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**Protocol #: 16-1932**
**Project Title: Helping moms to be healthy after baby**
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**Version Date: 09/08/2017**

**Hypotheses and Specific Aims**:

This protocol outlines details for both a main study and a Substudy.

Main study hypotheses:

1. The multicomponent novel weight loss intervention delivered in WIC will be feasible and acceptable.
2. This intervention will be associated with a greater weight change over 12 weeks compared to control.

Main study aims:

Aim 1: To evaluate the feasibility and acceptability of a multi-component novel weight loss intervention delivered in a WIC setting to a population of low-income, predominantly racial/ethnic minority, obese, postpartum women.

Aim 2: To evaluate differences in weight change between intervention and control participants to determine preliminary intervention efficacy over a 12-week period.

SUBstudy hypotheses:

1. The multicomponent novel weight loss intervention delivered in WIC will be acceptable.
2. This intervention will be associated with differences in diet, physical activity, and self-efficacy compared to control

SUBstudy aims:

Aim 1: To evaluate the acceptability of a multi-component novel weight loss intervention delivered in a WIC setting to a population of low-income, predominantly racial/ethnic minority, obese, postpartum women.

Aim 2: To evaluate differences in diet, physical activity, and self-efficacy, between intervention and control participants to determine preliminary intervention efficacy over a 12-week period.

## II. Background and Significance:

Low-income and minority women are at increased risk for postpartum weight retention (i.e. retaining weight after pregnancy) and consequent persistent obesity.[1,2] Women who have had children, especially racial/ethnic minority women who have had children, have 3 times the risk of obesity compared to women who have not had any children.[3] Pre-pregnancy obesity is an important contributor to postpartum weight retention.[4-6] Women who are obese pre-pregnancy are 3-5 times more likely to gain weight, rather than lose weight, in the postpartum period than non-obese women.[7] Addressing maternal weight during this time is critical given that obesity places women at increased risk for poor health outcomes (e.g. cardiovascular disease) and their offspring at increased risk for obesity.[8] Addressing maternal weight in the first year postpartum is essential given evidence that weight retained beyond this period is usually retained long-term and is an independent risk factor for obesity.[9]

Effective interventions addressing postpartum weight retention in low-income and racial/ethnic minority women are urgently needed. Translation of evidence on weight loss to the postpartum period in a community setting is lacking, yet holds great potential. WIC is an ideal location to translate such evidence given that WIC, staffed by educators and registered dietitians (RDs), interacts regularly with women in the postpartum period, offering nutrition education and supplemental foods.

Obesity science supports that weight loss interventions should be multi-component with regular points of contact.[10] Building upon this, we have designed a multi-component intervention that considers the demands on women in the postpartum period and utilizes technology for both provider decision support and for virtual contact with participants. The intervention will address diet, physical activity, and social support through the use of in-person meetings with WIC staff, text messaging, phone coaching, and Facebook. In-person meetings with WIC staff will occur monthly in addition to the typical quarterly appointments, and will focus on the mother vs. the more common emphasis primarily on the infant. HeartSmartMoms, an electronic provider decision support tool, which our team previously piloted in a WIC-based intervention (Puma et al, under review), will assist providers in using motivational interviewing (MI). MI has been shown to enhance weight loss.[11,12] Text messaging has also been used to enhance weight loss through the use of motivational messages as well as the encouragement of self-monitoring.[13] In-between monthly WIC visits, women will receive daily texts. Phone coaching will also be available. Finally, women will join a private WIC Facebook group where they can receive information from WIC educators and connect with other intervention participants for social support. Text messages, phone coaching, and Facebook were endorsed by WIC clients and will offer flexibility throughout the day as to when participants engage with intervention components.

## III. Preliminary Studies/Progress Report:

We conducted 4 focus groups with WIC clients (2 English and 2 Spanish). There was overwhelming support for the desire to have additional support for postpartum weight loss in the WIC setting. Women liked HeartSmartMoms and thought it could be helpful. Most women were open to having WIC visits focused more heavily focused on maternal lifestyle habits. Women were open to getting information via texts, some women wanted phone coaching, and women who used Facebook, liked the idea of connecting online with other mothers of young infants enrolled in WIC.

Co-investigators have experience in weight loss both clinically and in research studies. Dr. Nicklas has been involved in multiple studies focused on post-partum weight loss including protocols using lifestyle coaching. [14,15]

## IV. Research Methods

### A. Outcome Measure(s):

**Main study:**

**Primary:** Feasibility and acceptability:

- We will assess the ease of recruiting women for the study (number enrolled/number approached) and attrition from the study.
- We will also collect data on intervention adherence, including number of women who received the entire intervention, number of women who came to visits, use of HeartSmartMoms (HSM), participation in self-monitoring, use of phone coaching, and use of the Facebook group page.

**Secondary:**

- Change in weight over 12 week period

**Substudy:**

**Primary:** Feasibility and acceptability:

- We will conduct semi-structured interviews with intervention participants at the 12 week time point to understand their experience in the intervention and to obtain feedback on each component.

**Secondary:**

- Dietary saturated fat, trans fat, total sugars, "added sugars", fruit and fruit juice, vegetable intake, glycemic load and glycemic index
- Physical activity
- Self-efficacy related to diet and exercise
- Readiness to change
- Eating stimulus index

### B. Description of Population to be Enrolled:

Main study:
We will be working with low-income, English or Spanish-speaking postpartum mothers enrolled in the Aurora WIC clinic. The Aurora WIC clinic serves predominantly minority women; nearly 70% of women are racial/ethnic minorities. To be eligible for WIC, women must be low-income or ≤185% of the poverty level.

This population was chosen because they are at high risk for obesity in the postpartum period and weight retention and prolonged obesity.

Inclusion criteria:

- Adult woman (≥18 and <50 years old)
- Enrolled in WIC or with an infant enrolled in WIC;
- 3-12 months postpartum
- A pre-pregnancy BMI of 25 - 40 kg/$m^2$ (based on self-reported height and weight prior to pregnancy)
- Postpartum body mass index between 25 and 50 kg/$m^2$
- English- and/or Spanish-speaking
- Owns a mobile phone with texting functionality
    - In order to receive texts during the trial

Exclusion criteria:

- Health conditions impacting weight or ability to participate in a weight loss trial
    - Pregnancy or planned pregnancy in next 5 months
    - Any health problems or undergoing any treatments that might interfere with what participant eats or her ability to exercise
    - Medical provider recommendation to avoid exercise
- Plans to be in a different geographic area within the next 5 months
- Plans to stop coming to Aurora WIC in the next 5 months.
- Unable to give informed consent;
- Not able to read and understand English or Spanish at an $8^{th}$ grade level.
- Not willing to create a Facebook account if they do not already have one.
- Asked to follow-up in < 3 months at most recent WIC visit

Substudy:

The substudy will have 2 parts – Part A and B. Part A applies to the lifestyle group from the main study and will have 2 phases (1 and 2). This is split into 2 phases so that Phase 2 opportunity and the associated financial remuneration of Phase 2, is not known until the 12 week visit. We want a true assessment of the participation in the lifestyle intervention as it would be run in WIC, and thus do not want participants to stay in the intervention solely for the remuneration in the substudy. Part B applies to the observation group in the main study.

Part A Phase 1
Inclusion criteria:

- Participant in the lifestyle group in the Main study presenting for baseline visit

Exclusion criteria:

- None

Part A Phase 2
Inclusion criteria:

- Participant in the lifestyle group in the Main study presenting for 12 week visit
- Participated in Part A Phase 1

Exclusion criteria:

- None

Part B
Inclusion criteria:

- Participant in the observation group of the main study presenting for baseline visit

Exclusion criteria:

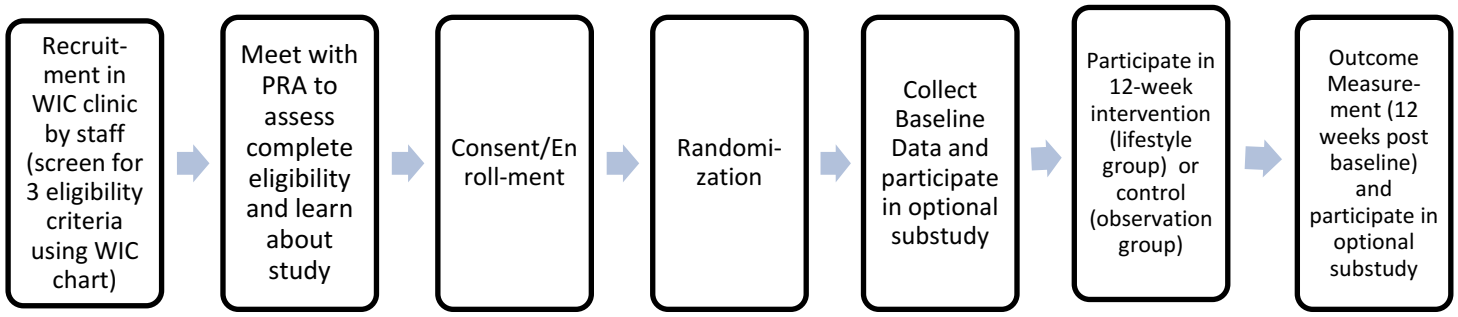
- None

## C. Study Design and Research Methods

Main study: We propose a pilot randomized controlled trial. We will pilot a multicomponent intervention delivered in a WIC setting. In order to attempt to model the intervention as it would be run in WIC, there will be no remuneration for participating other than the small gift ($5) at the beginning of the study.

Substudy: Women in the main study will be eligible for this substudy. The substudy is broken into 2 Parts (A-Lifestyle group from Main study , B- observation Group from Main study). We will ask participants to complete a survey and for some a semi-structured interview.

Here is an overview of our study process




**Setting:** The study (main and substudy) recruitment/enrollment, intervention delivery and data collection will occur at the Aurora WIC clinic. Over a year ago we partnered with WIC and over the last year developed this study protocol together, with input from WIC clients. All study activities will occur at this site except for data management, some phone/text contact with interested individuals/participants, and data analysis.

**Participant Recruitment, Screening, and Enrollment:**

Main study:

We will enroll up to 80 women, with a goal of 40 to complete the substudy Part A phase 2 or Part B. We will post flyers in the WIC office regarding the study opportunity and WIC staff will wear tags about the study (optional for WIC staff to wear)– see Appendix Q and R.

The UCD PRA will review the WIC records for upcoming appointments for each day and pre-identify those women who are 3-12 months postpartum. She will share the list of those with appointments meeting this criteria with the WIC staff, reminding them to introduce the study opportunity to the person at the end of the appointment.

WIC staff will introduce the study to postpartum women at the end of a visit to WIC. Before introducing the study to a person, the WIC staff person will screen for 3 eligibility criteria using data available to her. 1) Person is 3-12 months postpartum, 2) WIC is not recommending to come back to WIC prior to 3 months, and 3) if data is available, person meets current BMI eligibility. If the person meets these criteria, the WIC staff member will introduce the study to the person. They will also give them the flyer (Appendix C) with more information about the study and the screening questions for the person to review(Appendix A.2 page 1 only). This screening done by the WIC staff member ensures that the study is not offered to women who are not eligible based on data already available at WIC.

We will recognize WIC staff efforts to present the study to WIC clients meeting the above criteria by giving $5 gift cards. These gift cards will be given on about a weekly basis to WIC staff demonstrating active engagement in supporting the study. This includes, but is not limited to those presenting the study the most frequently to WIC clients, having a positive attitude about the study, or encouraging other WIC staff to help recruit for the study.

Women interested in learning more will then immediately meet with the PRA. If they cannot meet with the PRA, they will be offered times to return to meet with the PRA. An appointment will be set to meet with the PRA. If the WIC staff person making this appointment to meet with the PRA is not on the study protocol, then a text reminder will be sent to the interested person the day before their visit with the PRA. The text will be sent through the automated text reminder system used by WIC. No identifying information will be shared with the study team. If the person assisting the person in making an appointment with the PRA is on the study protocol, then they will offer a phone or text reminder to the participant from the study team, asking permission to share their name and phone number with the study team. If the person agrees to this, a text reminder (or phone call if preferred) will be sent to the person the day prior to their appointment to remind them about their appointment. This will be sent from the study team texting platform. No identifying information will be included in the text. If the person does not show up to their scheduled appointment, the study team will send a follow-up text asking if the person would like to reschedule the appointment.

During the meeting, the PRA will read the prescreening consent (Appendix A.1) and then assess eligibility using a series of questions and calculating the BMI after measuring the person's weight and height. (Appendix A.2) The questions address specific inclusion/exclusion criteria for the main study to assess eligibility and suitability for study participation. To ensure confidentiality, we will not record any identifiers on the screening questionnaire (Appendix A.2). We will retain the screening questionnaires as detailed in the screening consent language (Appendix A.1). The data on these sheets will help us to understand why people were not eligible. No identifying information will be written on the screening questionnaire

If the person is eligible, the RA will educate the person on the study procedures. To help with comprehension, the RA will give the participant a page with more in-depth study information, and a consent form (Appendix N and E).

The bilingual (English/Spanish) RA will describe the study in-depth and answer all questions. This will occur 1 on 1 or with multiple interested individuals at the same time. After answering all questions,

the RA will meet 1 on 1 to address any further questions the person may have about the study. The RA will then read the consent form to the person, who will have their own copy to read along. The consent contains information about the study procedures and risks. It also recommends that participants should check with their medical provider before starting to exercise. We will NOT require individuals to bring in a note from their medical provider. The RA will answer any questions as needed. For those ready, the RA will complete the informed consent process and enroll the person in the study. As part of the consent process, participants will be offered to take additional time if needed to decide. If they need additional time, they will be asked to call the RA if they decide they are interested in participating. If this happens, they will be asked to come meet in person with the RA at the WIC office to complete the informed consent process and enroll in the study. We will stress during this informed consent process that participation in our research study is voluntary, that subjects may withdraw from the study at any time, and that the investigators reserve the right to discontinue the research protocol at any time. A copy of the signed informed consent form will be given to each subject. Appendix E is the main study consent form.

The Aurora WIC sees over 700 women monthly. Over 50% of these women report being overweight or obese pre-pregnancy. Given these high numbers and the importance of this topic to women in WIC (as described by WIC clients during prior stakeholder meetings), we expect to complete enrollment within a 2-4 month time period.

Treatment assignment: Following informed consent, women will be randomly assigned to the lifestyle group (intervention) or observation group (control). We will use a computer program to randomize subjects using block randomization, to ensure equal numbers of intervention and control participants, given the small sample size. We will randomize in blocks of 10 using a random number generator where 1= intervention (Lifestyle group) and 2= control (Observation group). The RA will have sealed envelopes labeled and ordered from 1 up. The RA will open the next envelope in order of consenting to assign the participant to the intervention or control arm.

Substudy:

The substudy will be broken into 2 parts: Part A for Lifestyle group participants and Part B for the Observation group participants. Data collection varies slightly between these 2 groups as outlined in the study procedures. Only persons participating in the Main study are recruited to be in the Substudy. Screening for eligibility will be done by the PRA based on assigned group in the Main study. Enrollment will occur as follows:

Part A for lifestyle group involves completing 2 phases.

Part A: Phase 1 (labeled Part A.1) involves survey data collection around the time of the Main study's Baseline visit. This will occur either at the visit when the person is consented into the main study or at the baseline visit. After the person is consented into the main study and randomized to the lifestyle group, they can then complete data collection for the main study. Once this is done, they will then be offered the opportunity to participate in this substudy. If they are interested, the RA will conduct informed consent using the information sheet Appendix F.A.1.

Part A: Phase 2 (labeled Part A.2) involves survey and interview data collection at the Main study's 12 week visit. After completing data collection for the Main study at the 12 week visit, the PRA will introduce this study opportunity. If the person is interested, the RA will then complete informed consent, using the information sheet Appendix F.A.1., and enroll the person into the study.

These 2 phases will be presented to participants at these different time points in order to ensure that the substudy opportunity is not an incentive to participate in the main study.

Part B for the observation group involves survey data collection at both the baseline and 12 week visit. This substudy opportunity for data collection at 2 time points will be offered to participants at the baseline visit. If the person is interested, the RA will then complete informed consent, using the information sheet Appendix F-B, and enroll the person into the study.

## Study procedures:

Main study:

In this randomized controlled study participants will be randomly assigned to either an observation group (control) or a Lifestyle group (intervention). Both groups will receive the following:

1. Two visits to the WIC office for data collection as described below (Baseline and at 12 weeks).
2. Study visit reminder calls and/or texts either or both ~1 week and ~1-3 days before baseline and the 12 week study visit.
3. A small gift (less than $5 in value) at the baseline visit.

For each subject, the time from enrollment to study completion will be approximately 12-20 weeks, depending on timing of scheduling of the visits.

Baseline and 12 week study visits and parameters to be measured on all participants:

At the baseline study visit, we expect data collection to take < 30 minutes. We will collect data using a survey and anthropometric measurements.

- **Survey:** We will orally administer the survey (Appendix B) to participants to avoid literacy issues that are common in low-income populations. Survey questions will include the following:
    a. Demographics: Maternal age, education level, race, ethnicity, marital status, employment status, number of children, age of youngest child (months), ages of children at home, and acculturation level. To measure acculturation, we will use an adapted version of the Spanish and English language-use subscales of the Bidimensional Acculturation Scale for Latinos. [16] Each subscale contains 5 items about language use, with responses ranging from never (1) to always (5).
    b. We will also ask about smoking, formula and breastfeeding, and whether the mother has been or is diabetic or prediabetic, mother's weight before her recent pregnancy, and whether she is currently participating in any weight loss programs or is pregnant.

c. Contact information: We will ask for her name, address, phone numbers, email address, and contact information for someone we can call if we cannot reach the participant. We will ask her to identify the number she wants to receive texts and the email address where we send the Facebook invite, if she is in the Lifestyle group.

- **Anthropometrics:** Weight and height measured twice using WIC scales and stadiometer.

At the 12 week study visit, we expect data collection to take about 20 minutes, collecting anthropometric measurements and some survey data.

**Anthropometrics:** Weight and height measured twice using WIC scales and stadiometer.

**Survey:** We will orally administer the survey (Appendix J) to participants to avoid literacy issues that are common in low-income populations. Survey questions will include the following:

a. Demographics: Maternal employment status.
b. We will also ask about smoking, formula and breastfeeding, and whether the mother has been or is diabetic or prediabetic, and whether she is pregnant.

**Procedures by Arm of Study (Observation Group (Control) and Lifestyle Group (Intervention):**

Observation Group participants: Women in the observation group will receive usual WIC care, plus the opportunity to meet with a WIC RD at the 12 week visit. Written WIC materials on lifestyle recommendations will also be given to all observation group participants at the baseline visit. We will connect with the participant prior to the 12 week visit to make an appointment to meet with the WIC RD at that time. At the baseline visit, we will give them an information sheet telling them what to expect. (Appendix G)

Lifestyle group participants: Women in this group will receive typical WIC care plus the below described activities. The intervention will last 12 weeks.

Enhanced and more frequent WIC visits:

- Women will be seen by WIC educators/RDs monthly (at baseline, 4 weeks, and 8 weeks) versus the usual every 3 month visit. We will give women an information sheet at the baseline visit telling them a little bit about what to expect. (Appendix H) Immediately prior to seeing the WIC staff member, the participant will be asked to complete a survey on the iPad using the *HeartSmartMoms (HSM)app.* We previously trialed HSM in a WIC setting in the San Luis Valley. This app helps to facilitate quick identification of high-risk behaviors (e.g. high sugar-sweetened beverage intake, no vegetable or fruit intake) by asking questions about lifestyle behaviors (diet, physical activity, sedentary behaviors, sleep and perceptions of weight, readiness to change). *The participant study ID number will be used on this app so there is no identifiable information.* After filling this in, the WIC staff member or PRA will measure the participant's height and weight, enter it into HSM, and then will print out the HeartSmart printout, which identifies the participant's obesogenic behaviors for the WIC educator. The print out will also provide language consistent with motivational interviewing (MI) that can be used by the WIC educator to direct client counseling using MI techniques. The content of these visits will be patient-centered, so it will be tailored to each participant, but it will focus on

maternal healthy lifestyle behaviors – diet, physical activity, sedentary behaviors, and sleep. Educators will use *motivational interviewing (MI)* to help participants make lifestyle changes. The foundation of treatment of obesity lies in effective counseling of women to motivate healthy behaviors. National and state guidelines encourage patient-centered counseling such as MI. WIC staff will receive advanced training in MI. Educators will use this technique to help women set goals for healthier lifestyle habits, based on standard guidelines for lifestyle behaviors. WIC staff will ask each participant to set goals related to lifestyle change before the end of the visit. Staff will also offer educational materials on these topics to participants if applicable. Recommended behavior changes will be based on moving participants closer to recommended lifestyle behaviors.

Content areas to be covered in 1: 1 counseling, will include:

- MyPlate: This is recommended by the federal government. It helps WIC educators to talk about portions and variety or foods.
- Sugar-sweetened beverages: WIC staff will talk about limiting this in the diet.
- Healthy snack options: This will focus on healthy options for food between meals and when on the go. It will touch on quick ways to make a good choice.
- Taking time for self/taking care of yourself: Women will be encouraged to ask for help in order to be able to take care of themselves.
- Home environment: Educators will talk about how the food around one influences what one eats. For example, if there are no sugary drinks at home, it is easier to avoid them.
- Recipes: Educators will provide recipe ideas for healthy snacks and meals.
- Working and having a healthy lifestyle: Educators will talk about tips for staying healthy while working. For example, how planning ahead and having specific foods available helps.
- Physical activity: Participants will be encouraged to increase their physical activity gradually. They will be given a pedometer and encouraged to increase their amount of walking. Other types of exercise will be chosen by the participant. They will be encouraged to choose activities that they enjoy and to gradually increase the amount they are doing.
- Goal-setting: This will touch on the importance of setting small and realistic goals for changing behaviors.
- Stress-management: This will touch on the importance of managing stress and asking for help. It will include some ways to manage stress like asking for help, deep breathing, etc.

The suggested order in which these topics are reviewed is as follows: Baseline visit (physical activity, MyPlate), 4-week visit (Healthy snack options, stress-management, home environment, taking time for self), and 8-week visit (Sugar-sweetened beverages, working and having a healthy lifestyle). All counseling will be patient-centered. This means it will be guided by the patient's problem areas and interests. Hence, in 1:1 sessions not all of the above will be covered and other areas relevant to the topic may be addressed, as desired by the participant. Educational materials will be used with clients, as appropriate. Educational materials created for this study are included in Appendix O and content from the above areas. The 3 handouts for collaborative goal setting at each visit (Title of 'Goals' on top) include a location for putting the participant ID. After filling in this handout with the WIC educator, a copy will be made and the original will be given to the participant. The copy will be kept in order for the educator to

review past goals with each this participant at future study visits. Other educational materials that are typically used at WIC will also be used in this study, as appropriate.

The baseline, 4-week, and 8-week visit with WIC staff will be combined visits with the WIC educators and RDs.

In-between WIC visits:

We will offer 3 methods of contact between in-person WIC visits.

- *Text messages to motivate and prompt self-monitoring*: We will send a text to participants 2-7 times a week.
    - *Content*: We will use adapted content from a texting program developed at Denver Health that was an adaptation of the Diabetes Prevention Program tailored for low-income individuals.[13] This content related to healthy lifestyle behaviors including diet and exercise. We will send the message in the language requested by the participant. We will also send a weekly message asking participants to send us their average weekly step count from their pedometer and their weight. Self-monitoring is known to promote weight loss.[17]
        - Text content will be brief and will sometimes include a link to the facebook page. Topics will include: 1) Eating less fat and fewer calories, 2) Exercise, 3) healthy eating out 4) recipe modifications 5) Healthy Eating, with variety and balance, 6) motivation, and 7) sending in their weight and weekly step average.
            - Example texts:
                - Try to substitute high fat food for lower fat food, like using ground turkey instead of ground beef, or drink low-fat milk instead of whole.
                - Spread calories over the day by eating regular meals and snacks, and by planning ahead. How you eat is important, not just what you eat.
                - We tend to underestimate our portions! Did you know that a serving of meat (fish, chicken, beef, or pork) is the size of deck of cards?
                - Walking is a great activity. All you need is a pair of good walking shoes. If this is a new activity for you, start with a few minutes per day of gentle walking and slowly increase.
                - Change is hard, but a healthy lifestyle is worth it- start with little changes and gradually work up. You can do it!
    - Texting Platform: We will use an online texting platform to automate outgoing text messages. These will be sent to cellphones via the internet platform. We will not include any identifying information in the text messages. In case of incoming text messages from participants, a WIC staff member will oversee incoming text messages. An automated response to these incoming messages will be set up to say something like “Thanks for replying to us! No one can answer your message immediately, but we will get to it as soon as possible”. The PI or WIC staff member will review incoming messages Monday through Friday (once every other day) and respond as needed.
- *Facebook Group*: We will develop a private Facebook group page. This will be moderated daily by a bilingual WIC staff member (trained WIC educator with back up from a WIC RD) who will post

information on healthy lifestyle behaviors (based on national guidelines and WIC materials similar to in 1:1 counseling sessions described above) and answer questions posted by participants, should they arise. The moderator posts will be in both English and Spanish, and respondents can respond in their preferred language. We will also encourage group support amongst the participants. Evidence suggests mothers find support in mother-focused Facebook group pages.[18]

i. The PI or a co-I will be the administrator for the group. This allows her to reassign the moderator role if needed, ensure the group is private, and control the appearance of the group page.
ii. The WIC staff member will be the moderator of the Facebook group. This means she will have the ability to post things on the page, approve or deny membership to the group, approve or deny posts, remove posts and comments on posts, remove and block people from the group. She will make the site private, only accessible to those receiving an email invite to join. Participants will be sent an invite to join the group. Participants will see who else is a member of the group, but no one else will see who is a member of the group. If a study participant would like to join the group under a pseudonym to protect confidentiality, they will be allowed to do this, if they tell us their Facebook name (pseudonym). We will need to know their Facebook name to ensure only participants in the study are using the private Facebook group page. Members can interact with other members in the Facebook group through the Facebook page. The WIC staff member will remove posts deemed inappropriate or not helpful.
iii. We will observe all activity on the private Facebook group page, number and content of posts.

- *Phone coaching*: Phone coaching is an effective method to support weight loss in postpartum women.[19] We will text women weekly to remind them of the option of speaking with a WIC educator about lifestyle changes in between WIC visits. Women will be asked to call in to schedule a time to speak with the coach. During these appointments, participants will speak with the WIC educator or RD on their lifestyle goals and healthy lifestyle behaviors – similar to topics outlined above for in person WIC visits. Motivational interviewing techniques will be used. We expect calls will last 10-15 minutes and can occur daily M-F as needed by the participant, at a time convenient to both parties.

Pregnancy: These interventions are acceptable for the postpartum time period and would not be expected to cause harm if a subject becomes pregnant. If a subject becomes pregnant during the study, all research activities will stop and she will be excluded from the study at that point. These subjects will be excluded as they would affect study data and because pregnancy may require different care.

**Participant study activities:** Below is a table of all study activities, described for observation group and lifestyle group participants in the main study.

| | Baseline | Week 1 | Week 2 | Week 3 | Week 4 | Week 5 | Week 6 | Week 7 | Week 8 | Week 9 | Week 10 | Week 11 | Week 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **All participants** | | | | | | | | | | | | | |
| **Data collection – in-clinic** | X | | | | | | | | | | | | X |
| **Lifestyle Group participants only** | | | | | | | | | | | | | |
| **In-clinic intervention visits using HeartSmartMoms and lifestyle coaching using motivational interviewing** | X | | | | X | | | | X | | | | |
| **Outgoing texts 2-7/week** | | X | X | X | X | X | X | X | X | X | X | X | |
| **Facebook group participation** | | X | X | X | X | X | X | X | X | X | X | X | |
| **Pedometer use** | X | X | X | X | X | X | X | X | X | X | X | X | |
| **Weekly send in weight and step count** | | X | X | X | X | X | X | X | X | X | X | X | |
| **Weekly phone coaching** | | X | X | X | X | X | X | X | X | X | X | X | |

Please note: We will do our best to schedule visits 4 , 8 and 12 weeks after the baseline visit. However, given possible scheduling conflicts, we will allow a 2 week window around each of the visits.

Contacting participants for their study visits:
We will contact participants to schedule future study visits (baseline, 4, 8 and 12 weeks for lifestyle group participants and baseline and 12 weeks for observation group participants) by phone/text in order to schedule these visits. If we are unable to reach them by phone/text, we will use email and mail. Additionally, during the consent process, we will get permission from subjects to contact a family member or friend if we are having trouble getting in touch with the subject at any point in the study. We will use these methods if phone, text, mail, email do not work. Participants will also get text reminders about upcoming visits. If participants fail to show up for an appointment, we will contact them to reschedule.

WIC benefits: WIC administration of benefits to participants in this study will be as follows.

Observation Group: No changes for the Observation group participants.

Lifestyle Group: Standard practice at WIC is to administer benefits to WIC clients for the time period between visits. In other words, if a WIC client is scheduled to be seen in 3 months, then she would receive 3 months of benefits. If she is asked to be seen in 1 month, she will receive one month of benefits. We plan to mirror this in the Lifestyle group. Participants in the lifestyle group

will receive benefits for the length of time between scheduled visits – 4 weeks. We clearly outline this in the consent form. If a person fails to show up for a visit, and we are unable to reach them before the time when their previously administered benefits expire or they drop out of the study, then WIC will change the benefits to receive the amount they would have received if they were not in the study. In other words, if a participant in the Lifestyle group would have received 3 months of benefits if she was not enrolled, and she fails to show up to her 4 week visit and we cannot reach her or she opted to drop out, then WIC will give her the other 2 months of benefits she would have expected to receive prior to that 3 month visit. WIC clients use EBT cards, so benefits can be uploaded from WIC without the participant coming in. With these methods, we will mirror WIC standard practice and ensure participants do not experience undue burden as a research participant.

**Substudy:**

The substudy will be 2 parts – Part A(Lifestyle – 2 phases) and Part B (Observation group).

Part A: Phase 1 (Lifestyle Group): After enrollment into the substudy Part A, Phase 1, the RA will orally administer a survey (Appendix I) to participants to avoid literacy issues that are common in low-income populations. We expect data collection to take 30-45 minutes. Participants will receive a $25 gift card for their participation. Survey questions will include the following:

a. Diet Survey*:* We will use the Block Fat/Sugar/Fruit/Vegetable Screener which takes 10-12 minutes to complete and is available in English and Spanish.[20] This is a publically available questionnaire. This screener contains 55 questions. Portion size is asked for 32 food items. A series of "adjustment" questions ask about usual intake of low-fat/trans-fat free or low-carbohydrate/low-sugar versions of various foods. Analysis produces estimates of saturated fat, trans fat, total sugars, "added sugars" (in sweetened cereals, soft drinks, and sweets), fruit and fruit juice, vegetable intake, glycemic load and glycemic index. The bilingual research assistant will orally administer this. Data will provide estimates on dietary saturated fat, trans fat, total sugars, "added sugars" (in sweetened cereals, soft drinks, and sweets), fruit and fruit juice, vegetable intake, glycemic load and glycemic index. The Block booklets will be mailed to the company for analysis. The only identifier on each booklet will be the participant study ID number.
b. Pregnancy Physical Activity Questionnaire: We will use a slightly adapted version of the Pregnancy Physical Activity Questionnaire (PPAQ) Chasan-Taber L, Schmidt MD, Roberts DE, Hosmer D, Markenson G, Freedson PS. Development and Validation of a Pregnancy Physical Activity Questionnaire. Med Sci Sports Exer 2004 36(10):1750-1760.
c. Self-efficacy regarding diet and exercise: some items are from another study (unpublished) and some are from http://sallis.ucsd.edu/measure_selfefficacy.html
d. Eating Stimulus Index: http://europepmc.org/abstract/med/19699840
e. Perceived Stress Scale: A Global Measure of Perceived Stress, Author(s): Sheldon Cohen, Tom Kamarck and Robin Mermelstein Source: Journal of Health and Social Behavior, Vol. 24, No. 4 (Dec., 1983), pp. 385-396
f. Readiness to Change: Items are from another study

Part A: Phase 2:

At the 12 week visit, after enrollment into the substudy Part A, Phase 2, the RA will orally administer a survey (Appendix K) to participants to avoid literacy issues that are common in low-income populations. She will then conduct the semi-structured interview (Appendix D). The semi-structured interview will ask for participant perspective on the lifestyle program and their participation. (See Appendix D) This part of the interview will be audiorecorded.

We expect data collection to take overall 60-90 minutes. Participants will receive a $35 gift card for their participation. Survey questions will include the following:

a. Diet Survey*:* We will use the Block Fat/Sugar/Fruit/Vegetable Screener which takes 10-12 minutes to complete and is available in English and Spanish.[20] This is a publically available questionnaire. This screener contains 55 questions. Portion size is asked for 32 food items. A series of "adjustment" questions ask about usual intake of low-fat/trans-fat free or low-carbohydrate/low-sugar versions of various foods. Analysis produces estimates of saturated fat, trans fat, total sugars, "added sugars" (in sweetened cereals, soft drinks, and sweets), fruit and fruit juice, vegetable intake, glycemic load and glycemic index. The bilingual research assistant will orally administer this. Data will provide estimates on dietary saturated fat, trans fat, total sugars, "added sugars" (in sweetened cereals, soft drinks, and sweets), fruit and fruit juice, vegetable intake, glycemic load and glycemic index. The Block booklets will be mailed to the company for analysis. The only identifier on each booklet will be the participant study ID number.
b. Pregnancy Physical Activity Questionnaire: We will use a slightly adapted version of the Pregnancy Physical Activity Questionnaire (PPAQ) Chasan-Taber L, Schmidt MD, Roberts DE, Hosmer D, Markenson G, Freedson PS. Development and Validation of a Pregnancy Physical Activity Questionnaire. Med Sci Sports Exer 2004 36(10):1750-1760.
c. Self-efficacy regarding diet and exercise: some items are from another study (unpublished) and some are from http://sallis.ucsd.edu/measure_selfefficacy.html
d. Eating Stimulus Index: http://europepmc.org/abstract/med/19699840
e. Readiness to Change: Items are from another study

Part B: After enrollment, the RA will orally administer a survey (Appendix I) to all participants. We expect data collection to take 30-45 minutes. Survey questions will include:

a. Diet Survey*:* We will use the Block Fat/Sugar/Fruit/Vegetable Screener which takes 10-12 minutes to complete and is available in English and Spanish.[20] This is a publically available questionnaire. This screener contains 55 questions. Portion size is asked for 32 food items. A series of "adjustment" questions ask about usual intake of low-fat/trans-fat free or low-carbohydrate/low-sugar versions of various foods. Analysis produces estimates of saturated fat, trans fat, total sugars, "added sugars" (in sweetened cereals, soft drinks, and sweets), fruit and fruit juice, vegetable intake, glycemic load and glycemic index. The bilingual research assistant will orally administer this. Data will provide estimates on dietary saturated fat, trans fat, total sugars, "added sugars" (in sweetened cereals, soft drinks, and sweets), fruit and fruit juice, vegetable intake, glycemic load and glycemic index. The Block booklets will be mailed to the company for analysis. The only identifier on each booklet will be the participant study ID number.
b. Pregnancy Physical Activity Questionnaire: We will use a slightly adapted version of the Pregnancy Physical Activity Questionnaire (PPAQ) Chasan-Taber L, Schmidt MD, Roberts DE, Hosmer D, Markenson G, Freedson PS. Development and Validation of a

Pregnancy Physical Activity Questionnaire. Med Sci Sports Exer 2004 36(10):1750-1760.

c. Self-efficacy regarding diet and exercise: some items are from another study (unpublished) and some are from http://sallis.ucsd.edu/measure_selfefficacy.html
d. Eating Stimulus Index: http://europepmc.org/abstract/med/19699840
e. Perceived Stress Scale: A Global Measure of Perceived Stress, Author(s): Sheldon Cohen, Tom Kamarck and Robin Mermelstein Source: Journal of Health and Social Behavior, Vol. 24, No. 4 (Dec., 1983), pp. 385-396
f. Readiness to Change: Items are from another study

Then at the 12 week visit, the RA will orally administer a survey (Appendix K) to all participants. We expect data collection to take 30-45 minutes. Survey questions will include:

a. Diet Survey*:* We will use the Block Fat/Sugar/Fruit/Vegetable Screener which takes 10-12 minutes to complete and is available in English and Spanish.[20] This is a publically available questionnaire. This screener contains 55 questions. Portion size is asked for 32 food items. A series of "adjustment" questions ask about usual intake of low-fat/trans-fat free or low-carbohydrate/low-sugar versions of various foods. Analysis produces estimates of saturated fat, trans fat, total sugars, "added sugars" (in sweetened cereals, soft drinks, and sweets), fruit and fruit juice, vegetable intake, glycemic load and glycemic index. The bilingual research assistant will orally administer this. Data will provide estimates on dietary saturated fat, trans fat, total sugars, "added sugars" (in sweetened cereals, soft drinks, and sweets), fruit and fruit juice, vegetable intake, glycemic load and glycemic index. The Block booklets will be mailed to the company for analysis. The only identifier on each booklet will be the participant study ID number.
b. Pregnancy Physical Activity Questionnaire: We will use a slightly adapted version of the Pregnancy Physical Activity Questionnaire (PPAQ) Chasan-Taber L, Schmidt MD, Roberts DE, Hosmer D, Markenson G, Freedson PS. Development and Validation of a Pregnancy Physical Activity Questionnaire. Med Sci Sports Exer 2004 36(10):1750-1760.
c. Self-efficacy regarding diet and exercise: some items are from another study (unpublished) and some are from http://sallis.ucsd.edu/measure_selfefficacy.html
d. Eating Stimulus Index: http://europepmc.org/abstract/med/19699840
e. Readiness to Change: Items are from another study

Participants from the observation group will receive at the 12 week visit a $50 gift card for their participation.

Overview of data collection:

Data to be collected from study participants and when the data are to be collected

| **Variable** | **Baseline Visit 1** | **4 week visit (Lifestyle group only)** | **8 week visit (Lifestyle group only)** | **12 week visit** |
|---|---|---|---|---|
| Main study | | | | |
| Demographics Questionnaire | X | | | |

| | | | | |
|---|---|---|---|---|
| Smoking status | X | | | X |
| Breastfeeding history | X | | | X |
| Health questions | X | | | X |
| Weight | X | X | X | X |
| Height | X | | | |
| Substudy | | | | |
| Block Fat/Sugar/Fruit/Vegetable Screener | X | | | X |
| Pregnancy Physical Activity Questionnaire | X | | | X |
| Self-efficacy re: diet and exercise | X | | | X |
| Eating Stimulus Index | X | | | X |
| Perceived Stress Scale | X | | | |
| Readiness to change | X | | | X |
| Semi-structured interview on participant perspective on the acceptability of the intervention (lifestyle group participants only) | | | | X |

## D. Description, Risks and Justification of Procedures and Data Collection Tools:

Study procedures are listed below with related risks and justifications.

Main study:

Surveys: We will orally read survey questions to participants and responses. It may be tiring answering questions in our survey. Also, a participant may feel discomfort answering questions of a personal nature, but subjects can always choose not to answer any question.

Anthropometric measurements: We will measure heights and weights using WIC clinic scales and stadiometers. Participants may feel uncomfortable being weighed.

Lifestyle coaching: At the baseline, 4 and 8 week visits, intervention-arm participants will receive lifestyle coaching from WIC staff as described above. Participants may feel uncomfortable filling in the HeartSmartMoms survey, or answering lifestyle questions with the WIC staff. They may feel uncomfortable setting lifestyle behavior goals. Given that WIC staff will be using a patient-centered approach with motivational interviewing, this discomfort should be reduced. Motivational interviewing is a critical aspect of behavior change in weight loss intervention focused on behavior change.

Using a pedometer: Intervention participants will be asked to use a pedometer – clicked onto their clothing. Participants may find using a pedometer uncomfortable. They may find discomfort in seeing their step counts. We will educate participants on how to use the pedometer, to help ensure comfort. We will also counsel participants on how step counts can be helpful and to set realistic goals using this device.

Exercise: Lifestyle coaching will encourage exercise because it is an important part of weight loss interventions. There are risks associated with exercise. Exercise may cause sweating, fatigue, or

feeling out of breath. It is also possible that participants could develop soreness or injuries from increased exercise. Exercise can rarely cause abnormal heartbeats, chest pain, passing out, heart attack, stroke, or death, which are extremely rare events.

Weight Loss: The intervention will encourage weight loss. With a reduction in caloric intake, participants may experience hunger and fatigue. Sometimes people experience constipation, nausea, abdominal discomfort or diarrhea from diet changes. Headaches, trouble sleeping, changing in mood or psychological stress can also occur. Weight loss may occur too rapidly resulting in weakness and fatigue. Lifestyle coaching will counsel on gradual weight loss. WIC staff will be checking weights in intervention participants every 4 weeks and can counsel participants if weight loss is too rapid. The most serious but very rare side effect of reduced calorie diets is gallstone formation, which usually only occurs with extremely low fat diets, which will not be recommended in the intervention. WIC educators will have the support of WIC RDs for all participants. Study investigators are experienced in appropriate weight loss.

Changes in WIC benefits: Being asked to come in to WIC more frequently and having your WIC benefits given to you in 1 month amounts may cause you and your family stress and added burden.

Confidentiality: The Principal Investigator and her staff will take all reasonable measures to protect the confidentiality of each subject's records and data. Subject data will be referenced by number only. Research data on paper will be kept in a secured file cabinet in a secured office area. Research data kept online will be kept secure and confidential through password protection. Data will be stored in RedCap and on a secure University server. Data kept on HeartSmartMoms will have participant ID number, but no other identifiable information.

Substudy:

Surveys: We will orally read survey questions to participants and responses. It may be tiring answering questions in our survey. Also, a participant may feel discomfort answering questions of a personal nature, but subjects can always choose not to answer any question.

Confidentiality: The Principal Investigator and her staff will take all reasonable measures to protect the confidentiality of each subject's records and data. Subject data will be referenced by number only. Research data on paper will be kept in a secured file cabinet in a secured office area. Research data kept online will be kept secure and confidential through password protection. Data will be stored in RedCap. Audiorecordings will be stored on a secure University server. Data kept on HeartSmartMoms will have participant ID number, but no other identifiable information.

**E. Potential Scientific Problems:** This is a pilot intervention that has never been trialed before. It is based on information gathered from WIC staff, WIC leadership, WIC clients and is based on evidence from other settings. However, because it has never been trialed before, we may find significant feasibility and acceptability issues leading to significant attrition, making it impossible to complete Aim 2 for the main and substudies. Given that this is a feasibility trial, with a small sample

size, we may also not have enough power to detect differences between intervention and control participants if the differences are small.

## F. Data Analysis Plan:

Aim 1: To evaluate the feasibility and acceptability of a multi-component novel weight loss intervention delivered in a WIC setting to a population of low-income, predominantly racial/ethnic minority, obese, postpartum women.

- The RA will transcribe the audiorecorded responses to open-ended questions posed to participants and WIC staff on acceptability. We will use a thematic analytic approach to analyze the data. After reading and discussing all responses amongst team members, we will create a list of codes. We will then use an iterative process to revise codes as needed and identify main themes. We will use a software program (Atlas.ti) for coding. We will assess the ease of recruiting women for the study (number enrolled/number approached) and attrition from the study. We will also calculate the intervention adherence measures, including number of women who received the entire intervention, number of women who came to all visits, participation in self-monitoring, use of phone coaching, and use of the Facebook page. For the Facebook page, we will count the number of posts/individual and categorize the content based on the type of content we see.

Aim 2: To evaluate differences in diet, physical activity, self-efficacy, eating stimulus, and weight change between intervention and control participants to determine preliminary intervention efficacy over a 12-week period.

- We will conduct a univariate analysis of variables to evaluate for baseline group differences, distributions, and outliers for demographic, lifestyle and infant feeding variables. Student t-tests will be used to test for differences between intervention and control groups in change in weight (baseline to 12 wks) and in lifestyle habits using a 2-tailed alpha=0.05 for statistical significance. Dr. Thompson will conduct the analysis in consultation with the Child Health Research Biostatistical Core.

Sample Size: This is a feasibility trial, hence, we will not be powered to detect all clinically significant findings. The sample size was chosen based on the sample needed to achieve Aim1. The sample size is 40 (20 intervention and 20 control). We are asking for a sample size in the application up to 80 in case we have a large number of individuals enroll but not participate in the substudy. Given that this is a feasibility trial, we are unsure how difficult recruitment will be.

**G. Summarize Knowledge to be Gained:** We will learn whether the proposed intervention is feasible and acceptable, which will inform future efforts to design weight loss interventions in WIC settings. If it is feasible and acceptable, then this will support the need to evaluate this intervention on a larger scale. Findings from Aim 2 will help us to understand whether the intervention has an impact on lifestyle changes and weight. Again, this is important for understanding whether we should evaluate this intervention on a larger scale, and will inform sample size estimates for future work.

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