Study Title:	Partnering with WIC to Prevent Excessive Weight Gain in Pregnancy
NCT Number:	NCT03707834
Documents Included:	IRB Approved Protocol with Statistical Analysis Plan
Date of IRB Approval:	09/21/2021

1) Abstract of the study

Institute of Medicine guidelines for weight gain in pregnancy are clear, but evidence-based treatment approaches are not widely available. This evidence gap is particularly pressing for medically vulnerable women - those who are low income and often racial/ethnic minorities. These women have the highest rates of obesity, but almost no resources to support weight control in pregnancy. Without intervention, most will exceed Institute of Medicine recommended gains and incur significant morbidity for themselves and their children. There is preliminary data from our group supporting the efficacy of digital health platforms for delivering antenatal obesity treatment among the medically vulnerable. However, our inexpensive, easily scalable approach has not been integrated and tested in real world settings, limiting broad reach and dissemination potential. Dissemination considerations are especially pressing for socioeconomically disadvantaged and minority populations because of these groups' higher obesity risk, greater potential for experiencing obesity-related comorbidities in pregnancy, and limited finances to afford alternative treatments. The Women, Infants and Children (WIC) Food and Nutrition Program is the leading public health nutrition program for pregnant women and their children in the US, and thus, it is in a unique position to meaningfully impact the obesity epidemic among the more than 9 million disadvantaged participants it serves annually. Yet no demonstrations of effective gestational weight gain interventions exist in WIC. We propose a pragmatic trial designed to rigorously test our antenatal obesity treatment approach integrated into Philadelphia WIC community clinics. We have long-standing relationships with WIC staff and prior experience conducting pragmatic clinical trials in under-resourced settings. We will randomize 438 African American and Latina Philadelphia County WIC participants with obesity in early pregnancy to one of two treatment arms: 1) usual WIC care; or 2) healthy lifestyle intervention arm, which includes empirically supported behavior change goals, regular self-monitoring text messages with automated feedback, tailored skills training materials, and counseling from WIC nutritionists. Our primary outcome is prevalence of excessive gestational weight gain; we will additionally examine changes in diet and physical activity, health-related quality of life, and rates of adverse pregnancy outcomes. We will use the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework to evaluate the intervention's dissemination potential and cost effectiveness in the WIC setting. The proposed project will constitute the first systematic translation of a comprehensive antenatal obesity treatment program focused on low-income, racial/ethnic minorities, using the strengths of mHealth and WIC provider counseling for intervention delivery.

2) Protocol Title

Partnering with WIC to prevent excessive weight gain in pregnancy

3) Investigator

Sharon Herring, MD, MPH

4) Objectives

a. **Primary specific aim:** To determine whether the healthy lifestyle program lowers the prevalence of excessive gestational weight gain, compared to usual WIC care. Primary hypothesis: Participants randomized to the healthy lifestyle intervention arm will demonstrate significantly lower prevalence of excessive gestational weight gain, compared to those randomized to usual WIC care.
b. **Additional aims:**
    i. To compare trial arms with respect to changes in diet and physical activity, and rates of adverse pregnancy outcomes (including glucose intolerance, hypertension, and infant macrosomia).

    ii. To utilize the RE-AIM framework to evaluate the intervention's dissemination potential in WIC. We will assess: reach into the patient population; effectiveness on outcomes; organizational adoption; consistency of implementation; and maintenance of effects on 6- and 12-month maternal/child postpartum weights.

    iii. To quantify the intervention's cost-effectiveness.

5) Rationale and Significance

Nearly two-thirds of pregnant women exceed Institute of Medicine (IOM) weight gain guidelines.[1] Excessive gestational weight gain not only adversely affects the current pregnancy – by increasing risk of diabetes and hypertension, cesarean delivery, and infant macrosomia – but it also promotes new or persistent obesity in women and their children.[2,3] Ethnic minority women are at particular risk of greater gains because they are more likely to enter pregnancy obese,[4] reside in obesogenic environments,[5] and adopt obesity promoting behaviors (e.g., high caloric intake, physical inactivity).[6-8] However, these high risk women also suffer from a paucity of treatments. Without intervention, the implications are clear: most will exceed recommended gains in pregnancy and incur significant morbidity for themselves and their children.[9,10]

We are working to fill this treatment gap. For nearly a decade, our group of multidisciplinary researchers has partnered with African American and Latina women, primarily those of lower socioeconomic position, to develop innovative weight control treatments that: 1) focus on simple, empirically-supported behavior change goals, tailored to the target population;[11-13] and 2) use low-cost, mobile technologies that enjoy high penetration among racial/ethnic minorities (text messaging, social media) to deliver intervention content, promote social support, and allow for frequent yet convenient, interactive self-monitoring.[14] There is mounting evidence supporting the efficacy of this approach for delivering inexpensive, easily scalable weight control interventions,[15-18] particularly in pregnancy.[19] Our pilot intervention for this proposal cut the proportion of African American mothers gaining in excess of IOM guidelines in half.[19] While our study had high engagement and low attrition, the treatment was implemented in a single obstetric clinic using research staff for interpersonal support, limiting broad reach

and dissemination potential. We posit that mHealth interventions must be delivered with additional counseling from trusted, routine care providers to reliably produce clinically significant outcomes and sustain effects.[20-24] However, ***no demonstrations of effective gestational weight gain interventions have included brief provider counseling as a component***. Doing so is a high priority.

The next step is to integrate our promising pilot intervention into the Women, Infants and Children (WIC) Food and Nutrition Program, the leading public health nutrition program for low-income pregnant women and their children in the US.[25] WIC provides routine care for nearly 2 million pregnant women annually, yet standard care at WIC is inadequate for addressing antenatal obesity.[26] Mothers from our pilot revealed a ***need for WIC nutritionist involvement to enhance trust and receptivity of our messages***. We have spent the past year talking at length with WIC nutritionists through focus groups about integrating our interventions into daily practice, brainstorming strategies we plan to employ in this proposal.[27] For example, WIC nutritionists have voiced repeated frustrations about lack of time for patient follow-up between antenatal visits, as there is no method in place to maximize counseling for those who need it most. We plan to test an approach, grounded in theory and our preliminary work that will electronically alert providers if their patients are not achieving intervention goals, offering WIC nutritionists scripts for brief, tailored strategies to deliver by phone – so to increase efficiency and potentially lower costs.

We propose a pragmatic trial design in which we will randomize 438 African American and Latina Philadelphia County WIC participants with obesity in early pregnancy to either usual WIC care or a healthy lifestyle intervention arm. The intervention arm, adapted from our pilot with WIC nutritionist input, is a ***multi-level, systems-change antenatal obesity treatment approach***. At the patient level, we will provide empirically-supported behavior change goals, self-monitoring text messages with feedback, tailored skills training materials, and interpersonal support from trusted WIC providers. At the provider level, we will make it easier for WIC nutritionists to advise about weight gain in pregnancy by providing electronic patient progress reports and counseling recommendations. Our primary outcome is prevalence of excessive gestational weight gain. ***If successful, this approach can be quickly scaled to impact the entire WIC program.***

6) Resources and Setting

a. **<u>Recruitment Sites:</u>** To maximize recruitment, while WIC is conducting visits virtually, data queries and phone screening by WIC staff will include participants from all 10 of Philadelphia WIC's community clinic sites. Once sites resume in-person visits, we will resume in-person recruiting.

i. North Philadelphia WIC Clinic,1300 West Lehigh Avenue, Philadelphia, PA 19132
ii. Olney-Logan WIC Clinic, 5751 N. Broad Street, Philadelphia, PA 19141
iii. Aramingo WIC Clinic, 2401 East Tioga Street, Philadelphia, PA 19134

iv. South Philadelphia WIC Clinic, 1165 South Street, Philadelphia, PA 19147.
v. Northeast WIC Office, 7959 Bustleton Avenue, Philadelphia, PA 19152.
vi. Overbrook WIC Office, Overbrook Plaza, Store # 1400, 5610 Lancaster Avenue, Philadelphia, PA 19131
vii. Woodland WIC Office, 1741 South 54th Street, Philadelphia, PA 19143.
viii. St. Christopher WIC, Nelson Pavilion Bldg, 160 East Erie Avenue, Philadelphia, PA 19124
ix. Lehigh WIC Office, 217-33 West Lehigh Avenue, 2nd Fl. Philadelphia, PA 19133

b. Research Procedures Site:
Assessment visits (combined CORE Screening/Enrollment (CS/EN) [≤ 16 weeks gestation], end of pregnancy [36-38 weeks' gestation], 6-months postpartum, and 12-months postpartum) will occur over the phone with Temple research staff member. All staff will complete calls from a private space.

If public health guidelines allow and participants consent, these calls may be conducted as in-person visits at Temple's CORE office (3223 N. Broad Street, Suite 175) or if transportation is an issue, we will conduct these visits at the participants' home.

7) Prior Approvals

WIC is strongly supportive of our efforts (see updated approval letter attached from WIC).

8) Study Design

a. Recruitment Methods: Up to 600 women will be recruited and consented for this study. We plan to enroll and randomize a total of 438 participants (219 per arm). Based on prior studies (Herring PI, Protocol #20227, "The effects of an electronically-mediated, pregnancy and postpartum, behavioral intervention program on changes in weight and cardiometabolic biomarkers: Healthy4Baby" NIH K23HL106231-01 and Herring PI, Protocol #22201, "Targeting pregnancy-related weight gain to reduce disparities in obesity: a randomized control trial" HRSA R40MC26818), we will likely need to recruit and screen approximately 40% more women than our randomization target (as we anticipate no-shows to baseline visits).

b. Recruitment via advertisements and flyers: Study advertisements will be used and are attached. Subjects will be deemed eligible for screening by completing a phone screen with a WIC staff member. The phone screen will include questions related to determining if the subject meets the study's initial inclusion and exclusion criteria (see section 8e below for inclusion/exclusion

criteria). Research staff will devote time daily to fielding phone calls, scheduling study subjects for screening visits, and conducting screening visits.

c. **Recruitment via WIC's electronic patient database:** Potential participants for this clinical trial will include patients identified through WIC's electronic patient database, using the eligibility criteria described in the inclusion/exclusion criteria section below. We will target patients who are seen at the WIC sites described in the recruitment site section above (6a). Dr. Kilby, WIC Executive Director, has provided an updated letter of support for this study and its recruitment approach (see approval letter attached to this protocol). We've used a similar approach in previous studies. We are requesting a HIPAA waiver in order to identify potentially eligible patients via WIC's electronic patient database.
    i. Criteria used to develop the computable phenotype:
        1. Age in years (>= 18 years)
        2. Currently pregnant (≤ 16 weeks' gestation) within 30 days of the data query
        3. BMI ≥ 25kg/m2 within 30 days of the data query

    ii. Once a list of patients is generated using this phenotype by WIC staff, an IRB-trained WIC staff member Gloria Lobato, Lauren Brennan, or Sam Nash will text message or call identified patients in English and/or Spanish and explain the purpose of the study, assess interest, and evaluate eligibility (see WICProvider/Phone screen for script and eligibility questionnaire). All Spanish speaking participants will be screened by Gloria Lobato, who is bilingual. Participants who are initially eligible after phone screening (see inclusion/exclusion criteria below) will be scheduled for a combined CS/EN call or visit where they will be immediately consented in English or Spanish for the study by Temple study staff (note, all study visits for Spanish speaking participants will be administered by Alberly Perez, who is bilingual).
        1. Text messaging will be managed by above WIC staff. Phone numbers and participant information will be given to Temple staff only after participant agrees. Sample English text messages are:
            a. "Hi! WIC is working with Temple University on a new program to improve women's health. If you're interested, please let us know when we can call you!"
            b. "Hi! We just tried to call to let you know that WIC is working with Temple University on a new program to improve women's health. If you're interested, please let us know when we can call you again!"
        2. Sample Spanish text messages are:

a. "¡Hola! WIC está trabajando con la Universidad de Temple en un programa nuevo para mejorar la salud de las mujeres. Si está interesada, ¡por favor avísenos cuándo podemos llamarla!"
b. "¡Hola! Nosotros intentamos llamarle para informarle que WIC está trabajando con la Universidad de Temple en un programa nuevo para mejorar la salud de las mujeres. Si está interesada, ¡por favor avísenos cuándo podemos llamarla de nuevo!"

iii. Participants can contact the WIC staff/study team at any time if they wish to opt out of further contact regarding this trial and no further contact will be made. In that case, they will be reminded that they can contact WIC staff/study team at any time to learn more about the study if they change their mind. Refreshing the patients meeting the computable phenotype criteria will occur every 30 days after the initial data query. This refresh will capture newly identified patients for future recruitment. Only WIC staff will be given WIC client information until potential participants agree (via phone) to be contacted by Temple staff.

iv. All participants will be emailed or mailed a copy of the consent prior to their CS/EN call. During the CS/EN call or visit, staff will use Redcap to facilitate the process of consenting electronically. The link will be emailed or texted to the participant during the phone call or visit. Participants will then have to electronically sign the Informed Consent Form, HIPAA Authorization, and the Medical Record Release forms (prenatal, delivery, infant, and WIC). In the instance that Redcap is not working, we will continue to consent over the phone. The staff member consenting will sign for themselves, send a copy of the consent to the participant, and create a note-to-file explaining why the subject signed the consent on a different day.

v. Once consented in-person or during the CS/EN call, maternal height and weight will be measured or self-reported by the participant to ensure participants fall within the BMI eligibility range (see inclusion/exclusion criteria).

vi. They will then complete questionnaires (assessing sociodemographics, medication intake, psychosocial factors, health insurance, income, hospital and outpatient visits, quality of life, and executive functioning) read out-loud by Temple study staff to minimize literacy demands. Additionally, research staff will administer the ASA24 dietary recall during the combined CORE Screening/Enrollment visit or call (a tool that assesses participant dietary intake over the previous 24 hours).

vii. Participants will then be enrolled and randomized 1:1 per computer-generated assignments in REDCap to healthy lifestyle intervention (A0; n=219) or usual WIC care (SC; n=219). Randomization will be stratified on weight status (overweight vs. obesity) and ethnicity (African American vs. Latina). Dr. Herring and her staff will be blinded to group assignment until participants reach randomization. Participants who choose not to participate, or who are ineligible, will be referred back to their WIC providers/Obstetricians for health/nutrition information.

viii. If a call is needed/requested (e.g. due to Covid-19 restrictions on in-person vists), upon completion of the combined CS/EN call, participants will be sent via UPS a BodyTrace scale to use for weight at each time point. Additionally, they will be sent paper copies of their signed Informed Consent Form, the HIPAA Authorization, and the Medical Record Release forms (prenatal, delivery, infant, and WIC)

d. Inclusion and Exclusion Criteria

i. Inclusion Criteria: All participants must meet all of the following criteria at screening

1. Women at least 18 years of age
2. Measured BMI between ≥25 kg/m2
3. Self-identify as African American or Latina
4. Philadelphia WIC participant
5. Gestational age ≤16 weeks' by last menstrual period
6. Willingness to receive study texts
7. Own a cell phone with an unlimited text messaging plan
8. Able to participate in light to moderate physical activity (walking)
9. Participants must be willing to comply with all study-related procedures
10. Participants must be able to read and write fluently in English or Spanish

ii. Exclusion Criteria: If participants meet one of the following criteria, they will be excluded.

1. Prior bariatric surgery
2. Pre-existing medical condition and/or medication that could influence weight (e.g., diabetes, HIV, thyroid disorder, bulimia, anorexia, gallbladder disease)
3. Diagnosis contraindicating weight control (e.g., hyperemesis gravidarum)
4. Shared phone
5. Multiple pregnancy (e.g., twins)
6. Current and/or previous participant of our Temple-led obesity treatment interventions in pregnancy or the postpartum period

7. Serious or unstable medical or psychological conditions that, in the opinion of the investigator, would compromise the subject's safety for successful participation in the study

e. Study Timelines

i. The duration of a subject's participation in the study: Approximately 18 months. Participants will be followed for one year after delivery.

ii. The duration anticipated to enroll all subjects: approximately 30 months.

iii. The estimated date that the investigators will complete the study: December, 2023.

9) Study Procedures and Data Analysis

a. Data collection: This section reviews the types of data that will be collected, stored, and analyzed to meet the scientific goals of the study. Trained research staff will collect assessments for participants in intervention and usual care arms at multiple time points (Table 1). Our evaluation protocol will be similar to the ones we have used successfully in prior trials. If transportation is an issue, we will conduct visits at participants' homes.

b. We will additionally abstract data from participants' WIC records and obstetric charts, including 24-28 week oral glucose tolerance test (OGTT) results, prenatal weights, and infant birth weight at delivery. We have used this pragmatic approach to collect high-quality data from medical records in prior studies.[19,28] A detailed study timetable and list of all procedures at each visit are shown below:

Table 1: Summary of types of data collected

Measure	WIC/Phone Screening	Time point			
		CORE Screening/ Enrollment (CS/EN) Baseline	36-weeks' Gestation Follow-up 1	6-Mo Postpartum Follow-up 2	12-Month Postpartum Follow-up 3
Screening Eligibility Form	X				
Informed Consent		X			
Questionnaires		X	X	X	X
Maternal Weight		X	X	X	X
Maternal Height		X	X	X	X
Infant Weight				X	X
Infant Length				X	X
ASA-24: 24-Hour Recall of Food Intake		X	X		
Maternal Medical Record Review		X	X	X	X
WIC Medical Record Review		X	X	X	X

i. **Questionnaires.** Participants will complete several questionnaires at each time point (by phone or in-person, depending on participant preference and/or Covid-19 restrictions on in-person visits): Core Screening/Enrollment (CS/EN), 36-38 weeks' gestation (end of pregnancy), 6 months postpartum, and 12 months postpartum. All questionnaires will be read out-loud by study staff to minimize literacy demands. These questionnaires will contain the following items (with data collected and stored in REDCap):

1. Psychosocial measures: Using previously validated questionnaires (merged into a single screening and follow-up survey), participants will self-report: 1) food security via the 6-item USDA survey, 2) health literacy via the BRIEF: Health Literacy Screening Tool, 3) quality of life via the Short Form 12 or SF-12, and 4) questions about housing stability.
2. Economics: A variety of variables related to health insurance, work productivity, income, and hospital and outpatient visits will be collected to assess the cost-effectiveness of the intervention.
3. Sociodemographics: A variety of variables will be collected via self-report, including age, parity, marital status, smoking history, and education.
4. Concomitant medications and adverse events: At all visits, medications added/adjusted and adverse events will be recorded.
5. Infant feeding: Infant feeding behaviors and beliefs will be assessed from questions adapted from the Infant Feeding Style Questionnaire at 6 month and 12 month postpartum visits.
6. Executive functioning: Participants' executive functioning will be assessed using the BRIEF-A (Behavior Rating Inventory of Executive Function) at CS/EN.
7. Patient-provider interactions: This will be assessed at the 36-week (end of pregnancy) visit and the 6-month postpartum visit via the MOR: Mothers on Respect Index and the MADM Scale: Mothers Autonomy in Decision Making.

ii. **Weight and height.** Maternal weight will be measured at each time point either in-person or using a BodyTrace scale that will be sent to the participant after completion of the combined CS/EN call or visit. Height will be measured in-person or self-reported during the combined CS/EN call or visit.

iii. **Infant weight and length.** With the participant's optional consent, we will have them sign medical record release forms to get their infant's weight and length from their pediatrician. These will be used to

approximate measures at 6-months and 12-months of age and assess maintenance of intervention effects on infant weight/length.

iv. **24 Hour Dietary Recall (ASA-24).** Measures of dietary intake via electronic 24-hour recalls administered at combined CS/EN call or visit and at the end of pregnancy visit. More details are provided in the data analysis section below.

v. **Medical record review.** With the participant's consent, we will extract information about her medical history to confirm eligibility, health problems and weight during pregnancy, delivery records, and postpartum records.

WIC record review. With the participant's consent, we will extract information about nutritional topics/issues discussed at WIC visits occurring during the study period. We will extract maternal and infant weight and height data collected at WIC visits during the study period. We will also extract any changes to participants' address(es) and phone number(s) collected at WIC.

c. <u>Treatment:</u> This section reviews the two treatment arms in the study.

i. Eligible volunteers will be randomly assigned by Temple study staff, with use of a random-number generator in RedCap, to a treatment group consisting of either usual WIC care (SC) or an individual, healthy lifestyle intervention (AO) that consists of: 1) empirically supported behavior change goals; 2) self-monitoring of behavioral diet goals and weight gain via text messages with automated feedback; 3) tailored skills training materials; and 4) WIC nutritionist counseling.

ii. <u>Description of SC:</u> Participants assigned to the WIC usual care arm will receive usual care offered to pregnant women at WIC. Per WIC protocol, participants will be strongly encouraged to schedule routine prenatal care visits with their obstetricians, who will be informed of the patient's participation (but not randomization assignment) via letter (included in the original submission). We will ensure that WIC providers have access to self-help materials (e.g., brochures from the American College of Obstetricians and Gynecologists [ACOG]) and quarterly trainings on obesity treatment updates). Additionally, all participants randomized to SC will receive self-help materials compiled from American College of Obstetricians and Gynecologists [ACOG].

iii. <u>Description of AO:</u> In addition to usual WIC care described above, participants in the AO arm (or Healthy Lifestyle Group) will receive a multi-component, theory- and evidence-based antenatal obesity treatment. Rooted in Social Cognitive Theory, our intervention is

designed to enhance mothers' self-efficacy and intrinsic motivation for weight-related behavior change through goal setting and self-monitoring (self-regulatory processes), behavioral skills training (mastery experiences), interpersonal support (social persuasion), and social modeling strategies.[30-32] Also integrated is a Social Ecological Approach that highlights the complex interplay among individual-, family-, and community-level factors.[33,34] Thus, treatment emphasizes changing behavior across multiple spheres of influences and various settings (e.g., expanding an individual's nutrition knowledge, effectively dealing with constraints of income and access, modifying the home environment).

1. ***Behavior change goals:*** Our treatment focuses on adhering to a set of simple behavior change goals that directly/indirectly modify energy balance, chosen for their relevance to the target population, ease of self-monitoring, concreteness, and empirical support for weight control.[11,35-39] Our behavioral goals have proven efficacy, even in resource constrained settings.[15-19,28] During the combined CS/EN call, all participants in the AO group will receive 3 behavior change goals: 1. Limit starchy foods like white rice, mac & cheese, white bread, and potatoes to no more than 1 a day; 2. No sugary drinks; 3. Eat at least 1 green veggie a day. From our skills training library, videos will be immediately texted that focus on "how" to reach each goal rather than simply "what" to change and provide an orientation to the program. To foster novelty yet maximize behavioral habit formation, we will rotate participants' goals at 8-week intervals, aiming for repetition to achieve automaticity.[40,41] The second group of goals are: 1. No greasy foods; 2. Limit your sweet and salty snacks like chips, cookies, ice cream, and cake to no more than 1 baby-sized snack a day; 3. Eat at least 1 fruit a day. All participants will alternate between the two goal groups at 8 week intervals until they complete their end of pregnancy visit. To facilitate goal attainment, participants will receive a water bottle, measuring bowls and spoons, a magnetic shopping list, and a cookbook after completion of t the combined CS/EN call.

2. ***Interactive self-monitoring text messages:*** Regular self-monitoring is one of the most efficacious behavior change strategies,[42] though adherence notoriously wanes over time.[43] Texts are inexpensive to develop, simple to tailor, and immediately scalable. Greater self-efficacy and satisfaction is observed when text messages are encouraging and motivational in obesity treatment trials, with the use of testimonials from peers for support and tailored recipes/tips for concrete ideas.[44-46] We developed a robust texting system that incorporates these strategies that will be adapted for use in the proposed study. ***Fully automated monitoring texts matched to each participant's current behavior change goals*** will be sent 2 times weekly, at the time of her choosing.

Once a participant enters her data, she will ***receive immediate personalized self-monitoring feedback*** through text messaging to reinforce successes and/or offer motivational strategies (see example from Healthy Babies). We will additionally send intervention participants ***text message prompts to self-weigh weekly using study provided scales from BodyTrace.*** These scales transmit weight data directly through the cellular network. Progress will be displayed via links to web-based graphs that participants (and WIC nutritionists) can easily access to visualize gestational weight gains. We have used BodyTrace scales in several studies with >90% compliance for self-weighing.[28,48,49]

3. ***Tailored skills training materials:*** Tailored materials can enhance the personal relevancy of interventions, provide cues to action, and increase engagement.[50] We will offer intervention participants' skills training content that corresponds to their assigned behavior change goals via videos and text messages sent 3 times weekly (frequency of texts was determined with input from Healthy Babies participants and review of mHealth literature, suggesting that informational texts should not be delivered daily).[51-53] We have a library of materials that have been adapted for this study, with topics including (but not limited to): negotiating barriers; stress reduction; eating out; serving sizes; and engaging social support – all designed for mothers

from resource constrained settings with low-literacy levels (example skills text: “Craving something sweet? Instead of grabbing junk, eat applesauce, yogurt, or a fruit cup. Ur baby will thank u ☺”). We created ~1 minute videos including messages from WIC nutritionists and narratives from previous study participants, providing role models with information about cost and community resources to increase receptivity. All materials will be available in English and Spanish, with specific content tailored to ethnicity (either African American or Latina), to offer relevancy to all participants enrolled.

4. ***WIC provider counseling:*** There is evidence that WIC counseling is trusted,[54-56] yet WIC nutritionists find it difficult to adequately address gestational weight gain at routine visits.[27] Our treatment is designed to encourage a patient-centered counseling approach (e.g., responsive to individual preference, needs, and values) while at the same time overcome barriers, including: time constraints (by supplying progress reports and brief recommendations); failure to follow-up in-between visits (which will be largely automated); and fear of causing offense (which will be resolved through role play and group discussion). There is strong support for integrating our intervention into WIC care (see letter from initial IRB submission). Participants will have monthly to bimonthly study-related phone calls from a WIC nutritionist (aka, WIC Champion, Gloria Lobato) to set goals, overcome challenges, and give participants new information about diet and activity while they are in the program. These calls will last 15- 30 minutes and will be audiotaped (for training and feedback). Additionally, if participants agree, they will also receive in-person support at their regularly scheduled WIC visits every 2-3 months. While WIC is conducting visits virtually, we will not be using this approach. To inform counseling, we will supply the WIC champion with coaching protocols for new goal assignment calls that will be adapted from our prior pregnancy and postpartum weight control trials during study start-up. The goal assignment calls will take place in 8 week intervals for each participant. Additionally, the WIC champion will be notified when a participant in this group is -0.3kg from her weekly maximum IOM recommended weight gain targets or above[57] and the WIC champion will be asked to call these participants within 48 hours using adapted problem solving call scripts to enhance motivation for behavior change, deliver in-depth skills training, engage in problem solving, and provide social support. We will set a call ceiling of 1, 15-30 minute call monthly so to not overburden providers, but instead harness a potentially

important opportunity for impacting behavior change and ensuring safety.

5. ***Facebook and Instagram.*** In keeping with our strategy in prior studies, supplemental skills training materials, links to videos, and/or contests with prizes will be posted daily on an optional private Facebook (FB) group that participants will be invited to join at baseline. We chose to incorporate FB because data suggest a strong link between social influence and healthy (or risky) behaviors, particularly among young adults,[58] which we and others have leveraged through FBs unique communication features (e.g., frequent messaging/posts to increase exposure to weight-related skills; reciprocal interactions through instant messaging and/or FB "pokes" for persuasion).[59,60] Philadelphia WIC providers actively use FB to promote local programs and communicate with current patients, and thus, we do not anticipate difficulty maintaining/moderating our group page. To ensure confidentiality, this group will be completely private, have a generic name, and will not appear on profile pages. Evidence from Healthy4Baby and Healthy Babies and other studies using social networking sites within mHealth/eHealth interventions demonstrate efficacy for their use with obesity treatment.[18,19,61-65] Due to feedback from participants, we additionally added an optional private Instagram profile to allow participants to interact with other participants in the program and to learn new tips about staying healthy.

d. <u>Data Analyses:</u>

i. **Primary outcome.** ***The primary outcome is the proportion of women with excessive gestational weight gain,*** defined as the proportion of mothers exceeding weekly Institute of Medicine (IOM) weight gain targets (>0.32 kg/week for BMI 25-29.9 kg/m2; >0.27 kg/week for BMI ≥30 kg/m2) over the study period (from enrollment to end of pregnancy).[57] Total gestational weight gain will be calculated as the difference between weight in kilograms measured at 36-38 weeks' gestation (end of pregnancy) and weight at the baseline visit (in the first trimester or early second trimester of pregnancy). Weight in clinical gowns, without shoes, will be recorded in duplicate by trained staff using high-quality, calibrated SECA digital scales. We will also use BodyTrace scales for patients seeking a remote option (and/or during restrictions to in-person visits during the Covid-19 pandemic) that will be sent to the participant after completion of the combined CS/EN call. In the rare case that a mother delivers her infant before 36-38 weeks' gestation, we will abstract her last prenatal weight from her obstetric chart and call her within 2 weeks of delivery to administer our follow-up

survey. We expect to abstract weights in <10% of mothers based on previous experiences with the target population, Height will be measured to the nearest 0.1 cm using a calibrated stadiometer at participants' in-person baseline assessments or via self-report via phone.

ii. **Secondary and patient-centered outcomes.**

1. ***Dietary intake*** will be measured using the Automated Self-Administered 24-hour (ASA24) dietary assessment tool, a web application developed by NCI.[69] We will collect one 24-hour dietary recall during combined CS/EN visit or call and during the end of pregnancy visit. Data are summarized as intake of micro- and macronutrients, food groups, and dietary patterns. ASA24 has been validated against more expensive, time-consuming tools.[71] We have experience using this measure in diverse groups.[48,49]

2. ***Disorders of glucose tolerance*** (mild hyperglycemia, gestational diabetes) will be identified through routine glycemic screening as part of usual obstetric care between 24-28 weeks' gestation. Standard care dictates that venous blood is sampled for glucose 1 hour after a 50-gram oral glucose load. If the glucose result is ≥130 mg/dL, the participant will be referred for a 100-gram fasting 3-hour OGTT. Normal 3-hour OGTT glucose results include: <95 mg/dL at baseline, <180 mg/dL at 1 hour, <155 mg/dL at 2 hours, and <140mg/dL at 3 hours.77 In this study, we will define glucose intolerance in 2 ways: 1) 1-hour OGTT values ≥130 mg/dL (mild hyperglycemia), and 2) two or more abnormal values from the 3-hour OGTT (gestational diabetes). Glucose values ≥130 mg/dL are associated with adverse pregnancy outcomes and have been used by us and others to define milder states of glucose intolerance.[78-80] We have used this pragmatic approach to collect high-quality OGTT data in prior studies with almost no (<5%) missing values.[81]

3. ***Infant birth weight*** will be abstracted from delivery records. Macrosomia will be defined as infant birth weight ≥4000 grams. We will calculate sex-specific birth weight for gestational age percentile based on US national data.[83] To evaluate intervention safety, we will examine the proportion of small-for-gestational age (SGA) infants by group (e.g., those with birth weights <10th percentile for gestational age).

4. ***Sociodemographics and medical history.*** Participants will self-report age, adverse childhood experiences, food security, race/ethnicity, parity, income and employment, education level,

health status, tobacco use, household size, and marital status. We will abstract medical history from obstetric records, including comorbidities and prenatal/delivery complications.

5. ***RE-AIM outcomes.*** We will use the RE-AIM framework to evaluate dissemination potential.[84]

Reach will be evaluated in several ways. First, we will work with our WIC colleagues to identify the total number of eligible participants enrolled at WIC during the period of recruitment. Next, we will evaluate the proportion of the eligible WIC population who: 1) are reached by our study activities; 2) are interested in participation; 3) enroll; and 4) are excluded from participation. Lastly, we will assess the representativeness of our sample by comparing the sample's demographic features to that of the target population.

Effectiveness will be assessed via our primary, secondary and patient-centered outcomes.

Adoption is a measure of potential intervention uptake by WIC. We will quantitatively assess number of provider referrals for study entry.

Implementation will be examined on both the participant level and the WIC provider level. At the participant level, we will measure intervention engagement via: 1) number of responses to self-monitoring text prompts, text response time, and the type/frequency of texted videos viewed; 2) type/frequency of FB or Instagram posts and/or likes; and 3) number/duration of WIC provider visits and calls completed. Relying on an approach by Olson and colleagues, we will examine the extent to which level of engagement is associated with gestational weight gain.[85] We will also evaluate the consistency of the intervention across different patient/provider subgroups. At the WIC provider level, we will examine process data stored in our web application and perform chart reviews to assess documentation of weight-related counseling to measure intervention delivery fidelity.

Maintenance of weight change will be assessed at 6- and 12-months postpartum. We will determine the proportion of women in each treatment group at (+/- 0.9kg) or below early pregnancy weight by 6 months and 12 months postpartum. While observational data repeatedly suggest that excessive gestational weight gain is the strongest predictor of postpartum adiposity,[3] few studies have evaluated this relationship in the context of a clinical trial. With participant consent, we will additionally abstract their infant's weight and length from their pediatrician visits. These will be used to approximate measures at 6-months and 12-months of age and assess maintenance of intervention effects on infant weight/length.

iii. **Data analysis plan:**

1. **Primary aim.** We will use Fisher's exact test (for raw intervention effects) as well as multivariable logistic regression (for adjusted intervention effects), testing the effect of treatment group on the odds of excessive gestational weight gain while simultaneously adjusting for covariates discovered to be unbalanced between the trial arms at baseline. We will consider interaction effects of treatment by relevant baseline predictors when needed, (e.g., age, parity, BMI, and gestational age at enrollment), to evaluate the assumption of equal intervention effects between the 2 arms with respect to these covariates. Data will be analyzed using an intention-to-treat (ITT) approach where subjects are analyzed according to their treatment assignment at randomization, regardless of level of engagement. Since an ITT analysis is planned, 2 methods are proposed for accounting for missing data. First, multiple imputation methods will be used to estimate weight at 36-38 weeks' gestation based on intermediate outcomes, mediating variables, and data collected on subjects with complete follow-up.[87,88] A second approach will utilize model-based analyses with direct maximum likelihood methods.[89]

   Additionally, to take advantage of the longitudinal nature of this study, we will treat weight as a continuous measure, employing an advanced mixed-effects modeling approach to estimate individual and mean weight trajectories over time by treatment group. We will supplement weights collected by research staff with available electronic health record prenatal weight data abstracted from WIC and/or participants' obstetric records; we and others have found that the absolute agreement between research and prenatal clinic measured weights is extremely high, providing strong support for exchangeability.[90,91] Benefits of this modeling approach include: 1) ability to accommodate all available measured prenatal weight data; 2) allowance for varying and/or unequally-spaced intervals between measurements; and 3) high variability in the number of longitudinal assessments expected across subjects. Longitudinal trajectories could be modeled using splines or kernel density.[92] They will allow for an unbiased estimation of the overall intervention effect on gestational weight gain to better understand non-linear, dynamic changes in weight over time.

2. **Additional aims.** We will use parallel strategies to those described above for secondary and patient-centered outcomes.

If continuous data are not normally distributed, log or square-root transformation will be considered. We will control for confounders and evaluate effect modification as needed. RE-AIM outcomes will be analyzed in an exploratory fashion. Additional analyses investigating the mediating influence of dietary and physical activity changes will use bootstrapping for standard errors to estimate the direct, indirect, and total effects.[93-95]

3. **Cost-effectiveness.** We will conduct the cost-effectiveness analysis from both the societal perspective (payer and participant) and a third party payer's perspective using an Activity Based Costing approach. We will identify the key activities that drive overall costs, and assign all labor, materials and supplies, and contracted services costs to these activities using intervention tracking forms that have been successfully applied in prior studies.[96-98] All costs will be valued at market rates. We will also identify which costs are sunk (e.g., software development) costs and which are incremental costs; only the latter will be used in analysis. Participant time spent on intervention activities (excluding time costs for physical activity and other behavioral modification) will be tracked via surveys at assessment visits, and these costs will be monetized based on the average hourly wage of participants (or an imputed wage for those not working). These surveys will also include questions from the Medical Expenditure Panel Survey to identify differences in healthcare utilization across arms.[99]

   Once all costs are properly accounted for, we can derive an average incremental cost of healthy lifestyle intervention relative to WIC usual care. Although data does not exist on long term outcomes of mothers and children as a function of gestational weight gain to support a comprehensive cost effectiveness analysis in terms of costs per quality adjusted life years saved, we will report the incremental cost per unit reduction in prevalence of excessive gestational weight gain. We will compare this estimate to interventions targeting similar outcomes.[100-102] We will present results for the base case and for reasonable ranges of key parameter values. These estimates will prove useful to decision makers who may be interested to fund the intervention.

4. **Power and sample size.** Sample size estimates were determined to ensure power for detecting differences in trial arms on the primary study outcome, the proportion of women with excessive gestational weight gain. We used results from

our own preliminary studies along with published data from earlier trials in obese pregnant women to approximate our ability to detect differences in weight gain between trial arms. In our pilot study, Healthy Babies, 37% of intervention participants gained in excess of IOM guidelines compared to 66% of usual care.[19] We recognize, however, that our pilot study's sample size was small, and thus, ***we have made a more conservative assumption for the power analysis in this proposal*** – 15% difference between healthy lifestyle intervention and usual WIC care arms (e.g., prevalence of 40% in the intervention arm vs. 55% in usual care) – based on data that includes a range of between-group differences, from 12% to 30%.[15,49] Sample sizes of 186 per arm will provide power of at least 0.8 with a 2-sided alpha of 0.05. If the difference is 20% (e.g., 40% vs. 60%), the power will be at least 0.96. Conservatively assuming we will lose 15% for miscarriage or loss to follow-up, the required sample size is 219 subjects per arm or 438 total.

10) Withdrawal of Subjects

Participation in this study is completely voluntary. Participants may refuse to participate or stop participation in this study at any time and it will not affect their present or future care at WIC or Temple University.

11) Privacy & Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

Subjects will be identified only by a coded identification number. No names will be used on any source documents. Data entered into the database for analysis in RedCap (which is stored on Temple University's HIPAA secure servers) will contain only the subject identification numbers. Source documents will be stored in a locked file at CORE during active data collection and analysis. Only IRB and

Good Clinical Practice (GCP) trained staff will have access to individually identifiable information under supervision of the PI. The privacy, security, and durability of accumulated personal health information are of paramount importance. Specifically: physical access to computing resources (hard drives, servers, networking equipment) is secure, audited, and restricted to skilled, IRB- and GCP-trained personnel; virtual access (login and system administration) is encrypted, audited, and limited to skilled personnel; all software and servers are reachable only via a virtual private network (VPN); and all communication between our software's application programming interface (API) and third-party software is encrypted using SSL.

All surveys and measures will be administered in a private room – either at CORE, WIC, from a staff member's home, or in the patient's home – to allow patients to feel that their answers are private or confidential.

Study staff will communicate with participants via text message. In the Healthy Lifestyle Group, staff will also communicate with participants by phone. Intervention participants will be asked to weigh themselves on a cellular-connected scale. To send and receive phone calls and text messages, and to store study information and weights, we use companies such as Twilio, Google Cloud Platform, and BodyTrace. These companies will take measures to keep information safe on their servers (such as keeping the data encrypted), but no system is completely safe. This information is also included in the participant consent.

12) Risks to Subjects

a. Potential Risks:

Few risks or discomforts are anticipated or likely in this study. Participants may become uncomfortable when talking about their height or weight. It is assessed that these risks are small. All data will be collected over the phone with staff in a pirvate room during the call.

Participants may be uncomfortable answering questions (e.g., about demographics, dietary intake, or health-related quality of life). To minimize any discomfort by participants, staff members will be hired who have experience interacting with pregnant women. Additional instruction regarding appropriate interactions will be provided by the PI. When possible, questionnaires will be administered on mobile phones, tablet, or computer, with the use of audio to minimize social desirability bias and literacy demands. Further, participants who indicate being uncomfortable or appear to be uncomfortable will be given the opportunity to withdraw their participation at any time throughout the study. Discomfort will also be minimized by informing participants that all data will only be labeled with an identification (ID) number and only appropriate research staff will have access to this number.

The healthy lifestyle intervention itself presents few risks to participants. The intervention will encourage weight gain as recommended by ACOG and the Institute of Medicine during pregnancy based on BMI.[76, 85] Their recommendations have been evaluated and are part of the standard of care for pregnant women. Women will be encouraged to participate in physical activity and eating behaviors that are associated with the best outcomes for mother and fetus. Recommendations for physical activity and nutrition will not differ from established public health recommendations. There is a small risk of muscle sprains, other soft tissue injuries, or bone injuries from exercise; however, participants will be given information about proper stretching techniques and the importance of a warm-up and cool-down period to minimize injury.

Additionally, there is a small risk of loss of privacy due to the Facebook group and/or Instagram profile. All study participants have 3 different options for the manner in which they join the Facebook group, each corresponding to the level of privacy they wish to have: Option 1) Participants can choose to link their own existing private Facebook account with the private Facebook group, allowing other study participants to see all of the content on their individual Facebook page; Option 2) Participants can choose to link their own existing private Facebook account with restrictions to the private Facebook group, allowing other participants to see only the content on their individual Facebook pages that they permit them to view; Option 3) Participants can choose to create an alias Facebook account exclusively for joining the intervention, prohibiting the other participants from accessing any of the content on the individual Facebook pages that they maintain for personal, private use. It is important to recognize that non-members will not be able to view the group or obtain group membership. The primary purpose of the Facebook group is to enhance weight-related support and mentoring through online postings (videos, links and contests), “likes”, and Facebook mail. Participants will be told that they should use their discretion with the amount and extent to which they share sensitive information to the other members of the group. For Instagram, there are two options: Option 1) Participants can use their own existing Instagram profile to follow the private study Instagram profile; Option 2) Participants can choose to create an alias Instagram account exclusively for following the study Instagram profile, prohibiting other participants from accessing any of the content on their individual Instagram profile that they maintain for personal, private use. Study staff will review and respond to any comments made or messages sent on both social media platforms to dispel misinformation, provide support, and monitor progress, distress and/or side effects from the program.

b. <u>Protection Against Risk:</u>

i. **Planned procedures for minimizing or protecting against potential risks.** Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Subjects will be identified only by a coded ID number. No names will be used on any source documents. Data entered into the database for analysis will contain only the subject ID numbers. Source documents will be stored in a locked file cabinet in a secure location on Temple's Health Sciences Campus. Only the PI and Project Director will have access to participant contact information (e.g., name, phone number, postal address and/or email address). The web application used by WIC staff and Facebook platform will be maintained by a qualified vendor (Louis Clotman Design, LLC) and ***be fully compliant with HIPAA guidelines for patient privacy and data*** **security.** The vendor will comply with current data security standards as they evolve (also see Privacy addressed in section 11 above).

ii. **Additional protections for pregnant women and their fetuses.** There is minimal risk to both mother and fetus – the intervention will encourage weight gain as recommended by ACOG and the Institute of Medicine during pregnancy based on BMI. Their recommendations have been evaluated and are part of the standard of care for pregnant women. Women will be encouraged to participate in physical activity and eating behaviors that are associated with the best outcomes for mother and fetus. Recommendations for physical activity and nutrition will not differ from established public health recommendations.

iii. **Additional plans for ensuring medical or professional intervention in the event of adverse effects to the subjects.** It is not anticipated that there will be any adverse events. However, in the unlikely event that an adverse event does occur, the PI (Sharon Herring MD) will be notified immediately and any intervention will be handled directly by the PI (in consultation with Marisa Rose MD, Co-Investigator and Obstetrician/ Gynecologist, and Emily Oken MD, Professor of Population Medicine and Nutrition at Harvard Medical School). Dr. Rose is the designated medical monitor for the study; Dr. Oken is the lead Safety Officer. Both physician-scientists have a high degree of understanding about the potential risks involved with modifying antenatal diet and physical activity. All adverse events will be reported within a timely manner to the Temple University IRB. All IRB guidelines on reporting and monitoring adverse events and data will be followed strictly. Participants will be immediately referred to their obstetric providers if any clinical problems (including physical and emotional issues that do not qualify as an adverse event) are detected. Drs. Herring and Rose will also be available to assist participants and staff with clinical questions/concerns over the entire study period.

iv. **Provisions to Monitor the Data to Ensure the Safety of Subjects.** Annually, we will generate a summary report for Dr. Oken's (safety officer) review, including: description of recruitment and retention status; tables showing enrollment and demographics; and tables showing adverse events. In the present study, we expect that most, if any, reported complications will result from activities unrelated to the intervention.

13) Potential Benefits to Subjects

a. ***Potential Benefits to Research Participants and Others:***
Potential benefits for intervention study participants include improved lifestyle and a reduction in maternal/fetal adiposity and cardiometabolic risk. An additional benefit for some participants may be personal satisfaction in being part of a study that may have major public health implications for the community. Of particular importance is the fact that this project aims to provide an intervention in a culturally appropriate and sustainable manner. However, no benefit from participation can be guaranteed.

b. ***Risks to the Subjects are Reasonable in Relation to the Anticipated Benefits:***
Risks to subjects are minimal and therefore reasonable in relation to the anticipated benefits to the research subjects and society as a whole.

14) Costs to Subjects

If participants agree to take part in this research, they will receive $100 after completing all CS/EN questionnaires and being officially enrolled (to reimburse participants for time and travel). All enrolled participants will also receive a diaper bag and a scale to weigh themselves at each study time point after their CS/EN call. Mothers in the intervention group will have a water bottle, measuring bowls & spoons, and a cookbook included in their bag. Enrolled participants will additionally receive $75 after completion of their 36-week gestation call, and $50 after completion of their 6-month and 12-month postpartum calls. Total compensation for completing all assessments will be $275.00 (for both groups). Participants will either be texted or emailed VISA e-gift cards (preferred method) or mailed plastic VISA gift cards at the end of each visit. Participants in the intervention group will also be eligible to win a monthly raffle prize, valued between $75.00 and $100.00. Intervention participants will receive 1 raffle entry for each monitoring text they send. Monthly raffles will be held (run by study staff) on the last day of every month and winners will be contacted via text message. Septa passes will also be provided for transportation (if needed).

15) Informed Consent

All subjects for this study will be sent a consent form via e-mail or mail prior to the combined CS/EN call or visit. During the initial call/visit, study staff will review the Informed Consent describing this study and providing sufficient

information for subjects to make an informed decision about their participation in this study. The consent form is submitted with this protocol for review and approval by the IRB. The formal consent of a subject, using the IRB-approved consent form must be obtained before that subject is submitted to any study procedure.

Consent will be obtained electronically via Redcap prior to any study procedures being completed. Study staff will be trained to consent patients and provide a detailed explanation of all procedures, risks, and benefits.

Additionally, participants will be sent or given paper copies of their signed Informed Consent Form, the HIPAA Authorization, and the Medical Record Release forms (prenatal, delivery, infant, and WIC)

16) Non-English (Spanish) Speaking Subjects

Bilingual research staff have/will translate all study material (e.g. informed consent, HIPAA Authorization, medical record release, intervention content). All study visits and WIC champion calls for Spanish speaking participants will be administered by bilingual staff.

17) Vulnerable Populations

Additional protections for pregnant women and their fetuses is described in Section 12 (above).

18) Sharing of Results or Incidental Findings with Subjects

The study is registered on clinicaltrials.gov. Results of the study will be summarized on clinicaltrials.gov once the trial ends.

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