting metabolic rate, basal metabolic rate, metabolism
R56:
C-reactive protein/micronutrients (e.g., folate)
Maternal and infant labor and delivery complications
Maternal/Fetal hydration
Maternal/Fetal medical record data

2.0 Background

2.1 Scientific Background and Gaps

Managing gestational weight gain (GWG) offers immediate and lifelong health benefits such as reduced risk for pregnancy complications and metabolic syndrome in mothers, adverse birth outcomes, and CVD/obesity in both mothers and offspring.[1] Because overweight/obese pregnant women (OW/OBPW) often exceed the GWG guidelines,[1-4] managing weight gain in this population is critical. Intervention components of education, behavior modification, and healthy eating/physical activity behaviors have effectively controlled weight in non-pregnant[5-7] and in normal weight pregnant women.[8-10] However, they have been less useful at preventing high GWG in OW/OBPW in part because they have challenges with managing weight and may require a more hands-on and intensive approach [GAP #1]. An individually-tailored intervention that provides OW/OBPW with support for managing GWG on a weekly basis and is adapted to their unique needs over the course of pregnancy may be a highly promising way to prevent high GWG. For example, a woman exceeding GWG goals may require a higher dosage than a woman who is adequately managing her weight and there are likely individual differences in the points during pregnancy this dosage will need to be tailored. Because the specific dosage needed to prevent high GWG in OW/OBPW is not well understood, there is a critical need for research in this area [GAP #2]. Our multidisciplinary team has the expertise to develop this individually-tailored intervention.

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2.2 Previous Data

We have synergistically integrated methods and key principles from behavioral intervention, psychology, engineering, statistics, mathematics, physiology, biology, kinesiology, and nutritional sciences to construct a framework for an individually-tailored intervention that relies on principles from behavioral theory (planned behavior and self-regulation), energy balance, and control systems engineering (dynamical modeling, system identification, controller design) to moderate GWG in OW/OBPW.[11] Intervention program components of education, goal-setting, self-monitoring, and engaging in healthy eating/physical activity (HE/PA) behaviors are informed by past research[5-10,12,13] and evidence from the labs of the PI, Dr. Downs on explaining HE/PA behaviors with the Theory of Planned Behavior and interventions to promote prenatal health (e.g., Active MOMS DK075867-02)[14-22] and from the Co-I's, Drs. Savage and Rolls on effective weight management using a low energy density diet.[23-30] A mathematical energy balance model and computer-based applet developed by Drs. Rivera (Co-PI), Thomas (consultant), and Collins (Co-I) will be used to forecast GWG as a teaching tool to guide feedback in real time for GWG monitoring.[31] E-health technology tools will be used for self-monitoring of GWG and healthy eating/physical activity behaviors. Principles from adaptive intervention design (Collins)[32] and control systems engineering (Rivera)[33] will inform program dosages to manage GWG over time for each subject.

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2.3 Study Rationale

The research proposed here will establish the dosage of components needed to impact GWG and develop an efficient (optimized) intervention to effectively manage GWG in OW/OBPW before a randomized controlled trial (RCT) can be implemented.

Rationale for expanding recruitment to normal weight (body mass index 18.0 to 23.9) women: this control-only alternative will be offered to women who are not eligible for the intervention study because their body mass index is below the current cut-off of 24.0. The purpose of extending the control group is to fulfill the target enrollment for the ancillary grant (1R56HL126799-01).

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

- Pregnant women
- Overweight or obese [body mass index range 24- >40 (if BMI is > 40, consultation with woman's health care provider (PCP/OBGYN) will be made to determine eligibility and ensure she does not have any contraindications to exercise) PI Danielle Downs will have

communication with Dr. Hovick from MNPG to give information on the woman. We also have a physician consent form (see Physician Patient Consent to Participate in documents) that the physician will complete as to whether the woman is eligible or not eligible to participate.

- Normal weight women with a body mass index range of 18.0 to 23.9 can be enrolled in to the study as control participants (same measures of data collection, no opportunity for intervention).
- Ages 18-40 years [based on our pilot data this group comprises >85% of the live births in Central Pennsylvania]
- 1st, 2nd or 3rd pregnancy 6-16 weeks gestation
- Able to read, understand, and speak English
- Residing in and around State College, PA
- 1st and 2nd time pregnant mothers [none or one other live or still born, biological children > 25 weeks gestation prior to this pregnancy; it may be conceivable that a woman has a blended family due to a mixed marriage and she will not be excluded if she is a parent to a guardian, foster child, or step child]
- Access to a computer or willingness to come onsite to complete study materials
- Infants born to participants who are 6-10 weeks old

3.2 Exclusion Criteria

- Having more than one live or stillborn child > 25 weeks gestation; late-term pregnancy loss
- Diabetes at study entry [while future adaptations of this study will target women with diabetes, for the pilot study, they will be excluded to control for this confound]
- Contraindications to exercise in pregnancy [Hemodynamically significant heart disease, Restrictive lung disease, Incompetent cervix/cerclage, Persistent second [or third] trimester bleeding, Placenta previa after 26 weeks of gestation, Premature labor during the current pregnancy, Ruptured membranes, Preeclampsia/pregnancy-induced hypertension] per the ACOG guidelines [ACOG Committee on Obstetric Practice. [(2015, December). ACOG Committee opinion. Number 650: Physical Activity and Exercise During Pregnancy and the Postpartum Period. *Obstetrics and Gynecology, 126,*(6), 135-142].
- Having a body mass index less than 18 or over 40 (exclusion only if physician doesn't provide consent for BMI is over 40)
- Not planning to live in the area for the study duration
- Severe allergies or dietary restrictions that would preclude eating healthy foods
- Not able to read, understand, and/or speak English
- Cognitively impaired
- Currently smoking
- Infants not born to participants
- Infants younger than 6 weeks old

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

Safety reasons (develops a contraindication to exercise in pregnancy right after recruitment that would exclude her participation from the study; develops a fetal abnormality that requires her to withdrawal from the study per her provider's recommendation)
Failure of subject to adhere to protocol requirements (e.g., not completing assessments and intervention sessions)
Subject withdrawals from study
No returned contact from the subject after recruitment
Pregnancy loss [e.g., miscarriage after recruitment]

3.3.2 Follow-up for withdrawn subjects

Subjects will be withdrawn from the study based on the criteria listed above. We will make multiple attempts to contact the subjects who fail to return contact after recruitment [our general protocol is to call and email 3 times over a 2-week period, send 1 post card reminder the following week, make 1 additional call and if no contact, the subject is removed from the study] and her data will be coded as loss to follow-up. If a woman is removed for safety reasons, failure to adhere to protocol requirements, or withdraws from the study on her own, we will ask if we are able to continue to follow-up with her for the post-intervention assessments she is willing to complete. If the answer is NO, we will not contact the subject and keep the data that we have collected which will be coded as no follow-up. If the answer is YES, we will maintain protocol contact as applicable (e.g., email/phone) and obtain the appropriate follow-up measures (e.g., completing surveys) and these data will be coded as withdrawal-follow-up.

Subjects will be replaced in study 2 (randomized) according to the randomization scheme. Co-I, Allen Kunselman, HMC, is in charge of the randomization scheme.

4.0 Recruitment Methods

4.1 Identification of subjects

A study recruitment letter will be given to pregnant women who attend Mount Nittany Physician Group. Interested women will provide their contact information on the form and put it in a locked drop box in the waiting room. These forms will be picked up on a weekly basis by a study staff member. In addition, MNPG clinicians may tell their patients about our study and provide them with study information (phone number of a study staff member to contact for more information; website information). If women are interested, a screening process will take place right in the office. These screenings will be performed by the Research Coordinator or a member of the study team. The study team member will be trained in proper screening protocol. Screening will be done in a closed room in the doctor's office for privacy. Recruitment at Geisinger Grey's Woods OB/GYN office will also take place. If screening doesn't take place in the office, a phone screening will take place. Flyers will be available for women to contact for more information. We will also advertise for the study through public websites, hanging flyers at local businesses, and paper/radio advertisements. Infants of women who participated in the Healthy Mom Zone will be brought in to Noll Laboratory 6-8 weeks after birth.

4.2 Recruitment process

A study recruitment letter will be given to pregnant women who attend Mount Nittany Physician Group. Interested women will provide their contact information on the form and put it in a locked drop box in the waiting room. These forms will be picked up on a weekly basis by a study staff member. In addition, MNPG clinicians may tell their patients about our study and provide them with study information (phone number of a study staff member to contact for more information; website information). If women are interested, a screening process will take place right in the office. These screenings will be performed by the Research Coordinator or a member of the study team. The study team member will be trained in proper screening protocol. Screening will be done in a closed room in the doctor's office for privacy. We will also hang flyers in the waiting room and examination rooms with pull off tabs with study information. Recruitment at Geisinger Grey's Woods OB/GYN office will also take place. If screening doesn't take place in the office, a phone screening will take place. Flyers will be available for women to contact for more information. We will also advertise for the study by hanging tear-off flyers at local businesses, and paper/radio/website advertisements.

4.3 Recruitment materials

We will use a study interest/contact form, flyers, tear-off flyers, and paper/radio/website advertisements. I have included these documents as uploaded material.

4.4 Eligibility/screening of subjects

Interested women who call the laboratory phone number from the recruitment documents will be screened by phone by a study staff member. Women who provide their contact information on the study interest form will be called by a study staff member for screening. If women are interested at MNPG, they will be screened at the office. If eligible, the scheduling of the initial baseline visit will be done at that time. These screenings will be performed by the Research Coordinator or a member of the study team. The study team member will be trained in proper screening protocol. Screening will be done in a closed room in the doctor's office for privacy. In addition, the initial scheduling of the baseline visit will be done during screening for women who are eligible during the screening call. The screening scripts have been included as uploaded material.

5.0 Consent Process and Documentation

5.1 Consent Process

5.1.1 Obtaining Informed Consent

5.1.1.1 Timing and Location of Consent

Subjects will provide verbal assent during the initial phone screening or on site screening and written informed consent at the pre-intervention assessment at the Penn State Clinical Research Center.

5.1.1.2 Coercion or Undue Influence during Consent

Subjects will be told about their rights during the consent process and that study participation is voluntary. If subjects decline to participate in the study, the research team will respect the subject's wishes and no coercion will be used to try to persuade them to participate in the research study.

5.1.2 Waiver or alteration of the informed consent requirement

N/A

5.2 Consent Documentation

5.2.1 Written Documentation of Consent

See written informed consent document.

5.2.2 Waiver of Documentation of Consent

N/A

5.3 Consent – Other Considerations

5.3.1 Non-English Speaking Subjects

N/A. Need to be able to read, understand, and speak English.

5.3.2 Cognitively Impaired Adults

Cognitive impairment is an exclusion criteria.

5.3.2.1 Capability of Providing Consent

N/A

5.3.2.2 Adults Unable To Consent

N/A

5.3.2.3 Assent

N/A

5.3.3 Subjects who are not yet adults (infants, children, teenagers)

Inclusion criteria is 18-40 years. Infants of participants will be included. Children and teenagers are excluded.

5.3.3.1 Parental Permission

Parents of the infants (women who participated in the Healthy Mom Zone study) will give permission to the study staff for their infant to partake in the PeaPod measurement.

5.3.3.2 Assent

Assent will not be obtained from the infants because they will be too young (6-8 weeks old).

6.0 Study Design and Procedures

6.1 Study Design

Study 2 will test: (a) program delivery with decision rules for when/how to adapt dosages for an individual and (b) randomization/retention/data collection procedures with an intervention and control group in a cohort of OW/OBPW from ~6-35 weeks gestation with follow-up through delivery to 6-8-weeks postpartum. Final revisions will be made as needed to the intervention/ assessment protocols. The second stage of Study 2 is to use data collected from Study 2 and dynamical modeling from control systems engineering (system identification) to express progression of GWG over time. We will then identify a customized intervention plan for each woman based on her energy intake, PA, planned/self-regulatory behaviors and the extent to which she is meeting GWG goals over pregnancy. This will lead to final intervention modifications and result in an individually-tailored (adaptive) and optimized program. We will test the efficacy of this intervention for managing GWG in OW/OBPW in a future RCT. R56: We will also use the data collected in Study 2 to build and validate dynamical systems models that characterize fetal growth and infant birth weight as well as how fetal weight respond to changes in maternal sleep duration and stress.

The dynamical systems modeling aspect of the proposed research will be conducted in Study 2 on de-identified data that will be led by Co-Investigator, Dr. Daniel Rivera of Arizona State University (see more information below).

6.2 Study Procedures

6.2.1 STUDY 2 PROCEDURES.

Visit A: Pre-Intervention Assessment. Subject recruitment, screening, and enrollment have been described above. Thirty OW/OBPW who are interested and eligible will be asked to complete a pre-intervention assessment at the Penn State Clinical Research Center to identify the presence of any health issues that may preclude participation in the study. Study women will be carefully screened for medical abnormalities. Women will be escorted to an evaluation room by a project staff member who will then read them a study description, answer questions, and obtained written informed consent. Participants will be given study forms (e.g., where to park, what to do in the event of inclement weather and a session is cancelled, gift card compensation form, etc.; these have been uploaded in the documents section of CATS).

The clinician will assess height, weight, and blood pressure and perform a physical exam to identify health symptoms that may preclude participation (ACOG, 2015 guidelines). The clinician will review the physician consent form and medical history. If no negative health symptoms are present, women will be “cleared” for participation. If any abnormalities or issues are detected (or

health issues that will preclude participation based on the ACOG 2015 guidelines) during the CRC evaluation or baseline assessments we will, with permission of the subject, notify their healthcare provider immediately (or given a referral if she does not have a healthcare provider). We will not proceed with routine study testing if the managing provider deems it inadvisable to continue. All records will be kept with strict confidentiality.

During the CRC visit women will also have one blood draw done (less than 25 cc's per draw; will take less than 10 minutes) by a CRC nurse and have their body composition measured by BodPod, waist circumference, and skinfold. R01 and R56: Blood will be centrifuged and aliquoted by a trained research technician using standard biohazard safety procedures. Samples will then be frozen at -80^{o} C. Once all samples have been collected, they will be transported on dry ice to selected laboratories for analyses. The biomarkers selected for analysis (listed below) have been linked to fetal growth, metabolic syndrome and cardiovascular disease, which may be exacerbated in pregnancy due to high GWG or postpartum weight retention. The blood biomarker measurements that we will be assessing are as follows: Iron, CRP, Vitamin A, Vitamin D, Folate, Zinc, Selenium and Copper. Blood draws are being done for data collection purposes and study team has applied for an Institutional Biosafety Committee approval that was submitted on 12/14/15.

Women who are cleared for participation will be randomized into the intervention or control group. Once randomized, they will complete a series of paper based and online self-reported measures of their healthy eating [HE; Three Factor Eating Questionnaire-18], physical activity [PA; Leisure-Time Exercise Questionnaire], and weight [Pregnancy Weight Gain Attitude Scale], , temperament [Rothbart Adult Temperament Questionnaire], psychological well-being [Center for Epidemiological Studies Depression Inventory, Body Areas Satisfaction Scale and Figure Rating Scale, State Trait Anxiety Inventory, Perceived Stress Scale], self-regulation of HE and PA, self-control [Tangney Self-Control Scale], sleep [Pittsburgh Sleep Quality Index], motivational determinants [self-efficacy, attitude, subjective norm, perceived control, intention, beliefs], and sociodemographics. Descriptions of the measures can be found in Appendix A. For complete list and schedule of these measures, please see Appendix B. These surveys were all completed as part of the Study 1 protocol with no issues by participants (CATS 00000122).

Subjects will also complete trainings of the Remote Food Photography Method (RFPM) and My Fitness Pal for dietary intake, and the Breezing Device for metabolism. These measures and descriptions are included as uploaded materials. Women will also be sent-home with a waist-mounted activity monitor (i.e., Actigraph) and asked to wear it for the next 7 days, continuously except for showering and at bed time for an accurate assessment of their activity time (activity counts). They will also be asked to wear a wrist-worn activity monitor (e.g., Jawbone Up; looks like a bracelet) and asked to wear this non-stop for the next 7 days and not to take it off (it can be worn during showering and sleep) for a continuous assessment of activity and sleep patterns. The PI, Dr. Downs, has used this activity monitoring protocol in previous research, including IRB 24174 Active MOMS and our Study 1 protocol (CATS 00000122). There are no risks associated with using activity monitors in pregnancy. Women will then be scheduled for their first intervention session for the following week and they will return their waist-mounted activity monitor to a study staff member. They will wear the wrist-worn monitor for the remainder of the study. They will be given a standard food scale and weight scale (Wi-Fi Fit Bit Aria) to take home for use in the intervention. If participant agrees to participate, they will be asked to weigh themselves daily until delivery. Urine samples will be collected weekly during the prenatal period to assess basal cortisol level as it relates to stress.

R01 and R56: Participants will be asked to collect voided urine overnight, starting from the time participant falls asleep and ending with the last collection being first morning void after waking for the day. We will provide 1 collection container for whole the whole study for storage of all urine. We will also provide a urine collection hat for easy collection. Participants will track time they went to bed, time of any/all collections overnight and time of first morning void.

Participants may keep the urine collection container beside the toilet/in the bathroom overnight, and will be asked to refrigerate after first morning void until time of study visit, when they will bring urine collection container with them. We will provide a zip-top plastic bag for transportation. Study staff will process the urine samples in the CRC, following biohazard safety protocols. Urine samples for analysis will be transferred to cryovials by pipette and frozen in a -20 degree freezer located in the CRC. Cryovials will be labeled with participant ID # and date only (i.e. no personally identifying information). Once all samples have been collected, a research study staff member will transport samples to the Biobehavioral Core Lab for processing. Urinary free cortisol (UFC), creatinine and osmolality levels will be measured and UFC/creatinine ratio (Cort/Cr) calculated.

R01 and R56: Participants will also complete abdominal Ultrasound scans at 13-15 weeks gestation and every 5 weeks (+/- 5 days) thereafter in pregnancy, with a maximum of 6 ultrasound scans per participant. A letter will be sent notifying the participant's physician that his/her patient will be receiving ultrasound scans as part of a research study. Fetal growth indicators will be collected by a trained sonographer with Registered Diagnostic Medical Sonographer certification using 2D transabdominal sonography, using an ultrasound machine (Philips iU22 MATRIX) and probe (C5-1 Broadband Curved Array or X6-1 PureWave transducer). Women will enter the Clinical Research Center (CRC) to complete the ultrasound biometry. Each fetal ultrasound visit will last 20-30 minutes. Routine measures include: biparietal diameter (BPD), abdominal circumference (AC), femur length (FL), and head circumference (HC), heart rate (HR), amount of amniotic fluid and estimated placental volume, fetal fat mass measures (abdominal and mid-femur). Estimated fetal weight will be calculated using polynomial equations containing BPD, AC, FL, and HC. We will measure uterine and umbilical artery Doppler by ultrasound at each visit (per standard ultrasound procedures). Healthy Mom Zone fetal ultrasound scans are for research purposes only; they will not be 1) medical diagnostic scans (i.e., sonographer will not be examining fetus for structural abnormalities that may exist externally or internally) or 2) anatomical scans (i.e., sonographer will not disclose gender of fetus).

Although this scan is non-diagnostic in nature, following each, indicators of fetal growth collected by fetal ultrasound will be sent by Dr. Pauli (Co-I, OBGYN) at Hershey Medical Center within 24-72 hours to ensure safety of mother-infant dyads. Dr. Pauli will complete a Review Form for each scan to verify that the scan was reviewed and will highlight any potential medical issues that may be impacting gestational weight gain or infant weight. Dr. Pauli will send the review forms to study research staff, who will then hand deliver to participant's physician. Review forms with potential abnormalities noted will be delivered right away, while review forms with normal growth will be delivered to the practice on a weekly basis.

Visits B: Intervention Sessions and Weekly Assessments. During the intervention, all participants will start out at the Baseline level. The baseline level will last 2 weeks and there will be an assessment to determine weight gain over those 2 weeks (See Appendix C for description of adaptive steps). If weight gain has succeeded the recommended amount, participants will be adapted up to a new level of intervention. After every 4 weeks, an assessment will be performed and adaptations up will be made if necessary. The adaptations are as follows:

1. Baseline: one 30-min face to face session with intervention leader for education and guidance (self-monitoring, goal-setting) on GWG, HE, and PA and daily HE/PA self-monitoring (i.e., keeping track daily of their activity and eating patterns in a diary and completing the MyFitness Pal program either online or via a mobile phone app on 3 days per week (Please see Appendix D for outline of education content). The face-to-face session will take place in 128/208/223 Noll Laboratory. The written scripts for these intervention sessions and handouts are attached in the document section of CATS and labeled by week. The forms used to assess fidelity monitoring of these sessions are also attached in the

documents section. Participants are encouraged to get 150 min of moderate to vigorous intensity physical activity.

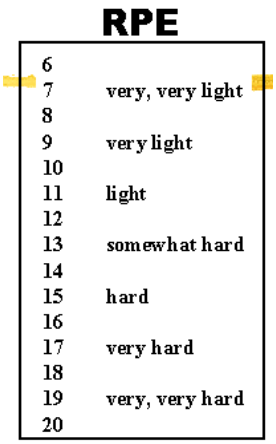
2. Baseline + Active Learning 1: Condition 1 description + adding 4 pearls integrated into cooking/grocery store demos: reinforcing messages and recipe booklet. A registered dietician will deliver these demonstrations with Safe Serve Certification in the Clinical Research Center kitchen in the Elmore Wing of Noll Laboratory. There will be 1 moderate to vigorous intensity physical activity session located in 223 Noll Laboratory with 5-min of introduction, 5-min of warm-up, 30-min of guided PA instruction lead by the intervention leader, and 5-min of cool-down. Women will have their choice to engage in physical activity via walking/light jogging on the treadmill, cycle ergometer, low impact guided aerobics, and resistance training (bands/5 and 10 pound weights); all activities following the USDHHS (2008) and ACOG (2015) national recommendations for regular moderate-intensity PA. The written scripts for these demonstrations and the forms to assess fidelity monitoring are attached in the documents section of CATS. For self-regulation, there will be If-Then action plans. The written scripts/handouts for these demonstrations are attached in the document section of CATS. The forms used to assess fidelity monitoring of these sessions are also attached in the documents section.
3. Baseline + Active Learning 2: Condition 1 description + the choice of a second 45-min physical activity session on site or walking with an instructor and will receive a workout booklet. Healthy eating active learning will include education and the use of portion size and containers. Self-regulation activities include charting healthy eating and physical activity behaviors and use weight data to regulate eating and exercise behaviors by using action plans. The written scripts/handouts for these demonstrations are attached in the document section of CATS. The forms used to assess fidelity monitoring of these sessions are also attached in the documents section
4. Baseline + Active Learning 3: Condition 1 description + grocery store receipt/pantry analysis; grocery store tour/activities; favorite recipe makeover, a third 45-minute physical activity session with the choice of coming on site or at home and we will provide feedback regarding their self-regulation/monitoring behaviors.
5. Baseline + Active Learning 4: Condition 1 description + adding 1 meal replacement (lunch or dinner) for 7 days, a fourth physical activity session with the choice of on site or at home and a weekly text/call/email feedback and encouragement for self-regulation/monitoring. The meal will be frozen meals, packaged for the week and they will meet the recommended dietary guidelines for pregnant women for lunch or dinner. The written scripts/handouts for these demonstrations are attached in the document section of CATS. The forms used to assess fidelity monitoring of these sessions are also attached in the documents section
6. Baseline + Active Learning 5: Condition 1 description + adding 1 meal replacement (lunch or dinner) for 7 days, a fourth physical activity session with the choice of on site or at home and text/call/email feedback and encouragement for self-regulation/monitoring 3x/week. The meal will be frozen meals, packaged for the week and they will meet the recommended dietary guidelines for pregnant women for lunch or dinner. The written scripts/handouts for these demonstrations are attached in the document section of CATS. The forms used to assess fidelity monitoring of these sessions are also attached in the documents section

After the follow-up assessment at gestational week 35, the participants will be followed through delivery and up to 6- weeks postpartum.

During the exercise session, we will employ the same symptoms monitoring system that we used in Active MOMS IRB #24174 and CATS

Symptom Checklist	Pre	5-min	15-min	25-min	Post
Dizziness					
Nausea					
Headache					
Abdominal Pain/Pressure					
Cramping or contractions					
Chest pain					
Calf pain or swelling					
Fluid leakage (urine, amniotic, blood)					
Unusual change in fetal movement					

00000122. A CRC nurse will be present for a portion of the exercise session to provide oversight to the subject monitoring during normal business hours. Trained fitness instructors with CPR training will be present at all times during the after-hours exercise sessions. If there should be a need for immediate medical care, assistance from the CRC would be solicited during normal business hours and after-hours, 911 would be called. A study staff member will also be present at all times during an exercise session. If immediate medical attention is needed, the study staff member will call 911, Penn State police and alert the PI. Subjects will be monitored by a trained study staff member at all times, and will be asked at pre-exercise, at 5-min, 15-min, 25-min, and post-exercise to report (a) standard rating of perceived exertion (Borg Scale) and (b) symptoms checklist (ACOG, 2015):



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Visit C Post-Intervention Assessment. Same procedures as followed in Visit A Pre-Intervention Assessment with the exception of randomization and the CRC medical history review. There will be a semi-structured intervention exit interview. These interviews will be conducted with the women in the intervention to understand their thoughts, preferences, and barriers to the intervention dosage they received over the intervention. The will be asked to talk about their experiences with the program. A study facilitator will provide a brief overview of the interview questions to explore their beliefs and preferences for the intervention they just participated in. Questions to be asked to women are provided in the measures section of the protocol. Interviews will be audio taped using an Olympus DM-420 digital voice recorder and are expected to take 60 minutes. Content will be downloaded and transcribed using N Vivo software. Standard formative research methods including principles of thematic analysis will be used to code, categorize, and organize data. Content analysis will be used to identify common categories of ideas and descriptive statistics used to rank-order salient themes.

Accessing Prenatal and Labor/Delivery Data. After study completion, with subject's HIPAA authorization, we will access their medical record data for prenatal (e.g., gestational weight gain, diagnosis of gestational diabetes, complications, etc.) and labor/delivery data. A subject can chose to not allow us to have access – and she can decide to provide the health information she wants to share. A study staff member will work with the subject's OBGYN provider to coordinate access to this data (e.g., electronic medical record access or hard copy of the prenatal and labor/delivery data).

Visit D Postpartum Assessment and Weekly Measurements At 6-8 weeks postpartum, women will return to Noll Lab to complete maternal and infant measurements; they will be expected to bring their infant with them to this session but if they do not want their infant involved, they will still be asked to complete the measurements asked of them. Women will be asked to (1) weigh themselves using the Aria Wi-Fi scale for a 7-day period, (2) wear the Jawbone wrist-worn activity monitor for a 7-day period, (3) complete one Breezing device measurement, (4) provide one urine sample, (5) one BodPod assessment, and (6) take photographs of their food for 2 weekdays and 1 weekend day. While on site, the women's babies will (1) complete a PeaPod measurement. The baby's test takes place in a similar small space with a window where the baby can be seen the entire time. The baby's test is two minutes long, and typically only one test is needed. We can stop the test at any point. The baby will be placed in the warm measurement space free of any clothing or blankets. The PeaPod measurement is similar to the BodPod measurement.

Postpartum Survey Women will be emailed a link to a postpartum survey 2-6 weeks after delivery. Women will complete this survey on REDCap. Women without access to the Internet will be sent the survey via the mail. The survey has been uploaded as study materials.

- R56: The additional normal weight (body mass index 18.0-23.9) subjects will be assigned to the control group (i.e. will not be randomized); these subjects will complete all measures to expand data collection of indicators of fetal growth as well as self-report data.

6.3 Duration of Participation

Visit A Pre-Intervention Assessment: 120 minutes (can be split into two 60-minute sessions or if participants choose, can be one 120 minute session).
Visit B Intervention Sessions: For those in the intervention group, they will be participating in one 30-min/week education session. Given the adaptive "step-up dosage" nature of this intervention, participation will increase as the dosage increases, *ranging from 1 day per week of 30-min to up to 4-days/week for 150 minutes plus 10-30 min/week of guided instructor feedback.*
Visit C Post-Intervention Assessment: 60 minutes for the interview and 20 minutes for the postpartum survey.

7.0 Data and Specimen Banking

7.1 Data and/or specimens being stored

Blood specimens will be stored a -80^{o}C freezer. Urine samples will be stored in a -20 ^{o}C freezer.

7.2 Location of storage

Specimens will be stored in a -80^{o}C -20 ^{o}C and freezer space located in the Clinical Research Center.

7.3 Duration of storage

All biological samples except whole blood will be transported to designated locations/laboratories for analyses on the same day as collection,

7.4 Access to data and/or specimens

Freezers are kept in a locked room. Only research staff will access the biological samples.

7.5 Procedures to release data or specimens

Frozen samples will be shipped on dry ice to selected laboratories for analysis the same day as collection, either delivered by research technician to local laboratories or by using a company compliant with biohazard safety protocols for shipping. Laboratories will be sent biological samples with a participant ID# (we will not be sending personally identifying information). All laboratory results will be identified by participant ID# only.

7.6 Process for returning results

Since the blood work and urine samples are non-diagnostic, we will not be sharing the results with the participants unless otherwise asked for.

8.0 Statistical Plan

8.1 Sample size determination

For Study 2, Julios[50] effectively argues a sample size of 12 per group is adequate to assess feasibility, address regulatory considerations, and obtain sufficient precision of the mean and variance to perform a formal sample size and power calculation for the future RCT. The primary endpoint of the future RCT will be powered on GWG. Factoring in an anticipated 20% subject drop-out based on our pilot work,[50-52] we will recruit a total of 30 subjects (i.e., 15 per group).

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8.2 Statistical methods

Biostatistician, Co-I Kunselman, will be responsible for coordinating data management and statistical design/analyses aspects required for feasibility studies including data cleaning, analytical set construction, documentation, analyses, and preparation of data summaries for reporting purposes. He will provide leadership in designing/formatting data collection forms to reduce data collection/recording errors and develop a well-defined/comprehensive data quality assurance program to ensure complete, accurate, and valid data, while limiting variability in data collection/recording. Study data will be managed using REDCap (Research Electronic Data Capture), is a secure web application designed to support data capture for research studies, providing user-friendly web-based case reports, real-time data entry validation (data types/range checks) audit trails, and a de-identified data export mechanism to statistical packages (SPSS, SAS, Stata, R/S-Plus). **Analysis Plan.** Study 2 is to establish feasibility; descriptive statistics, including means/standard deviations (continuous variables) and frequencies (categorical variables) will be used to characterize the data. Study 2 will provide estimates for the primary endpoint (GWG) to power a future RCT. Linear mixed-effects models will be used to assess differences between intervention and control groups with respect to changes in continuous outcomes over time (from pre- to post-intervention; daily/weekly) on GWG and related health outcomes. Generalized estimating equations with a logit link will be used to assess differences between intervention and control groups for dichotomous outcomes over time. Because this is a

pilot study, the primary focus of these analyses is for parameter estimation; any hypothesis test will be interpreted with extreme caution to guide the future RCT as this pilot study is deliberately not powered to make definitive claims. All modeling development and simulation will be done in Matlab with SIMULINK and the use of functional data analysis modeling for time-varying modeling will rely on SAS. **Participant Dropout & Other Missing Data.** While every attempt will be made to collect complete data and prevent participant dropout, missing data are inevitable. We have inflated the sample size for Study 2 as described above. We will compare characteristics of those with missing data to those with complete data. These feasibility studies will provide valuable information to minimize missing data in the future RCT (e.g., they will help determine reasons for drop-out, assess which methods for data collection need to be modified/changed, examine data collection and retention of the control group, etc).

9.0 Confidentiality, Privacy and Data Management

9.1 Confidentiality

Data will be secured using password protected computer files, locked file cabinets for hard copy data, locked offices and laboratory space within locked facilities (Rec Hall for the Exercise Psychology Laboratory and Noll Laboratory where the intervention will be delivered). Subject data will also be coded with participant IDs for coding purposes. Data will be entered and stored in the secure REDcap system. Ultrasound scan data and biological specimens will be identified by participant ID # only and will not include any personal identifiers. The same participant ID #'s will be used for these data as for the parent Healthy Mom Zone study. A master list linking participant identifying information and participant ID #'s will be stored in a locked, secure location. Only authorized personnel listed on the protocol will have access to data and specimens.

9.1.1 Identifiers associated with data and/or specimens

Identifiers will include name, home address, telephone number, email address, medical record data.

9.1.1.1 Use of Codes, Master List

A list containing a code associating the identified data with the participant ID will be stored in the secure Redcap system. Access to the identified data will be limited to project staff who will need to understand this information for contact and tracking purposes (reminder calls, repeated data collection, etc.) which will include:

The PI, Dr. Danielle Downs
Project Coordinator, Abigail Pauley who will be directly working with the scheduling of participants, reminders and Redcap
Project Staff Member Lindsey Hess who will also be working with the scheduling of participants, reminders, and Redcap

This list will be destroyed for 5 years after the study has been completed per American Psychological Association guidelines.

9.1.2 Storage of Data and/or Specimens

Electronic data will be stored in the secure Redcap system. Hard copy of data will be stored in locked file cabinets in locked laboratory space. Data will be saved for 5 years after the study has been completed per American Psychological Association guidelines. This study will be issued a Certificate of Confidentiality. Researchers will not disclose or provide any identifiable information without the subject's prior consent or where permitted according to NIH's Policy on Issuing Certificates of Confidentiality.

9.1.3 Access to Data and/or Specimens

Access to the data will have different levels in the Redcap system. As noted above, the PI Dr. Downs, Lindsey Hess, and Abigail Pauley will have access to fully identified data. The other collaborators and research assistants will have access to deidentified data. Non-PSU study team members will be made aware they are also subject to the disclosure restrictions according to NIH's Policy on Issuing Certificates of Confidentiality.

9.1.4 Transferring Data and/or Specimens

De-identified electronic data will be shared with the PSU collaborators and Dr. Daniel Rivera at Arizona State University via the secure Redcap system. The researchers do not plan to release identifiable information collected in the study. However, if researchers consider releasing identifiable information in the future – the individual or institution receiving the identifiable information will be made aware they are also subject to the requirements of subsection 301(d) of the Public Health Service Act.

9.2 Privacy

We will take all possible steps to ensure confidentiality. Subjects will be continually ensured through the consent process, data collection procedures, and intervention sessions that they are not obligated to participate in this study and that their answers will be held with strict confidentiality. We will be using the secure system of Redcap for data entry, collection, storage, and management. The security of the research project data will be maintained through network hardware and user authentication (usernames and passwords). Access to Redcap will be restricted. Back-ups of the project data files will occur every night, with user data backed-up incrementally Monday through Thursday and complete back-ups every Friday. Archival back-ups, stored indefinitely, are cut on the last weekend of every month. Section 9.1.3. illustrates who will have access to which levels of data in Redcap.

As far as privacy for the subjects, they will complete a consent form for participation which explains the study. HIPAA authorization will be obtained from subjects in order for us to have access to their medical record data to obtain their prenatal record (e.g., gestational weight gain, complications, etc) and labor/delivery data. A subject can chose to not allow us to have access – and she can decide to provide the health information she wants to share.

Steps to protect subject privacy and privacy interest include using Subject ID codes, limiting the access to identified data, conducting the intervention in a closed-door facility with limited traffic and access, not disclosing who is participating in the study in any public fashion (never identifying individual subjects in research presentations, discussions, etc.), using the secure Redcap system for subjects to enter their data and not answering study questions out loud in public places or laboratory spaces with others present, and conducting the physical assessments in the CRC.

10.0 Data and Safety Monitoring Plan

This research does not involve more than minimal risk to the subjects. However, because this is a federally-funded study, a DSMP was required by the granting agency and therefore, we have a DSMP. This research involves minimal risk to the subjects as defined in SOP HRP-001 "Minimal Risk is the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

10.1 Periodic evaluation of data

Daily weight data will be collected for intervention monitoring. Weekly HE and PA behaviors, self-regulation, psychological well-being, motivational determinants of HE and PA, and weight behaviors will also be collected and used to inform the intervention counseling in the following week. Also, as described above, will also collect PA session data on symptoms monitoring at pre-exercise, 5-min, 15-min, 25-min, and post-exercise.

See attached protocol for unexpected or adverse events monitoring.

10.2 Data that are reviewed

Definition of adverse event. An adverse event shall be defined as any detrimental change in the participant's condition, whether it is related to study interventions, study outcomes, or to another unrelated illness.

Adverse events unrelated to the study interventions. Adverse events due to illnesses unrelated to study interventions may be grounds for withdrawal if the illness is considered significant by the study investigators or if the participant is no longer able to effectively participate in the study. A significant illness would be one that would compromise the women's ability to function normally and thrive such as the diagnosis of a disease requiring ongoing and intensive treatment and/or one requiring repeated hospitalizations or physician visits. Subjects experiencing routine, minor, self-limited acute illnesses that typically occur during pregnancy and do not affect long-term growth will not be recorded, and the women will continue to participate in the study. Examples of minor illnesses include bronchiolitis, upper respiratory infections, and urinary tract infections. Examples of minor unanticipated events from the PA session may be minor aches, a cold, feeling uncomfortable, mild nausea. Medications for acute, self-limited illnesses such as those stated above will not be recorded, but chronic medication use (≥ 1 month) will be recorded. Further surgical conditions that could impact HE, PA and GWG will be recorded and if the participant's physician determines that these conditions can affect prenatal weight gain, the participant will be withdrawn from the study.

Documentation of an AE unrelated to the study interventions that are not considered minor illnesses and those that can significantly affect the baby will be recorded on the AE form and reported to the IRB. See the protocol for unexpected or adverse events for actions and reporting of the unexpected events and AEs.

Adverse events potentially related to the study interventions. While the majority of OW/OBPW have excessive GWG (over the threshold ranges for prepregnancy weight category as illustrated in the table below:

Institute of Medicine Weight Gain Recommendations for Pregnancy

Prepregnancy Weight Category	Body Mass Index*	Recommended Range of Total Weight (lb)	Recommended Rates of Weight Gain† in the Second and Third Trimesters (lb) (Mean Range [lb/wk])
Underweight	Less than 18.5	28–40	1 (1–1.3)
Normal Weight	18.5–24.9	25–35	1 (0.8–1)
Overweight	25–29.9	15–25	0.6 (0.5–0.7)
Obese (includes all classes)	30 and greater	11–20	0.5 (0.4–0.6)

*Body mass index is calculated as weight in kilograms divided by height in meters squared or as weight in pounds multiplied by 703 divided by height in inches.
†Calculations assume a 1.1–4.4 lb weight gain in the first trimester.
Modified from Institute of Medicine (US). Weight gain during pregnancy: reexamining the guidelines. Washington, DC. National Academies Press; 2009. ©2009 National Academy of Sciences.

It is theoretically possible that behavioral interventions designed to manage GWG in OW/OBPW could result in energy imbalance and insufficient weight gain. The pilot studies that serve as the foundation for the current study **did not** find an association between study interventions and these adverse events. However, we will be monitoring weight on a daily basis and examining GWG on a weekly basis and will consult with co-investigator, Dr. Rick Legro, OBGYN to identify

if a woman has insufficient weight gain for gestational week. Indicators of insufficient weight gain are, for example, weight loss of >3% in a week, or 0% weight gain in a 4-week cycle. OW/OBPW should gain, on average, .5 lb per week, so we will use this as a threshold to understand the context of the weekly GWG relative to her overall GWG and clinical insight. We will consult with the participants OBGYN provider and Dr. Legro to determine if the participant should be removed from the study for insufficient GWG.

The study's informed consent document will include information indicating that the study team will communicate with the participant's OBGYN or Primary Care Provider. The study team will ensure that open lines of communication exist with the healthcare provider in addition to the weight monitoring and review. To establish the lines of communication between the study team and the PCPs, upon participant randomization, the participant is required to have a physician consent form completed to "clear her" for study participation. Healthcare providers will also be directly notified about their patient's participation in the study. A brief description of the study will be shared with them as well as a contact number to call the study team should the provider become concerned about insufficient GWG by their patient. Recognizing that weight monitoring is typically performed at all regularly scheduled primary care appointments, we will ask providers for their collaboration in monitoring prenatal weight gain in that we would like to be alerted to any concerns that their patient is demonstrating insufficient weight gain.

During each face to face visit, staff will calculate weight, BMI, and weight change. If the adverse risk for inadequate weight is identified, we will modify treatment (i.e., recommending increased energy intake). The PIs will review weight and applet data at least twice monthly and then contact the healthcare providers and co-investigator, Dr. Legro when appropriate after each individual is closely evaluated as described below. For any individual who meets initial screening criteria for weight gain concerns, numerous factors will be considered in determining whether the women's weight gain is problematic and/or related to study interventions. Examples of such factors include nausea, vomiting, and interval illness. If either the healthcare provider or the study investigators believe that it is possible that these growth patterns are a negative result from study participation, the women will be withdrawn from the study.

Co-Investigator, Kunselman, our biostatistician, will include protocol compliance with inclusion and exclusion criteria, participant compliance with the interventions, and adverse events in consultation with the PI Dr. Downs, Co-I, Legro, and study staff (Lindsey Hess, Abigail Pauley).

10.3 Method of collection of safety information

The DSMP for this study focuses on close monitoring of GWG in conjunction with a safety officer and data and safety monitoring board (DSMB), along with prompt reporting of excessive adverse events and any serious adverse events to the NIH/NHLBI and to the Institutional Review Board (IRB). Because behavioral interventions aimed at preventing excessive GWG could theoretically result in insufficient weight gain by study participants, individual participant weight will be closely monitored by the investigators in conjunction with the participants' primary care providers as described below in detail (see above in section 10.2 for more information). The DSMB will also closely monitor fetal growth, blood and urine findings. Safety reports will be sent to the study statistician, the PIs, and the safety officer quarterly. At least once per year, the DSMB will convene to review study progress and issues related to the safety of the study interventions. Meetings may be more frequent than once per year if the need for such meetings becomes apparent to the safety officer, PIs, IRB, or NIH/NHLBI. The project manager will be responsible for assembling the data and producing these reports in conjunction with the study statistical team, as well as assuring that all parties obtain copies of these reports.

10.4 Frequency of data collection

As described in study design and procedures section, daily weight data will be collected for intervention monitoring. This data will be reviewed by the program leader in weekly face-to-face sessions. Participants who lose weight will be flagged and their data will be sent to the physician

on staff for review. The frequency of data review for this study differs according to the type of data and can be summarized in the following table:

Data type	Frequency of review
Subject accrual (protocol adherence regarding demographics, inclusion/exclusion)	Bi-Yearly
Adverse event rates including X Y Z (examples) analyses	Bi-Yearly
Individual out of range weight gain	Continuous
Discontinued subjects and Stopping rules report	Bi-Yearly

10.5 Individual's reviewing the data

Our safety officer is Dr. Stephanie Estes and we have an established DSMB including:

Stephanie J. Estes, MD. The safety officer for this trial will be Stephanie J. Estes, MD. Dr. Estes is a reproductive endocrinologist and Director of Robotic Surgery at Penn State Hershey Obstetrics and Gynecology. Dr. Estes has an MD degree from Penn State Hershey College of Medicine. She completes her OB/Gyn residency at Abington Memorial Hospital, and a fellowship in Reproductive Endocrinology at Bringham & Women's Hospital. An OB/Gyn, she is very familiar with normal and abnormal patterns of infant growth and maternal weight gain during pregnancy. As Safety Officer, Dr. Estes will review the reports sent by the project manager (at the frequency outlined above) and will use the checklist attached to this document to determine whether there is any corrective action, trigger of an DSMB review, or stopping rule violation that should be communicated to the study investigators, the IRB, and the NIDDK. She will also serve as the Chair of all DSMB meetings.

Kathleen Rasmussen, Sc.D. Professor of Nutrition in the Division of Nutritional Sciences and International Professor of Nutritional Science at Cornell University. Dr. Rasmussen received her AB degree from Brown University in molecular biology and both her ScM and ScD degrees from Harvard University in nutrition. She has experience running intervention studies and observational studies, and studies the relationship between maternal nutritional status during the reproductive period and short- and long-term maternal and child health outcomes. Her research has been supported by NIH, USDA and numerous other organizations. Dr. Rasmussen has been a member of several expert committees at the Institute of Medicine, served as the chair of the Committee on Reexamination of IOM Pregnancy Weight Guidelines, and just completed chairing a committee to disseminate these new guidelines. Dr. Rasmussen is the Program Director of Training in Maternal and Child Nutrition, NIH/NICHD. She is an internationally known for her research on maternal and child nutrition and her expertise makes her ideal as a content expert for the topic of the study and recruitment and retention of overweight and obese pregnant women.

Kelly Evenson, PhD. Dr. Evenson is a Research Professor in the Department of Epidemiology at The University of North Carolina as Chapel Hill's Gillings School of Global Public Health. Dr. Evenson holds a master's degree in exercise physiology from the University of Wisconsin–La Crosse and a doctorate in epidemiology from UNC. Dr. Evenson has collaborated on or led a number of studies on physical activity intervention, measurement, and analysis, with a special focus on policies and environments that support physical activity. Her research interests include studying changes in physical activity behavior from pregnancy through postpartum and the influence of the physical environment and policies on physical activity. These interests make her ideal as a content expert for the topic of this study.

Colin MacNeill, M.D. Dr. MacNeill is a practicing OB/Gyn at Penn State Hershey Obsetrics and Gynecology and Assistant Professor of Obstetrics and Gynecology at Penn State Hershey College of Medicine.

Lynn Parker Klees, MA, RD, CDE, LDN Lynn Parker Klees is an instructor in the Department Nutritional Sciences at Penn State University. She has expertise in dietetics and clinical management of pregnant women with gestational diabetes.

The Safety Officer will review data and safety reports quarterly and lead the DSMB meeting at least once per year with more frequent meetings as necessary. Meetings will be organized by the Safety Officer with help from administrative staff associated with the IRB. As stated above, our board has been established and under CATS00000122, we have had two meetings and are scheduled for another meeting in Spring 2016.

10.6 Frequency of review of cumulative data

The frequency of cumulate data review for this study is outlined above and will occur yearly or more frequently as determined by the data safety monitoring committee.

10.7 Statistical tests

Descriptive frequencies, means, and trajectories for weight and GWG.

10.8 Suspension of research

As outlined above, we will continuously monitor adverse event rates in all participants. The safety officer, together with the study investigators, will alert the IRB and the NIH if a greater than or equal to 20% adverse event rate potentially due to study interventions should occur in the treatment group or if significant differences between treatment groups occur.

Discontinuing subjects from the study. Any subject with a physician-diagnosed serious adverse event related to the study interventions will be discontinued from the study. Should insufficient weight gain be detected and the cause of this weight gain is potentially related to the study interventions as determined by the PIs after consultation with the participant's primary care provider, the participant will be discontinued from the study. Other non-minor concurrent illnesses or major changes in the family social environment would also lead to discontinuation as determined by the investigators alone or in consultation with the PCP.

If a woman experiences a contraindication to exercise in pregnancy that precludes her continued participation, she will be discontinued from the study. These are: Hemodynamically significant heart disease, Restrictive lung disease, Incompetent cervix/cerclage, Persistent second [or third] trimester bleeding, Placenta previa after 26 weeks of gestation, Premature labor during the current pregnancy, Ruptured membranes, Preeclampsia/pregnancy-induced hypertension] per the ACOG guidelines [(2015, December). ACOG Committee opinion. Number 650: Physical Activity and Exercise During Pregnancy and the Postpartum Period. *Obstetrics and Gynecology, 126,*(6), 135-142].

If she experiences a warning sign to continuing exercise (moderate to severe dizziness, nausea, headache, abdominal pain/pressure, cramping or contractions, chest pain, calf pain or swelling, fluid leakage, unusual change in fetal movement; see our protocol for unexpected or AE), she will discontinue or stop exercising, immediately.

Criteria for stopping the trial. It is exceedingly unlikely that any new, outside information will become available during this trial that would necessitate stopping the trial. There are two situations, however, that could potentially necessitate stopping the trial: 1) poor recruitment and/or retention and 2) disparate serious adverse events related to GWG.

11.0 Risks

This research does not involve more than minimal risk to the participants as defined in SOP HRP-001 "Minimal Risk is the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Engaging in regular moderate-

intensity PA and eating a healthy diet are not high risk activities. The education, active learning, goal-setting, and self-monitoring procedures employed in this study do not place the participants at risk for harm. There are some minimal risks associated with engaging in physical activity (e.g., sore muscles, dizziness, etc) that are no greater than those ordinarily encountered in daily life or during the performance of routine activity. Women with obstetric and medical complications and or who meet the ACOG (2015) criteria for a contraindication to exercise will be excluded from study participation. There are no known risks of a mother eating a healthy diet and engaging in PA to the fetus. Most epidemiological data and the USDHHS (2008) guidelines illustrate benefits to the mother and the fetus such as improved stamina during delivery, lower rates of emergency C-sections, and reduced complications during delivery among healthy mothers. CRC nurses will check in during the exercise sessions during normal business hours. Trained fitness instructors with CPR training will be present at all times during the after-hours exercise sessions. If there should be a need for immediate medical care, assistance from the CRC would be solicited during normal business hours and after-hours, 911 would be called. A study staff member will also be present at all times during an exercise session. If immediate medical attention is needed, the study staff member will call 911, Penn State police and alert the PI.

There are no known economic, legal, or social risks associated with participation in this study. Some of the self-reported surveys may ask questions about your thoughts or feelings and make you feel uncomfortable, but they are not expected to cause feelings different from what is experienced in everyday life (e.g., completing a survey in a magazine or at the doctor's office). There are no risks associated with wearing activity monitors or using the breathing device for measuring metabolism. There are no risks associated with participating in the interview. Some discomfort may be experiences while in the BodPod if there is fear of small-enclosed spaces. The capsule has a window to see out of and to let light in. There is a blue button to press that will stop the measurement and let the participant out immediately. There are no risks to the women or child having a PeaPod measurement done. Mild nausea or dislike of food items may occur during the healthy eating demonstration due to normal pregnancy symptoms. There is a risk of loss of confidentiality if information or the participant's identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. See examples in the privacy section.

Some women experience minimal discomfort from the ultrasound scan. The sonographer may need to press firmly on the abdomen to get a clear image of the fetus. Having multiple ultrasound examinations during pregnancy does not result in negative short- or long-term effects on the physical or developmental growth of the baby. Official Statement on Safety in Training and Research Work (Approved, March 1997): "Diagnostic ultrasound has been in use since the late 1950's. There are no confirmed adverse biological effects on patients resulting from this usage. Although no hazard has been identified that would preclude the prudent and conservative use of diagnostic ultrasound in education and research, experience from normal diagnostic practice may or may not be relevant to the extended exposure times and altered exposure conditions. It is therefore considered appropriate to make the following recommendation: In those special situations in which examinations are to be carried out for purposes other than direct medical benefit to the individual being examined, the subject should be informed of the anticipated conditions, and how these compare with conditions for normal practice."

Blood draws may cause mild pain, swelling or bleeding. Participants may feel a small pinch or slight discomfort when the needle is inserted. If the initial blood draw is unsuccessful it may need to be repeated, with permission. There may be some bruising (blood under the surface of the skin), which can be minimized by pressing on the site after the needle is removed. There is also a slight chance of infection, dizziness or fainting. These risks will be minimized and most likely eliminated by having trained staff draw the blood in a clinical setting using sterile supplies. If dizziness or fainting occurs, the symptoms will be alleviated by having the woman lie flat with her feet raised. If these should occur, we may ask that the woman remain at the clinic until we have checked her blood pressure and we are sure that she feels well. Syringes used for venous blood draws will be used only once and then immediately discarded in a biohazardous waste container approved for sharps. Any staff member collecting or

processing blood will wear protective gloves at all times and will be training in safe techniques to minimize risk to the staff member.

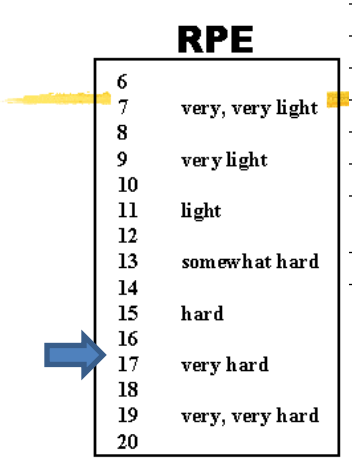
Adverse events will be tracked and reported (see below in the DSMP section for more information) by the trained study staff with oversight from the CRC nurse. Safety-related events will be monitored and reported as required by the DSMP and the IRB. Intervention staff reporting and managing adverse events will inform the PI and in consultation with the study's Safety Officer, will determine if it is an unanticipated AE or unanticipated non-AE. Women with any health complications discovered at any time during the assessments will be referred for follow-up with their healthcare provider or given a list of local providers if they do not have a regular physician. Women who are not achieving appropriate GWG will be given the option to have a follow-up individual phone counseling session that week with the intervention facilitator to further discuss problem solving strategies. If any medical issues are uncovered that may be impacting their GWG, they will be referred to follow-up with their physician and Co-I, Dr. Legro will provide clinical consultation to determine if any changes to the intervention protocol should be made. See below for the monitoring plan for GWG in the DSMP section. Women in the intervention group who develop gestational diabetes during the study will receive the standard of prenatal care by their obstetrician or healthcare provider in which an established standard of care plan is provided for the treatment and management of gestational diabetes. The protocol for unexpected or adverse event during an exercise session is below:

I. REASONS FOR ACTION

Symptoms Checklist: Warning Signs to Stop Exercise (ACOG, 2015):

Moderate to severe:
AND/OR:
RPE 15 or higher during exercise:

Symptom Checklist	Pre	5-min	15-min	25-min	Post
Dizziness					
Nausea					
Headache					
Regular painful cor					
Dyspnea before ex					
Chest pain					
Calf pain or swelli					
Fluid leakage (urin blood)					
Muscle weakness a					



II. ACTION

1. **STOP** activity
2. Place participant in position of comfort.
3. Call CRC if Monday-Friday (8 am – 5 pm) at 814-865-7103. Send research assistant or staff person for help to CRC if needed (CRC is directly around the corner to the Left). Phone 911 if necessary.
4. If the CRC is closed or no nurse is present, phone 911 if necessary.
5. Notify participant's emergency contact person(s) as needed and/or per participant's request
6. Call PI Dr. Downs 814-571-4908.
7. Complete ORP significant event form (nurse or staff member).
8. Report on study AE log (nurse or staff member).
9. PI Dr. Downs need to submit a report to IRB within 5 weekdays; IRB determines if problems represent unanticipated problems that would potentially cause harm.
10. See below for reporting AE and unanticipated problems.

12.0 Potential Benefits to Subjects and Others

12.1 Potential Benefits to Subjects

The minimal risks to the participants are greatly outweighed by the benefits of the intervention they receive and the anticipated benefits to themselves and to others if the intervention is shown to be effective. The potential benefit to the participants is greater understanding of healthy behaviors that, if started in pregnancy could positively affect both maternal and fetal short- and long-term health. They will also receive significantly more information on appropriate weight gain in pregnancy, nutrition and healthy eating, self-regulatory behaviors, and psychological health than is usually possible in routine obstetric care. Subjects in the intervention group may achieve better adherence to the Institute of Medicine GWG guidelines (table cited above), which may reduce their risk of hypertension, diabetes, obstetrical complications, and postpartum weight retention.

12.2 Potential Benefits to Others

The benefit of this research to others is the possible development of a novel approach to pregnancy care, which can positively impact maternal/child health in the future, particularly for OW/OB women.

13.0 Sharing Results with Subjects

Subjects will complete HIPAA forms if they want us to share information with their physician; we will share information on their physical activity, healthy eating, weight, goal-setting, and self-monitoring behaviors on a weekly basis as part of the intervention counseling and feedback component. This information will be presented to the participant during the sessions.

14.0 Economic Burden to Subjects

14.1 Costs

None known.

14.2 Compensation for research-related injury

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

15.0 Number of Subjects

Study 2: target = 30 + anticipated 50 screened failures + 20% dropout (6) + 20 additional control subjects = 106

16.0 Resources Available

16.1 Facilities and locations

Dr. Downs, the PI, is the Director of the Exercise Psychology Laboratory (EPL) at Penn State and has been here since 2002. She has extensive experience with conducting research through her laboratory, Noll laboratory, the CRC, and associated centers and affiliations at Penn State. She has two laboratory spaces, the Exercise Psychology Lab is in Recreation Building and the Healthy Mom Zone Laboratory for the sole purpose of this project is located in Noll Laboratory, directly next to the CRC. The lab spaces are equipped with computer/data analysis and workspace resources and the exercise area is equipped with a Quinton Q65 treadmill, Quinton Q710 ECG monitoring system, a Medical Graphics metabolic monitoring system, and activity

monitoring devices. In addition, Dr. Downs owns or has copyright access to nearly 100 psychological tests and measurements, with those listed in this study. Dr. Downs advises both doctoral and undergraduate students. The EPL is capable of 100% availability for this project. Dr. Downs also has personal office space in Recreation Building that is separate from her laboratory and is equipped with a PC, laser printer, and all of the computer/data analysis software in the laboratory. Dr. Downs is requesting funds for a laptop computer to assist with the pre- and post-intervention assessment data collection as well as for use at the face-to-face intervention sessions for the intervention instructor to upload intervention participant data from the online system such as fitbit.com for daily weight self-monitoring.

The Noll laboratory space specific to this project includes two rooms for exercise participation, healthy eating counseling and demonstrations, office/project management space, fitness equipment (treadmill, recumbent bicycle, resistance bands, hand weights, core balls, mats, space for low-impact aerobics), desk space for one-on-one education consultation, and refrigerator and storage for food snacks and water.

Noll Laboratory

Noll Laboratory is housed in its own dedicated building with over 30,000 square feet of research space containing a vast array of specialized instrumentation, equipment and chambers for the measurement of physiological processes under various environmental conditions. Noll Laboratory is supported by 5 technical (computer and electrical/equipment maintenance and repair) and 1 administrative staff person to support research. Faculty affiliated with the Department of Kinesiology in the Penn State College of Health and Human Development have access to Noll Laboratory facilities for research purposes.

Clinical Research Center

The Clinical Research Center (CRC) facilities at the Penn State University Park campus (three floors and 14,000 square feet) add to the capability for accomplishing the proposed work. The GCRC staff is supportive of this proposal and are prepared to assist in research activities as described in the proposal. More specifically, The CRC facilities will be used to perform the baseline and follow-up assessments and to conduct the physical activity interventions. The CRC was originally supported by a grant (M01-17032) from the National Center for Research Resources of the National Institutes of Health to provide personnel and facilities for investigator initiated peer-reviewed research with human subjects. Since July 1995, approximately 50 protocols and 40 investigators have used the CRC site in Noll Physiology Laboratory at the University Park site. The GCRC hosts investigators funded by NIH and other federal, state and local agencies as well as by the private sector. If needed, the CRC provides inpatient and outpatient rooms, expert support personnel including nurses, computer system manager and biostatistician; and supplies and equipment necessary to perform quality clinical research studies. A skilled research staff of physicians, registered nurses, three medical assistants, and a physician's assistant experienced in research procedures is available. *For the proposed research, the GCRC will provide the nurse time, on-call physician time, and necessary supplies and equipment to do the baseline and follow-up assessments.* The CRC includes a comprehensive list of nutritional services including registered dieticians, a certified dietary manager, and student kitchen employees. Nutrition staff skills and support services are provided for study protocols to include nutrition counseling, dietary analysis, metabolic kitchen, and a "house diet" for meal and snack replacements.

For the dynamical modeling aspects of this project:

ARIZONA STATE UNIVERSITY: Pursuing a goal to become a model for the New American University, Arizona State University (ASU) provides an infrastructure that promotes its primary mission, which includes transforming society, promoting entrepreneurship, conducting application-focused research, and fusing intellectual disciplines. Focus on such innovative, transformative research has led to ASU's research awards surpassing $347 M in 2010 alone.

Researchers at ASU have access to library facilities with nearly $11 M in electronic and print resources, including 4.5 million volumes, 2.6 million unique titles, and over 91,000 serial titles. ASU's My Apps web application offers Dr. Rivera remote access to over 100 software packages. Dr. Rivera and his research group conduct research primarily in ASU's Control Systems Engineering Laboratory (CSEL). CSEL is located in the Engineering Research Center (ERC) on ASU's Tempe campus. ERC is approximately 670 sq. ft. and is occupied by one part time and four full-time predoctoral students. This space features a meeting area equipped for video and phone conferences, high speed wired and wireless internet access, laser printing, five Dell PCs with Windows operating system, one Dell PC with UNIX operating system, and two Macintosh computers with the OSX operating system. Investigators in CSEL also have access to Saguaro 2, a supercomputer maintained by ASU's High Performance Computing Initiative. Software packages that are readily available to investigators include Microsoft Office, Mathematica technical computing and computational software, SPSS data mining and statistical analysis software, and MATLAB with Simulink for simulation and control design. The laboratory also has access to TOMLAB and CPLEX optimization software that will be used in the development and testing of the hybrid Model Predictive Control algorithm that serves as the decision policy for the optimized behavioral intervention.

16.2 Feasibility of recruiting the required number of subjects

For Study 2, we will recruit 30 OW/OBPW who meet the eligibility requirements. We do not anticipate any issues with retaining this sample for the study. We will use our past experience with recruiting/retaining pregnant women to recruit OW/OBPW for the proposed research. The PI, Dr. Downs, has years of experience recruiting pregnant women and recruited 127 pregnant women into the Active MOMS RCT, DK07586702 (52% pre-pregnancy OW/OB; <5% drop-out) from State College, PA. MNPG OBGYNs patient population is large and contributes to the >1,200 births per year at MNMC. We were also successful with recruiting our target of 24 participants for study 1 in CATS 00000122.

R56: For the study 2 extension of control subjects, we will recruit up to 20 additional normal weight women who meet the eligibility requirements.

16.3 PI Time devoted to conducting the research

The PI, Dr. Downs has 25% academic year time and 50% summer year time dedicated to this project.

16.4 Availability of medical or psychological resources

We do not anticipate the need for medical or psychological resources due to study participation; however, the participants will have access to CRC clinical staff, a study staff nurse, and we will work in conjunction with their healthcare provider of any AEs are identified. We will also make referrals to medical or psychological resources if needed. During the intervention, participants will complete surveys at baseline and follow-up sessions. There are measures in the surveys that may display symptomology of depression or other psychological disorders. If there so happens to be a participant that displays a high "score" that could be evident of symptomology of a disorder, the CRC and study staff will have references for psychological referrals. For example, in the baseline and follow-up on site survey, there is a measure called the Center for Epidemiologic Studies Depression Scale (CES-D) that measures current levels of depressive symptomology (with emphasis on the affective component, depressed mood) in the general population. If the final score shows a high level of symptomology (>16), the CRC nurse or study staff will give the participant a handout with local phone numbers for assistance and referrals as necessary. If the CRC nurse detects any psychological issues, she will refer the participant to her OBGYN or primary care provider or provide a list of local clinics if the participant does not have her own healthcare provider. We will also recommend that the participant follow-up with her OBGYN or primary care provider to talk about her symptoms. For the exercise sessions, CRC nurses will check in during the sessions during normal business hours. Trained fitness instructors with CPR training will be present at all times during the after-hours exercise

sessions. If there should be a need for immediate medical care, assistance from the CRC would be solicited during normal business hours and after-hours, 911 would be called. A study staff member will also be present at all times during an exercise session. If immediate medical attention is needed, the study staff member will call 911, Penn State police and alert the PI.

16.5 Process for informing Study Team

All study staff are required to have CITI, HIPAA, Laboratory Safety and study protocol training. Study staff will be informed on a weekly basis of study activities at face-to-face meetings, phone calls, and emails; collaborators will be informed of activities on a bi-monthly basis or more frequently as needed.

17.0 Other Approvals

NHLBI funding 1R01HL119245-01
R56 funding 1R56HL126799-01
CTSI Pilot Funding Award
CATS 00000122
Institutional Biosafety Committee (IBC #46853)

18.0 Subject Stipend and/or Travel Reimbursements

Reimbursement:

<u>All participants will receive:</u>
$100 for the pre-intervention assessments
$200 for the post-intervention assessments
Wi-Fi weight scale to keep upon completion of the study ($125 value)
If the study is completed in its entirety an additional $200
Free parking on PSU campus
Picture of baby after each scan

<u>Those also randomized to the intervention will receive:</u>
$15 per month in merchandise gift-cards for self-monitoring x 6 months = $90 total
A food scale ($25 value)
Total of compensation in gifts and money: $740

<u>Additional compensation at the Postpartum period:</u>
$25 for completing the Remote Food Photography during the 3rd trimester
$50 for your baby's measurements
$50 for your postpartum onsite measurements
$75 for the weekly measurements
Totaling $200.

<u>R56: The additional normal weight control subjects will receive up to $300 in compensation for data collection only:</u>
$25 for each study visit (baseline, follow-up, and postpartum) for a total of up to $75
$5 per week for daily weighing, urine collection, and surveys for a total of up to $200
A bonus $25 for completing all visits and measures
Free parking on Penn State campus during your in-person visits
Free childcare during in-person visits to the Penn State campus (must schedule in advance)

Procedures will be followed for reporting payments to the University for tax purposes.

19.0 Multi-Site Research

19.1 Communication Plans

While our collaborator, Dr. Rivera, at ASU will be receiving the de-identified data for dynamical modeling purposes, we will NOT be collecting data at ASU – so this is not a multi-site trial. But relevant is that we will communicate on a weekly basis with Dr. Rivera through a scheduled conference call. Dr. Rivera will have access to Redcap for data purposes through a Friends of Penn State account and will have access to de-identified data.

19.2 Data Submission and Security Plan

Dr. Rivera will be conducting secondary data analysis; he will not have access to the full data set. He will have access to the multiple point (daily, weekly) data, but not identified data.

19.3 Subject Enrollment

NA

19.4 Reporting of Adverse Events and New Information

NA

19.5 Audit and Monitoring Plans

NA

20.0 Adverse Event Reporting

20.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures. See above information in the DSMP and our protocol for reporting AEs in the uploaded document.

20.2 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.).

21.0 Study Monitoring, Auditing and Inspecting

21.1 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

22.0 References

Incorporated throughout the protocol.

23.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

23.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☒ Authorization will be obtained and documented as part of the consent process.

☐ Partial waiver is requested for recruitment purposes only *(Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained)*

☐ Full waiver is requested for entire research study *(e.g., medical record review studies)*

☐ Alteration is requested to waive requirement for written documentation of authorization

24.0 Appendix

Appendix A. List of Measures and Descriptions

A. Weight, GWG, and Height

i. Weight and GWG will be assessed: (1) pre- and post-intervention at the CRC using standard procedures (measured in duplicate to nearest kg using a high precision stand-on adult scale) and (2) daily at home using the FitBit Aria Wi-Fi Smart Scale (www.fitbit.com; weights will be wirelessly uploaded to online program). GWG will be standardized: target weight gain will be determined for each woman based on BMI status (OW = 15-25 lb, OB = 11-20 lb).[1] For the criterion measure to determine when to adapt the intervention, weight gain will be calculated to determine if a woman is gaining < her goal (-), at the exact amount of her goal (0), or > her goal (+). Pre-pregnancy weight and GWG from the first prenatal visit to the last pre-delivery weight will also be obtained from clinical records.[72]

ii. Height will be assessed at pre-and post-intervention with a stadiometer using standard CRC procedures.

B. Healthy Eating Behavior Measures

i. *Three Factor Eating Questionnaire*: The Three Factor Eating Questionnaire is a 51-item questionnaire developed by Stunkard and Messick (1985) to measure three dimensions of human eating behavior: 1) dietary restraint, or cognitive control of eating behavior, 2) dietary disinhibition, or disinhibition of cognitive control of eating, and 3) susceptibility to hunger. We are only using 18 items of the revised TFEQ from Cappelleri (2009). These items are known as TFEQ-R18 as reported in (de Lauzon et al., 2004).

C. Physical Activity Behavior Measures

i. *Leisure Time Exercise Questionnaire:* The Leisure-Time Exercise Questionnaire (LTEQ) is a 3 item questionnaire developed by Godin and Shephard (1985) to measure the amount and intensity of exercise a person engages in during a one week period. The LTEQ's original validated version is based on 15 minute bouts of leisure exercise. The LTEQ assesses the amount of strenuous (e.g., running, fast swimming), moderate (e.g., brisk walking, tennis), and mild exercise (e.g., easy walking, golf) that is done for at least 15-min during leisure-time in the past week. A total metabolic equivalent (MET) score is generated by multiplying the intensity level by the estimated rate of

energy expenditure [total LTEQ = (9 x strenuous) + (5 x moderate) + (3 x mild)]. Previous research using this measure has modified the quantification of exercise to include average minutes rather than metabolic equivalents across a week to better examine whether or not participants were meeting exercise guidelines (Courneya et al., 2004; Courneya, et al., 2007). Thus, outcomes can be quantified in MET equivalents or by multiplying reported values of strenuous, moderate, and mild physical activity (PA) by 15 to get total min/week for each type and then adding those values together to total min of weekly exercise.

ii. *Physical Activity (PA) Log*: Women will be completing a daily PA log asking them series of questions: 'what time they put their activity monitor on and what time they took it off', 'if they were physically active that day'- if yes 'what activities they did', if it was a normal day in terms of their physical activity and if no, an 'explanation of why'.

iii. *Actigraph wGt3X-BTI:* Women will be wearing the Actigraph monitor for 7 days during their free living immediately following their baseline appointment and again for 7 days immediately following their final appointment. Women will also be wearing the Actigraph for 3 weeks during the intervention phase of the study – the Actigraph is being counterbalanced with the UP Jawbone where half of the women will wear the Actigraph for the first two weeks of the intervention phase and the other half for the last two weeks of the intervention phase.

iv. *UP Jawbone*: Women will be wearing the UP Jawbone for the entire six week intervention. UP will track how you sleep, move and eat so the women will be able to make smarter choices. Women will be wearing the UP Jawbone in counterbalance with the Actigraph wGt3X-BTI.

D. Personality Measures

i. *Adult Temperament Questionnaire*: The Adult Temperament Questionnaire (ATQ) is a 177 item (77 item short form) questionnaire adapted from the Physiological Reactions Questionnaire developed by Derryberry and Rothbart (1988) that assesses the constructs associated with adult temperament. Based upon the results from recent studies (Rothbart, Ahadi, & Evans, 2000; Evans & Rothbart, in preparation) we have formulated a self-report model of temperament that includes general constructs of effortful control, negative affect, extraversion/surgency, and orienting sensitivity. The general constructs are referred to as factor scales (i.e., they have resulted in superfactors) and the sub-constructs are referred to as scales. Both the normal and short form include the same constructs. We are using the Effortful Control and Negative Affect Subscales of the Rothert Adult Temperament.

The three factors included in the Effortful Control Subscale are as follows:
- Attentional Control: Capacity to focus attention as well as to shift attention when desired,
- Inhibitory Control: Capacity to focus attention as well as to shift attention when desired.
- Activation Control: Capacity to perform an action when there is a strong tendency to avoid it.

The four factors included in the Negative Affect Subscale are as follows:
- Fear: Negative affect related to anticipation of distress.
- Sadness: Negative affect and lowered mood and energy related to exposure to suffering, disappointment, and object loss.
- Discomfort: Negative affect related to sensory qualities of stimulation, including intensity, rate or complexity of visual, auditory, smell/taste, and tactile stimulation.
- Frustration: Negative affect related to interruption of ongoing tasks or goal blocking.

E. Psychological Well Being Measures

i. *Body Area Satisfaction Scale:* The Body Area Satisfaction Scale (BASS) measure is a 9-item subscale originating from the Multidimensional Body-Self Relations Questionnaire (MBSRQ), which is a 69-item self-report inventory for the assessment of self-attitudinal aspects of the construct of body-image. Developed by Cash (1990), the BASS assesses one's personal satisfaction with body parts such as arms, legs, and face in which participants rate their degree of body satisfaction with each specified body party from 1 (very dissatisfied) to 5 (very satisfied).

ii. *Center for Epidemiological Studies Depression Scale*: The Center for Epidemiological Studies Depression (CES-D) scale is a 20 item self-report scale developed by Radloff (1977) that is designed to measure current levels of depressive symptomology (with emphasis on the affective component, depressed mood) in the general population. The CES-D is a short scale including items selected from a pool of items from previously validated depression scales and the major components of depressive symptomology were identified from the clinical literature and factor analytic studies. These components included: depressed mood, feelings of guilt and worthlessness, feelings of helplessness and hopelessness, psychomotor retardation, loss of appetite, and sleep disturbance. To emphasize current state, the directions read "How often this past week did you…" The 20 item scale asked participants to indicate the occurrence of the 20 items on a 5 point Likert scale. Responses included in the scale range from "rarely/not at all" to "most days" and incorporate an additional "does not apply to me" option for each item. A cut off score of 16 is used to determine case status (depressed versus not depressed).

iii. *Pregnancy Figure Rating Scale*: The Body Figures Rating Scale is a 3-item scale that was developed by Stunkard, Sorenson and Schulsinger (1983), to assess body dissatisfaction. The scale consists of a set of nine male and female figures that range from underweight to overweight. Subjects are asked to rate the nine figures based on their current body size and their ideal body size which has been adapted to pregnancy figures. Subjects are asked to rate the figures based on the following instructional protocol: (a) current size (i.e. which figure looks the most like you) and (b) ideal size (i.e. which figure would you like to look like). The difference between the ratings is a discrepancy index and is considered to represent the individual's level of dissatisfaction.

iv. *State-Trait Anxiety Inventory*: The State-Trait Anxiety Inventory (STAI) is a 20-item questionnaire developed by Spielberger (1983), to measure state and trait anxiety. The State version of the STAI is being used for the current study. This scale consists of twenty items that evaluate how respondents feel "right now, at this moment." In responding to the STAI State-Anxiety scale, participants choose the response statement that best describes the intensity of their feelings: (1) not at all; (2) somewhat; (3) moderately so; (4) very much so. The state version of the STAI can also be used to evaluate how someone felt at a particular time in the recent past and how they anticipant they will feel either in a specific situation that is likely to be encountered in the future or in a variety of hypothetical situations.

v. *Perceived Stress Scale*: The Perceived Stress Scale (PSS) is a 10-item scale developed by Cohen (1988) that measures the degree to which situations in one's life are appraised as stressful. The PSS was designed for use with community samples with at least a junior high-school education. The 14 items are easy to understand and the response alternatives (never, almost never, neutral, sometimes, fairly often, very often) are simple to grasp. The questions are quite general in nature and hence relatively free of content specific to any sub-population group.

F. Self-Regulation Measures

i. *Self-Regulation of Healthy Eating:* These items were taken from Ryan Rhodes items for self-regulation of PA and adapted for HE behaviors. Therefore, these items are novel for assessing self-regulation of healthy eating. Ryan has indicated that these items work really well as an index for PA self-regulation because these behaviors are naturally inter-connected but to look at specific self-regulatory behaviors:

- Item #1: self-monitoring
- Item #2: goal-setting
- Item # 3: action planning
- Item #4: coping planning
- Item #5: scheduling
- Item #6, 7, 8, and 9
- Items 10 &11: affective

There are also 2 sets of 8 questions—first 8 examine prospective behaviors while the second set assesses retrospective behaviors.

ii. *Self-Regulation of Physical Activity*: These items are taken from Ryan Rhodes. Ryan has indicated that these items work really well as an index because these behaviors are naturally inter-connected but to look at specific self-regulatory behaviors:

- Item #1: self-monitoring
- Item #2: goal-setting
- Item # 3: action planning
- Item #4: coping planning
- Item #5: scheduling
- Item #6, 7, 8, 9: cuing - #6 was developed by Ryan, 7, 8, and 9 we developed
- Items 10 & 11: affective

There are also 2 sets of 8 questions—first 8 examine prospective behaviors while the second set assesses retrospective behaviors.

iii. *Tangney Self-Control Scale:* The Tangney Self Control Scale is a 13-item scale, developed by Tangney et al. (2004), designed to measure the degree of self-control participants have in their lives. Tangney and colleagues began by generating a larger pool of 93 items that encompassed all the spheres of self-control failure covered in an extensive review they conducted on published studies on self-control processes and failures (i.e., control over thoughts, emotional control, impulse control, performance regulation, and habit breaking). Items were rated on a 5-point scale, anchored from 1 “not at all like me” to 5 “very much like me.” Using both rational and empirical methods, the scale was reduced to its final form comprising 36 items, based on an analysis of Study 1 data. Items with low item-total correlations, duplicate or nearly duplicate items, and items likely to vary substantially by gender differences were deleted. Based on a review of item-total correlations from both Study 1 and Study 2, Tangney and colleagues also constructed a 13-item Brief Self-Control Scale. For the current study, we are using the shorter, 13 item version of the SCS.

G. Sleep Behavior Measures

i. *Pittsburgh Sleep Quality Index*: The Pittsburgh Sleep Quality Index (PSQI) is an 18-item measure developed by Smyth (2003) to measure the quality and patterns of sleep in older adults. It differentiates “poor” from “good” sleep by measuring seven areas: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication and daytime dysfunction over the last month. The participant self-rates each of these seven areas

of sleep. Scoring of answers is based on a 0 to 3 scale, whereby 3 reflects the negative extreme on the Likert Scale. Although there are several questions that request the evaluation of the participant's bedmate or roommate, these are not scored (these questions are not reflected in the form being used for the current study).

H. Social Cognitive Measures

i. *Weight Efficacy Life-Style Questionnaire*: The Weight Efficacy Life-Style Questionnaire (WEL) is a 20-item measure that was developed by Clark and colleagues (1991) to assess a participant's confidence to successfully resist the desire to eat. The measure was initially 40 items adapted from Condiotte and Lichtenstein's (1981) Smoking Confidence Questionnaire. A validation study of the questionnaire revealed a 5 component solution, resulting in a final questionnaire of 20 items. The five components or subscales include: Negative Emotions, Availability, Social Pressure, Physical Discomfort, and Positive Activities. Participants are asked to rate their confidence about being able to successfully resist the desire to eat using a 10-point scale ranging from 0 (not confident) to 9 (very confident).

ii. *Sui Healthy Eating and Physical Activity Self Efficacy:* The Sui Healthy Eating and Physical Activity Self Efficacy measure is an 8-item measure developed by Sui, Turnbull, & Dodd (2013) to evaluate overweight and obese women's perceptions of making behavior change during pregnancy. They explored women's beliefs through self-administered questionnaires and semi-structured face-to-face interviews. The questions were designed according to the Health Belief Model. The results from their questionnaire findings yielded interesting themes in regards to women's self-efficacy to make behavior change during pregnancy. Therefore, we took 8 items under self-efficacy themes from table 3 in the manuscript and adapted them into a questionnaire.

I. Sociodemographic Measures: Participants will be completing measures assessing general demographic information, their health history and family health history as well as their pregnancy history and complications in any previous pregnancies they may have had that did go to full term.

J. Theory of Planned Behavior Measures

i. Healthy Eating

a. *Beliefs:* These items were developed from the work of Blanchard et al. (2009a; 2009b), Murnaghan et al. (2010) and the research team to assess Theory of Planned Behavior (TPB) behavioral, control, and normative beliefs about healthy eating. There are eight items to assess behavioral beliefs. The question stem asks "Eating healthy foods (fruits, vegetables, whole grains) each day in the next week will…" with responses ranging from 1 (extremely unlikely) to 7 (extremely likely) for each of the seven items (e.g., help to control my weight, improve my health). For the normative beliefs, there are seven items. The question stem asks "During the next week, the following people definitely think I should eat healthy foods (fruits, vegetables, whole grains) each day…" with responses ranging from 1 (not strongly) to 7 (very strongly). Example items include significant others such as husband/partner/fiancé, friends, co-workers. For the control beliefs, there are ten items. The question stem asks "How difficult will it be for you to eat healthy foods (fruits, vegetables, whole grains) each day in the next week given the following…" with responses ranging from 1 (not difficult) to 7 (extremely difficult). The items women respond to represent a variety of barriers they are likely to face towards eating healthy such as "I don't have access to healthy foods like fruits and vegetables," "I don't know how make/prepare healthy foods/meals," or "My life is extremely busy and I have limited time to prepare healthy foods."

b. *Main Constructs*: The Theory of Planned Behavior (TPB) Healthy Eating Main Constructs measure is a 38-item measure developed from the work of Blanchard et al. (2009a; 2009b), Murnaghan et al. (2010), as well as from the recommendations of Azjen (1991) and the research team to assess the main constructs of the TPB (i.e., attitude, subjective norm, perceived behavioral control, intention) as they relate to healthy eating behavior.

Attitude: 14 items are used to assess attitude using seven semantic differential pairs. Seven items ask women to describe how they feel about eating healthy foods each day in the next week and the other seven items were developed by the research team to understand how women feel about limiting sugary beverages, eating chips, candy, baked goods, and fried foods each day in the next week. Participants rate each pair on a 7 point Likert scale. The semantic differential pairs include: 1) useless-useful, 2) harmful-beneficial, 3) bad–good, 4) foolish–wise, 5) unpleasant–pleasant, 6) unenjoyable–enjoyable, and 7) boring–interesting. The additional items that ask about limiting sugary beverages and unhealthy foods were developed by the research team. We used the same 7 semantic differential pairs that are being used to assess PA behavior related TPB constructs for consistency in measuring attitude across the two behaviors.

Subjective Norm: Subjective norm is assessed with six items with responses ranging from 1 (strongly disagree/disagree) to 7 (strongly agree/ agree). Three items measure how women perceive that significant others in their life feel about them eating healthy each day in the next week and the other three items are regarding how they perceive significant others feel about them limiting sugary beverages, eating chips, candy, baked goods, and fried foods each day in the next week. The items about limiting sugary beverages and unhealthy foods were developed by the research team. The subjective norm items are the same items being asked for PA behavior related TPB constructs for consistency in measuring subjective norm across the two behaviors.

Perceived Behavioral Control: Six items are used to assess perceived behavioral control. Three questions ask women to respond on a 7 point Likert scale from 1 (extremely difficult/very little control/strongly disagree) to 7 (extremely easy/complete control/strongly agree) in regards to the ease in which they can eat healthy each day in the next week. Three questions ask women to respond using the same 7 point Likert scale ranging from 1 (extremely difficult/very little control/strongly disagree) to 7 (extremely easy/complete control/strongly agree) in regards to the ease in which they can limit drinking sugary beverages, eating chips, candy, baked goods, and fried foods each day in the next week. These items are the same 3 items we ask in regards to perceived behavioral control for PA to achieve consistency in measuring perceived behavioral control across the two behaviors.

Intention: 12 items are used to assess intention for healthy eating. We used the three items that have been used in the PESS study and added adapted those to healthy eating. We also added three 3 items that asked about women's intentions to limit drinking sugary beverages, eating chips, candy, baked goods, and fried foods. The remaining six items were developed from work by Ryan Rhodes. Three of the added items pertain to women's intentions, motivation, and plans to eat healthy each day in the next week and the other pertain to women's intentions to limit drinking sugary beverages and unhealthy foods. Responses range from 1 (strongly disagree/definitely not/not at all) to 7 (strongly agree/definitely/very much).

ii. Physical Activity

a. *Beliefs:* These items were developed from the work of Blanchard et al. (2009a; 2009b), Murnaghan et al. (2010, and the research team to assess Theory of Planned Behavior (TPB) behavioral, control, and normative beliefs about physical activity behavior. There are 8 items that assess behavioral beliefs, 9 items assess control

beliefs, and 7 items assess normative beliefs. All 3 constructs are assessed using a 7 point Likert Scale. For the behavioral beliefs the question stem asks “Being physically active in the next week will...” with responses ranging from 1 (extremely unlikely) to 7 (extremely likely). For the control beliefs, the question stem asks “How difficult will it be for you to be physically active in the next week given the following...” with responses ranging from 1 (not difficult) to 7 (extremely difficult). For the normative beliefs, the question stem asks “How strongly will these people approve of you being physically active in the next week…?” with responses ranging from 1 (not strongly) to 7 (very strongly).

b. *Main Constructs*: The Theory of Planned Behavior (TPB) Physical Activity Main Constructs measure is a 19-item measure developed from the recommendations of Azjen (1991) and by the research team to assess the main constructs of the TPB (i.e., attitude, subjective norm, perceived behavioral control, intention) as they relate to physical activity behavior.

Attitude: 7 items are used to assess attitude using 7 semantic differential pairs that describe how women feel about being active each day in the next week. Participants rate each pair on a 7 point Likert scale. The semantic differential pairs include: 1) useless-useful, 2) harmful-beneficial, 3) bad–good, 4) foolish–wise, 5) unpleasant–pleasant, 6) unenjoyable–enjoyable, and 7) boring–interesting.

Subjective Norm: Subjective norm is assessed with 3 items with responses ranging from 1 (strongly disagree/disagree) to 7 (strongly agree/ agree) in regards to how women perceive that significant others in their life feel about them being physically each day in the next week. *Perceived Behavioral Control:* 3 items are used to assess perceived behavioral control. Questions ask women to respond on a 7 point Likert scale from 1 (extremely difficult/very little control/strongly disagree) to 7 (extremely easy/complete control/strongly agree) in regards to the ease in which they can exercise each day in the next week.

Intention: 6 items are used to assess intention for physical activity. We used the 3 items that have been used in the PESS study and added 3 items that Ryan Rhodes commonly uses in his research. Questions pertain to women’s intentions, motivation, and plans to be physically active each day in the next week. Responses range from 1 (strongly disagree/definitely not/not at all) to 7 (strongly agree/definitely/very much).

K. Weight Beliefs Measures

i. *Pregnancy Weight Gain Attitude Scale*: The PWGAS is an 18-item questionnaire developed by Palmer, Jennings, & Massey (1985), to evaluate and assess plausible attitudes of pregnant women towards their weight gain during pregnancy. A Likert scale is used ranging from 1 (strongly agree) to 5 (strongly disagree). The scores on individual statements are summed to yield a composite score. Higher total scores indicate a more positive attitude towards gaining weight in pregnancy while lower scores indicate a more negative attitudes towards pregnancy weight gain.

L. Bloodwork: Blood work will be obtained according to standard CRC procedures and our established assays once at baseline and once in the third trimester of pregnancy. Less than 25 cc’s of blood will be drawn by trained nursing staff. Participants do not need to be fasting. We will ask participants two questions at the time of each blood draw: 1) what time did you eat last? And 2) what did you eat? These biomarkers are linked to metabolic syndrome (and may be exacerbated in pregnancy due to high GWG) and thus, they will be important outcomes of the future RCT. The biomarkers selected for

analysis (listed below) have been linked to fetal growth, metabolic syndrome and cardiovascular disease, which may be exacerbated in pregnancy due to high GWG or postpartum weight retention. The blood biomarker measurements that we will be assessing are as follows: Iron, CRP, Vitamin A, Vitamin D, Folate, Zinc, Selenium and Copper. Blood will be centrifuged and aliquotted by a trained research technician using standard biohazard safety procedures. Samples will then be frozen at -80° C. Once all samples have been collected, they will be transported on dry ice to selected laboratories for analyses.

M. Urine: Urine samples will be collected weekly during the prenatal period to assess basal cortisol level as it relates to stress. Participants will be asked to collect voided urine overnight, starting from the time participant falls asleep and ending with the last collection being first morning void after waking for the day. We will provide 1 collection container for whole the whole study for storage of all urine. We will also provide a urine collection hat for easy collection. Participants will track time they went to bed, time of any/all collections overnight and time of first morning void. Participants may keep the urine collection container beside the toilet/in the bathroom overnight, and will be asked to refrigerate after first morning void until time of study visit, when they will bring urine collection container with them. We will provide a zip-top plastic bag for transportation. Study staff will process the urine samples in the CRC, following biohazard safety protocols. Urine samples for analysis will be transferred to cryovials by pipette and frozen in a -20 degree freezer located in the CRC. Cryovials will be labeled with participant ID # and date only (i.e. no personally identifying information). Once all samples have been collected, a research study staff member will transport samples to the Biobehavioral Core Lab for processing. Urinary free cortisol (UFC) and creatinine levels will be measured and UFC/creatinine ratio (Cort/Cr) calculated.

N. Adiposity (Body Composition)

Standard CRC procedures will be used to assess:

i. *Maternal waist circumference* using an inelastic tape in area between ribs and iliac crest and recorded to nearest 0.1 cm

ii. *Skin fold Thickness* measured at five sites per the Anthropometric Standardization Reference Manual[75]

iii. *Air-displacement Plesmography* [BOD POD; Life Measurement, Inc, Concord, CA) measuring weight (mass) and volume to calculate body density (mass/volume) and percent body fat. (PeaPod for infants)]

O. Dietary Intake

i. *Remote Food Photography Method:* The Remote Food Photography Method© (RFPM) and the SmartIntake™ smartphone app were developed by Corby Martin, Ph.D., H. Raymond Allen, Ph.D. and colleagues at the Pennington Biomedical Research Center as a way to accurately measure the energy intake of adults in free-living conditions. RFPM as been validated and is currently used in multiple studies across the country. Using a smartphone, participants capture images (photos) of all food and beverages consumed both prior to consuming the meal or snack and of the leftover food or beverage that was not consumed. These images and accompanying food identifier data (e.g., barcodes, PLU numbers, food descriptions) are emailed to Pennington Biomedical Research Center (PBRC) and are stored in the Automated Data Management Utility (ADMU). These images are used to estimate energy intake by trained PBRC staff.

ii. *MyFitness Pal:* Web-based and smartphone app dietary intake tracker. Participants will have accounts created for them and will record their diets 3days/week.

P. Metabolism

i. *The Breezing Device*: An indirect calorimetry analyzer that measures the rate of oxygen consumption and carbon dioxide production and determines how much energy the body is burning

due to the metabolism of nutrients (named Resting Energy Expenditure, REE), and the type of nutrients the body uses to produce energy (Energy source = respiratory quotient, RQ). Developed at Arizona State University. The Breezing is a cellphone-size, battery operated, portable technology that syncs with smartphones. This tracker takes a traditional laboratory-based measurement and makes it faster, more affordable and mobile. Breezing has a 99.8% correlation with the gold standard method, Douglas Bag (Forzani, Tao, et.al., Clinical Nutrition, 2013).

Appendix B. Schedule of Assessment for Self-Reported Measures

HMZ SELF-REPORTED MEASURES: CONSTRUCT GROUPING

Survey #	Measure	# items	Data Collection	Pre (Onsite)	Pre (7-day)	Weekly	Biweekly	Monthly	Post (Onsite)	Post (7-day)
Demographics and Health Data										
1	**Demographics (SF-12 included)** ***7 min 31 sec***	13	REDCAP (DDE)	**P[a]**	**--**	--	--	--	--	--
2	**Health Hx** ***Included with the demographics***	85	REDCAP (DDE)	**P[a]**	**--**	--	--	--	--	--
3	**CRC Medical Hx** ***8 min 23 sec***	108	REDCAP (DDE)	**P[a]**	**--**	--	--	--	--	--
Theory of Planned Behavior										
1	**TPB PA ATT, SN, PBC, INT** ***3 min 17 sec***	19	REDCAP SURVEYS	--	**O**	**--**	--	**O**	**O**	--
2	**TPB PA Beliefs** ***3 min 25 sec***	25	REDCAP SURVEYS	--	**O**	--	**O (CB)**	**O (NB/BB)**	**O**	--
3	**TPB HE ATT, SN, PBC, INT** ***3 min 18 sec***	37	REDCAP SURVEYS	--	**O**	**--**	--	**O**	**O**	--
4	**TPB HE Beliefs** ***3 min 43 sec***	26	REDCAP SURVEYS	**--**	**O**	**--**	**O (CB)**	**O (NB/BB)**	**O**	--
Self-Regulation										
1	**PA Self-Regulation** ***3 min 10 sec***	22	REDCAP SURVEYS	--	**O**	--	**O**	--	**O**	--
2	**HE Self-Regulation** ***3 min 2 sec***	22	REDCAP SURVEYS	--	**O**	--	**O**	--	**O**	--
3	**Tangney Brief Self-Control Scale** ***2 min 1 sec***	13	REDCAP SURVEYS	--	**O**	--	--	**O**	**O**	--
Self-Efficacy										
1	**Sui SE (HE/PA)** ***2 min 9 sec***	8	REDCAP SURVEYS	--	**O**	--	--	**O**	**O**	--
2	**Clark Weight SE** ***2 min 35 sec***	17	REDCAP SURVEYS	--	**O**	--	--	**O**	**O**	**--**

Notes. P = paper; O = online; DDE = double data entry. [a]Before Clinical Research Center Physical Exam.

Survey #	Measure	# items	Data Collection	Pre (Onsite)	Pre (7-day)	Weekly	Biweekly	Monthly	Post (Onsite)	Post (7-day)
Behavior										
1	**3-Factor Eating Quest (TFEQ18)** ***2 min 24 sec***	18	REDCAP SURVEYS	--	**O**	--	--	**O**	**O**	**--**
2	**Leisure-Time EX Quest (LTEQ)** ***1 min 50 sec***	3	REDCAP SURVEYS	--	**O**	--	--	**O**	**O**	**--**
3	**Pittsburgh Sleep Quality Index (PSQI)** ***2 min 30 sec***	18	REDCAP SURVEYS	--	**O**	--	--	**O**	**O**	**--**
4	**ACT Tracking** ***1 min 3 sec***	3	REDCAP (DDE)	--	**P**	**--**	--	**P (daily with ACT)**	--	**P**
Weight										
1	**Palmer Attitudes Towards Weight in Pregnancy (PWGAS)** ***2 min 43 sec***	18	REDCAP SURVEYS	**--**	**O**	**--**	**--**	**O**	**O**	**--**
Psychosocial										
1	**Center for Epidem. Studies Depression Scale (CES-D)** ***3 min 7 sec***	20	REDCAP SURVEYS	**P[a]**	--	--	--	**O (with system in place to check)**	**P**	--
2	**State Trait Anxiety Inventory (STAI)** ***2 min 36 sec***	20	REDCAP SURVEYS	**P[a]**	--	--	**O 6 Item**	**O 20 Item**	**P**	**--**
3	**Body Areas Satisfaction Scale (BASS)** ***1 min 55 sec***	9	REDCAP SURVEYS	**P[a]**	--	--	--	**O**	**P**	**--**
4	**Perceived Stress Scale (PSS)** ***3 min 6 sec***	10	REDCAP SURVEYS	**P**		**X (P?)**		**--**	**P**	
5	**Rothbart Adult Temperament** ***3 min 4 sec***	45	REDCAP SURVEYS	**P[a]**	--	--	--	**--**	**--**	**--**
6	**Pregnancy Figure Rating Scale (PFRS)** ***1 min 27 sec***	6	REDCAP SURVEYS		**O**			**O**	**O**	**--**

Survey #	Measure	# items	Data Collection	Pre (Onsite)	Pre (7-day)	Weekly	Biweekly	Monthly	Post (Onsite)	Post (7-day)
Dietary Intake										
1	**RFPM**	--	PHONE, APP	**X**	--	--		**3 (2 weekday, 1 weekend at week Baseline, 16, 22, 28, 35 (post) weeks are gestational week)**	**X**	--
2	**MyFitnessPal**	--	PHONE APP, WEBSITE	--	--	**O (3-5 days/ week)**	--	--	--	--
Resting Metabolic Rate										
1	**Breezing Device**	--	BREEZING DEVICE, PHONE APP	**X**	--	--	--	**3 (2 weekday, 1 weekend at week Baseline, 16, 22, 28, 35(post) weeks are gestational week)**	**X**	--
Notes. P = paper; O = online; DDE = double data entry. [a]Before Clinical Research Center Physical Exam.										

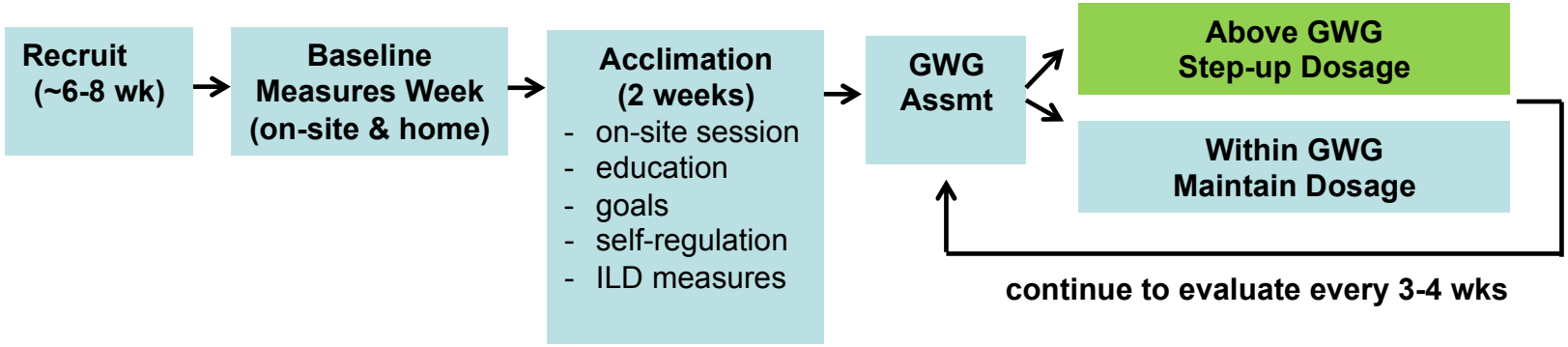
SCHEDULE OF ASSESSMENT FOR OBJECTIVE PA ASSESSMENTS

Measure	# of items	Data Collection	Pre (Onsite)	Pre (7-day)	Weekly	Biweekly	Monthly	Post (Onsite)	Post (7-day)
Actigraph Accelerometer	--	Enter in excel file sheet NOT IN REDCAP	--	**X**	--	--	**X (1 week, at week Baseline, 16, 22, 28, 35(post)))**	--	**X**
Up Jawbone Wrist Monitor	--	Phone App, Enter in excel file sheet NOT IN REDCAP	--	**X (daily)**	**X (daily)**	--	--	--	**X (daily)**
Aria Fitbit W-Fi	--	At home Website, Enter in excel file sheet	--	**X (daily)**	**X (daily)**	--	--	--	**X (daily)**
Standardized Scale	--	CRC/Noll Enter in excel file sheet	**X**	--	**X (session)**	--	--	**X**	--
Medical Record Data	--	REDCAP (DDE)	**--**	--	**--**	--	**Monthly prenatal visits**	**--**	--

HMZ SCHEDULE OF ASSESSMENT FOR OTHER PHYSICAL ASSESSMENTS

Measure	# of items	Location	Pre (Onsite)	Pre (7-day)	Weekly	Biweekly	Monthly	Post (Onsite)	Post (7-day)
BodPod	--	128 Noll	**X**	--	--	--	--	**X**	--
Blood	--	CRC	**X**	--	--	--	--	**X**	--
Cortisol (Urine)	--	CRC	**X**	--	**X**	--	**--**	**X**	--

Appendix C. Baseline Assessment and Adaptive Step-Layout



Gestational Week	Study Week	Lesson #	Adaptation
8	**1**		**BASELINE ASSESSMENT** (Onsite visit + home surveys and GWG/HE/PA monitoring)
9	**2**	1	**BASELINE INTERVENTION** Education Modules [GWG, PA/HE, Self-Monitoring, Goal-Setting; Using guideline recommendations (GWG, HE, PA)]; Focus on health of baby/weekly "fun facts" Encouraged to get 150 min MVPA per week [to meet this goal, aiming to walk 10,000 steps/day and increase intensity (e.g., jogging/workout) as appropriate] GWG/PA/Self-Monitoring/Goal-Setting education delivered by PA instructor; HE counseling delivered by RD
10	**3**	2	
11	**4**	3	
12	**5**	4	
GWG Assessment and Decision Rules for Adapting Intervention			
13 (2nd Tri)	**6**	5	**Baseline Intervention +** **STEP-UP 1: Active Learning I** **HE Active Learning:** 4 Pearls Integrated into Cooking/Grocery Store Demo's: Reinforcing Messages + Recipe Booklet **PA Active Learning:** 1st MVPA Session in Lab (combo treadmill, cycle, low impact aerobics, resistance exercises) in addition to 10,000 steps **Self-Regulation Active Learning[a]:** If-Then Action Plans (attach mental contrasting and implementation intentions to goal-setting)
14	**7**	6	
15	**8**	7	
16	**9**	8	
GWG Assessment and Decision Rules for Adapting Intervention			
17	**10**	9	**Baseline Intervention +** **Step-Up 1 +** **STEP-UP 2: Active Learning II** **HE Active Learning:** Portion Sizes and Containers **PA Active Learning:** 2nd MVPA: Choice of Lab workout or walking with instructor + Workout Booklet (and 10,000 steps) **Self-Regulation Active Learning[b]:** Participants engage in charting their own HE/PA behaviors; use weight data to regulate eating and exercise behaviors; tie this process into action plans
18	**11**	10	
19	**12**	11	
20	**13**	12	
GWG Assessment and Decision Rules for Adapting Intervention			
21	**14**	13	**Baseline Intervention +** **Step-Up 1 +** **Step-Up 2 +** **STEP-UP 3: Active Learning III** **HE Active Learning:** Grocery store receipt/pantry analysis; grocery store tour/activities; favorite recipe make-over **PA Active Learning:** 3rd MVPA session: Choice of Lab (individual or group?) or at-home workout **Self-Regulation Active Learning:** We monitor HE/PA daily and provide feedback "check" (EMA-I)
22	**15**	14	
23	**16**	15	
24	**17**	16	
GWG Assessment and Decision Rules for Adapting Intervention			
25	**18**	17	**Baseline Intervention +** **Step-Up 1 +** **Step-Up 2 +** **Step-Up 3 +** **STEP-UP 4: Active Learning IV** **HE Active Learning:** 1 MR/day for 7 days (give bulk frozen 7 meals for either lunch/dinner)
26	**19**	18	
27	**20**	19	

Gestational Week	Study Week	Lesson #	Adaptation					
28 (3rd TRI)	21	20					**PA Active Learning:** 4th MVPA session: Choice of lab (indiv or group?) or at-home workout **Self-Regulation Active Learning:** (1 x/week) Text/Call/Email Feedback & Encouragement	
GWG Assessment and Decision Rules for Adapting Intervention								
29	22	21	**Baseline Intervention +**	**Step-Up 1 +**	**Step-Up 2 +**	**Step-Up 3 +**	**Step-Up 4 +**	**STEP-UP 5: Active Learning V** **HE Active Learning:** Same as step-up 4 **PA Active Learning:** Same as step-up 4 **Self-Regulation Active Learning:** (3 x/week) Text/Call/Email FB & Encourage
30	23	22						
31	24	23						
32	25	24						
33	26	25						
34	27	26						
35	28		**FOLLOW-UP ASSESSMENT** (Onsite visit + home surveys and GWG/HE/PA monitoring)					
36-40	29-33	--	**MAINTAIN LAST DOSAGE UNTIL DELIVERY**					

Appendix D. Intervention Content Outline
Green cells = Baseline Intervention, delivered

			Given At Session				Emailed	
Gest Week	**Study Week**	**Lesson #**	**PA Education**	**HE Education**	**Self-Monitoring**	**Goal-Setting/Action Plans**	**Featured Evidence/ Baby's Health**	**Baby Fun Facts**
8	**1**	**Baseline Assessment Session**						
9	**2**	1	- Importance of EX in Pregnancy - EX Definitions and Principles - EX/ PA Guidelines - Safety Checklist / EX to avoid	- Dietary guidelines - Hunger and fullness cues - 1st TRI: "Eating for two" (in relation to GWG guidelines)	- SM overview & strategies **HE:** MyFitnessPal overview **PA:** Sleep/PA Log and Jawbone/ Actigraph overview **GWG:** GWG Plot, reminder about daily weighing	- Overview of goal setting principles - Establish HE and PA goals - Establish action plans	- Featured Evidence: "Mom's Healthy Lifestyle Choices Impact on Baby - Overview of how mom's food and PA choices impact baby - Why important to change habits now (future health risks for baby)	I. Your baby is as big as a green olive! II. Your baby's heart is almost completely developed III. … eyelids are forming IV. … fingers and toes are now only slightly webbed, and the tail (yes, your baby had one) is gone.
10	**3**	2	- Benefits of EX for Pregnancy - The Importance of Sleep in Pregnancy - Sleep & the Brain - Things to Know About Sleep in the 1st Trimester - Being Active: A choice and way of life - 1st TRI Myths, Concerns, Fears	- Smaller portions (serving vs. portion) - Focus on tools for portion size: food scale, nutrition labels, visuals (portion size kit; use small vs. large portion images and calorie counts)	Same	- Review goals from previous session and set goals for next session - Review HE/PA action plans **PA Goals:** Meet PA guidelines, Min MVPA, Time of day/Mode **Healthy Eating:** Target calories, food groups	- Featured evidence: "Early GWG effects on Baby Health	I. Your baby is as big as a prune! II. Your baby… is starting to do occasional breathing movements! III. has working arm joints, and the cartilage and bones are forming. IV. … fingernails and hair are starting to appear, too. V. … eyelids begin to fuse for protection.
11	**4**	3	- Tips for EX in the 1st Trimester	- Introduce calorie density (what is it, how to	Same	Same	- Featured evidence: "Mom's Exercise Reduces Baby's	I. Your baby is as big as a lime! II. Your baby's … genitals begin to take on

			Given At Session				Emailed	
Gest Week	**Study Week**	**Lesson #**	**PA Education**	**HE Education**	**Self-Monitoring**	**Goal-Setting/Action Plans**	**Featured Evidence/ Baby's Health**	**Baby Fun Facts**
			- Why EX is Good For Sleep - Sleep & Hormones - Hydration during EX - Eating as fuel for EX - Step Count with Jawbone	calculate) - How to decrease calorie density - Switching out high for low kcal foods - Increasing fruits and vegetables - Water - Whole grains - Fiber			Risk for Childhood Obesity"	either male or female forms! III. Nearly all the organs and body structures are formed and beginning to function. IV. Your baby can sigh, stretch, move its head, and suck its thumb!
12	**5**	4	- EX and Stress Reduction I - Basics for Good Sleep - What to DO If You Can't Fall Asleep - Sound Sleep - 2nd TRI Myths, Concerns, Fears - (Stress Monster Worksheet)	- Fats and sugars - Empty calories - SSB (juice, Gatorade, soda, caffeine)	Same	Same	- Featured evidence: Sleep	I. Your baby is as big as a plum! II. Your baby's… arms, legs, and fingers are growing out and tapering to look more like a newborn's! III. … is about to enter the growth and maturation stage, in which the organs and tissues will grow and develop rapidly. IV. … is now developing reflexes.
13 (2nd Tri)	**6**	5	- Understanding EX Barriers & Roadblocks - Problem-Solving Techniques - What To Do if You Are Sick or Injured - What to Know About Sleep in the 2nd Trimester - Exercises Role in Helping Me Prepare for Labor & Delivery - (Barriers to Being Active Quiz)	- 2nd TRI: "eating for two" (in relation to GWG guidelines) - Snacking (what, when, how much) - Eating late evening/Emotional eating - Cravings	Same	Same	- Featured evidence: "Mom's Exercise and Baby Brain Development"	I. Your baby is as big as a peach! II. Your baby… is forming vocal cords and teeth III. … and already has fingerprints. IV. … begins to produce and excrete urine. V. … is flexing the new and developing muscles and joints in your womb.
14	**7**	6	- Talking Back to Negative Thoughts - What Does it Mean to be Sedentary & Why is it Bad? - Recommendations for Sitting & Standing - Jawbone "Idle Alert" - Life-Long Activity	- Eating away from home - Special occasions - Planning ahead (eating away from home, holidays, vacations, special occasions)	Same	Same		I. Your baby is as big as a lemon! II. Your baby… is growing lanugo, a thin, peach-fuzz-like hair, all over for warmth! III. If you could see your baby's face, you might be able to see a wince and grimace, because the facial muscles are developing and flexing.
15	**8**	7	- Increasing Social Support - Benefits of Group Exercise		Same	Same	- Featured evidence: "Social Support"	I. Your baby is as big as a naval orange! II. You probably can't feel it yet, but your baby squirming a ton! III. … and might even be hiccupping in there. IV. Starting now, female fetuses show mouth movements more often than males.
16	**9**	8		- Grocery store: planning meals in advance, grocery	- How to create effective goals and action plan (Up until this point we have provided standard			I. Your baby is as big as an Avocado! II. Your baby… is listening to your voice,

			Given At Session				Emailed	
Gest Week	**Study Week**	**Lesson #**	**PA Education**	**HE Education**	**Self-Monitoring**	**Goal-Setting/Action Plans**	**Featured Evidence/ Baby's Health**	**Baby Fun Facts**
				list, tricks and tips for grocery shopping	set goals, now we will have a lesson on creating their own)			thanks to tiny bone formations. III. … is growing hair, lashes, and eyebrows. IV. … is forming taste buds. V. At any time, you will begin to feel fetal movement as the baby's bones harden, and starts a growth spurt.
17	**10**	9	- Staying Motivated I - Rewards for EX - Tips to Reduce Swelling - Tips for EX in 2nd TRI		Same	Same		I. Your baby is as big as an onion! II. Your baby… is growing some meat on the new bones- putting on some fat. III. … and is growing a stronger, thicker umbilical cord.
18	**11**	10		- Eating environment - Social support/home environment	Same	Same		I. Your baby is as big as a sweet potato! II. Your baby… is yawning, hiccupping, sucking and swallowing. III. … is twisting, rolling, punching, kicking IV. … retinas have become light sensitive, and your baby may be able to detect a glow if you shine bright lights at your belly (even though their eyelids are sealed).
19	**12**	11	- Understanding 3rd Trimester EX Barriers & Roadblocks - Overcoming Barriers - Tips to Reduce Sitting (Home, Work, Travel) - Easy Ways to Exercise At (Home, Work, Travel)		Same	Same		I. Your baby is as big as a mango! II. Your baby… is developing a protective coating over the skin, called the vernix caseosa. It's greasy and white and you may see some of it at the time of birth. III. … is working on the five senses. Nerve cells for a sense of taste, hearing, sight and smell are developing in the brain. IV. If your baby is a girl, early ovaries contain follicles with forming eggs.
20	**13**	12		- Mindfulness/eating with awareness (not eating in front of TV, tasting the flavors, savoring, enjoying what you are eating, etc.)	Same	Same		I. Your baby is as big as a banana! II. Your baby… has got working taste buds III. Now… is gulping down several ounces of amniotic fluid each day- that's significantly more than before. IV. … sweat glands formed.
21	**14**	13	- Exercise Goals, Review & Progress - Reminders for Step Count, Idle Alert, Sleep - Important Keys to Remember About Goal Setting (Goal Review & Progress Worksheet)		Same	Same	- Featured Evidence: "Mom's Exercise and Baby Heart Health"	I. Your baby is as big as a pomegranate! II. As your baby's… digestive system preps for the outside world, your baby's manufacturing meconium- a tarry black substance you'll find in the first dirty diaper. III. … eyebrows/eyelids are fully developed. IV. … eyelids are sealed, but eyes are active.
22	**15**	14		- HE Review/Progress, Overcoming Barriers	Same	Same		I. Your baby is as big as a papaya! II. Your baby… is sleeping in cycles- about 12-14 hours per day. III. Blood is travelling through the umbilical cord at four miles per hour, fueling growth with oxygen and nutrients.
23	**16**	15	- EX in 3rd TRI: Common Myths,		Same	Same		I. Your baby is as big as a grapefruit! II. Your baby… is forming little nipples.

			Given At Session				Emailed	
Gest Week	**Study Week**	**Lesson #**	**PA Education**	**HE Education**	**Self-Monitoring**	**Goal-Setting/Action Plans**	**Featured Evidence/ Baby's Health**	**Baby Fun Facts**
			Concerns, Fears - Sleep in the 3rd Trimester - Tips for 3rd TRI EX and improving sleep					III. … face is fully formed now- just needs a little extra fat to fill it out. IV. … is listening to your voice and your heartbeat- and even loud sounds like cars honking and dogs barking.
24	**17**	16		- 3rd TRI: "eating for two" (in relation to GWG guidelines) - Review lessons to date	Same	Same		I. Your baby is as big as a cantaloupe! II. Your baby's… see-through skin is gradually becoming more opaque. It's got a new pink glow, thanks to the small capillaries that have recently formed.
25	**18**	17	- What is Stress, Manage in 3rd Tri, How Does it Impact Me & My Baby - Create WIN Statement - Fatigue/EX in 3rd TRI - Warning Signs of Overdoing It - 3rd TRI EX Guidelines		Same	Same	- Featured evidence: "Mom's Exercise Improves Mood and Beats Baby Blues"	I. Your baby is as big as a cauliflower! II. Your baby… is enjoying a sense of equilibrium, now knows up from down. III. … is growing more fat and more hair too! IV. … can now touch/hold feet/make a fist. V. Partner may hear baby's heartbeat by pressing his ear against your belly.
26	**19**	18		- HE and stress management	Same	Same		I. Your baby is as big as a head of lettuce! II. Your baby's… eyelashes are now fully growth. III. … is getting an immune system ready for life on the outside by soaking up your antibodies. IV. This week marks a major milestone in your baby's hearing system (cochlea and peripheral sensory end organs), which began fine development during week eighteen, is now completely formed, and over the next few weeks, your baby will become increasingly sensitive to sound.
27	**20**	19	- Benefits of EX For Labor & Delivery - EX Until Your Due Date (Staying Motivated to Delivery) - Tell Tale Signs of Labor - EX to Help with Labor (Courtenay's Email)		Same	Same	- Featured evidence: "Mom's late pregnancy exercise and ease of labor and delivery"	I. Your baby is as big as a rutabaga! II. Your baby… is practicing inhaling and exhaling with the rapidly developing lungs. III. It's official: Baby's showing brain activity! - brain will keep on getting more complex.
28 (3rd Tri)	**21**	20		- Stocking a healthier kitchen – what's in the pantry? - Quick and easy meals	Same	Same		I. Your baby is as big as an eggplant! II. Your baby… is starting to develop more fat, so the wrinkly skin will start to get smoother. III. … lungs are mature enough for survival in the outside world. IV. … can now taste and smell and produce tears.
29	**22**	21	- Tips in the Weeks Leading Up to Labor - Tips for Preparing for		Same	Same		I. Your baby is as big as an acorn squash! II. Your baby… is growing white fat deposits under the skin, and has energy is

			Given At Session				Emailed	
Gest Week	**Study Week**	**Lesson #**	**PA Education**	**HE Education**	**Self-Monitoring**	**Goal-Setting/Action Plans**	**Featured Evidence/ Baby's Health**	**Baby Fun Facts**
			Labor & Delivery - Tips for Pain Management - Planning Ahead… Check Off Your "To Do" List					surging because of it. III. … adrenal glands are producing a chemical which will be made into estriol (a form of estrogen) by the placenta. This estriol is thought to stimulate the production of prolactin by your body, and the prolactin makes you produce milk. So even if your baby comes early, you'll still be able to breastfeed.
30	**23**	22		- Creative Cooking: Using a crockpot and leftovers	Same	Same		I. Your baby is as big as a cucumber! II. Your baby's… skin is getting smoother. III. … is now strong enough to grasp a finger. IV. … most important organ, the brain, continues to develop at a rapid pace.
31	**24**	23	- EX Postpartum: Common Fears, Myths, Concerns - Beginning Postpartum EX - Benefits of Postpartum EX - Starting to EX Postpartum		Same	Same	- Featured Evidence: Exercise and Postpartum	I. Your baby is as big as a pineapple! II. Your baby… is going through major brain and nerve development. III. …irises now react to light. IV. All five senses are in working order. V. … begins to run out of room as with an increasing weight. You should feel about ten kicks in an hour.
32	**25**	24	17	- Benefits of breastfeeding	Same	Same		I. Your baby is as big as a squash. II. Your baby… is getting ready for descent- and is likely to be in the head-down position now. III. …REM (dream- cycle) sleep is beginning.
33	**26**	25	- Staying Motivated to EX During Postpartum - EX & Postpartum Weight Loss - EX & Stress Reduction: After the Baby is Born - Postpartum Depression: How EX Can Help		Same	Same		I. Your baby is as big as a Durian II. Your baby… keeps open eyes while awake. III. … bones are hardening. IV. … is also in the process of receiving your antibodies.
34	**27**	26	- Lessons learned for lifelong Activity - Increasing Social Support After Baby - The Perfect Postnatal Workout - Fun Activities for You & Baby - Tips for staying active,	- Lessons learned on HE as a Lifestyle (lessons learned not just for pregnancy) - Weight retention - Increase Social Support for HE After Baby	Lessons Learned	Lessons Learned		I. Your baby is as big as a coconut! II. Your baby's… hearing is fully developed, and is responding best to high pitched noises. III. …nervous system and immune system are still maturing. IV. If it's a boy, his testes have probably fully descended.

			Given At Session				Emailed	
Gest Week	**Study Week**	**Lesson #**	**PA Education**	**HE Education**	**Self-Monitoring**	**Goal-Setting/Action Plans**	**Featured Evidence/ Baby's Health**	**Baby Fun Facts**
			quality sleep, decreasing sitting time, routine, and (as applicable) preparing for the next pregnancy					
35	**28**	**Follow-up Assessment Session**						