A smartphone intervention for WIC mothers to improve nutrition and weight gain during pregnancy

"SmartMoms in WIC"

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Version Date	Approved Amendment
2/5/2024	Changed Dr. Daniel Hsia to Co-investigator and added Dr. Robert Dubin as Medical Investigator in preparation for Dr. Daniel Hsia's move from PBRC
6/24/2022	Modified the protocol and consent to update recruiting language to changes made due to COVID-19 pandemic related to WIC demographic report referrals, removed skinfold thickness and waist, hip circumferences from measurement since COVID-19 pandemic has affected the ability to complete the procedures while curbside, and updated HIPAA version to the newest PBRC language
3/19/2021	Modified the protocol and consent to change the gestational age range limit at S1 and V1, removed the food and activity diary, and moved the dietary recall and accelerometry from V1 to S1
7/14/2020	Requested Privacy Board approval for a HIPAA waiver to be able to receive reports from WIC Clinics that include demographic information (Contact info, DOB, Gestational Age, Expected Due Date, etc.)
7/2/2020	Updated recruitment strategy to facilitate curbside visits, included a waiver of consent documentation to allow clinic staff to directly contact WIC recipients
4/21/2020	Updated Data Safety Monitoring Plan and reporting requirements for AEs, SAEs, safety alerts for both clinic and intervention
3/18/2020	Changed range for V1 to start at 10 weeks gestational age
3/18/2020	Added statement regarding obtaining medical information from providers
9/6/19	Clarified visit length
9/6/19	Provided information on Facebook privacy and policies
7/10/19	Added blood pressure to screening visit
7/10/19	Added Household Chaos questionnaire to clinic visits
6/4/19	Updated randomization to occur using REDCap
6/4/19	Clarified operational items (recruitment channels, inclusion/exclusion, intervention group details, compensation methods, LDH IRB contacts)
2/8/19	Removed DSMB and created a DSMP as per NIH requirements for a low-risk study

A smartphone intervention for WIC mothers to improve nutrition and weight gain during pregnancy

"SmartMoms in WIC"
-Phase 2-

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PROTOCOL

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1. SUMMARY

The nutritional status and weight gain trajectories of women during pregnancy influence birth outcomes, health, and the long-term risk for chronic disease for both the mother and child. In 2015, more than one in eight women in the U.S. lived in poverty and women with low incomes are the most vulnerable to poor energy-dense nutrition, sedentary behavior, excess gestational weight gain (GWG) and poor birth outcomes. There is a critical need for scalable and effective healthcare services targeting these under-served, minority women through community-based lifestyle interventions. Especially lifestyle interventions during pregnancy positioned to reduce excess gestational weight gain may reduce risk factors for chronic disease in women and obesity in children. The USDA Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) – a National program – is highly suited to deliver scalable lifestyle interventions in low income and nutritionally at risk pregnant women. However, for the specific population, there is a dearth of clinical trials testing efficacious, well-designed, culturally relevant and appropriately powered interventions aimed to promote healthy weight gain.

Smartphone use is highly prevalent in low income populations and allows for delivery of intensive, theoretically supported behavior change interventions. Moreover, *e*-Health interventions overturn many of the reported barriers for intervention adherence and completion. Therefore, the overarching goal of this research is to adapt an innovative smartphone-based, patient-centered, pragmatic and scalable intensive lifestyle intervention called 'SmartMoms®', previously shown to foster appropriate gestational weight gain according to Institute of Medicine (IOM) guidelines [1], for dissemination to pregnant women served by WIC.

In Phase 1 of the current study, SmartMoms® will be adapted for low-income women, taking into account cultural sensitivities and an appropriate level of health literacy, using formative research (qualitative survey of 614 WIC clients and staff, structured interviews with WIC mothers) and systematic consultations with a Community Advisory Board and a WIC Peer Advisory Group. As the IRB has determined that phase 1 is not defined as "human subjects research", phase 1 is not included in the current protocol (please see 'Not Human Subjects Research Determination' letter, July 19th 2018). In the proposed phase 2, we aim to test the effectiveness of SmartMoms® in a state-wide, randomized controlled trial in 432 low-income women enrolled in the Louisiana WIC program. We hypothesize that, compared to WIC patients receiving usual care, participants receiving SmartMoms® will have a greater adherence to the 2009 IOM gestational weight gain guidelines and significant improvements in physiological and behavioral factors.

2. STUDY AIMS

This proposed study '*SmartMoms® in WIC*', will test the overarching hypothesis that compared to WIC participants receiving usual care, participants receiving SmartMoms® will have greater adherence to the 2009 IOM gestational weight gain guidelines and significant improvements in physiological and behavioral factors. The primary aim of the study is to test the efficacy of SmartMoms® for improving the incidence of appropriate gestational weight gain (GWG) in a multi-site randomized controlled trial within the Louisiana WIC program that randomizes 432 pregnant women (N=144 normal weight, N=144 overweight, N=144 obese) to either SmartMoms® or Usual Care.

2.1. Hypotheses

Relative to WIC participants receiving Usual Care, participants receiving SmartMoms® will have a:
A: higher incidence of appropriate GWG according to the 2009 IOM guidelines
B: smaller deviation in GWG per week from the 2009 IOM guidelines
C: significant improvements in both physiological and behavioral factors including diet quality, physical activity, birth outcomes, postpartum weight loss, quality of life and mood and WIC food voucher redemption rates.

2.2. Endpoints

Primary endpoint:

- Incidence of appropriate weight gain in pregnancy as defined by the 2009 IOM Guidelines [2].

Secondary endpoints:

- Rate of GWG per week
- Maternal diet (24h recall)
- Physical activity (Accelerometry, Pregnancy Physical Activity Questionnaire)
- Quality of life and stress (Depression Anxiety Stress Scales-21, Quality of Life Inventory, Household Chaos Questionnaire)
- Maternal and infant birth outcomes
- Infant feeding style (Infant Feeding Style questionnaire and Breastfeeding Questionnaire)
- WIC food voucher redemption rate
- Postpartum weight retention (measured 1, 6 and 12 months after delivery)

Exploratory endpoints: This study is also powered for a comparison of GWG between BMI categories. As an exploratory aim we will test whether maternal body mass index (BMI) is a moderator of intervention effects on GWG (relative to Usual Care).

Planned post-hoc analyses include testing moderators of intervention effects on GWG in BMI categories, race/ethnicity groups and in the SmartMoms® group only, intervention adherence.

3. BACKGROUND AND SIGNIFICANCE

Pregnancy is critical nutritional time point that influences the immediate and long-term health of both mother and child. While the health and nutritional status of women (eg. obesity, smoking etc.) prior to pregnancy is arguably the most important for long-term health outcomes [3], the nutritional status of women during pregnancy including GWG influences birth outcomes, maternal and infant health, and long-term risk for chronic disease in the mother and child [4]. Lifestyle interventions during pregnancy that aim to foster healthy GWG [5-7] may lower the risk of adverse birth outcomes and maternal [8] and childhood [9, 10] obesity. Women who are economically disadvantaged are the most vulnerable to maternal obesity [11, 12], excess weight gain in pregnancy [13, 14] and poor birth outcomes [15-18]. According to the U.S. Census Bureau, in 2015 more than one in eight women and one in four children in the U.S. lived in poverty [19]. Therefore to positively impact the health of the most vulnerable populations' to the effects of obesity there is a critical need for scalable and effective healthcare services that target GWG. The federally-funded program WIC has an unprecedented position to deliver scalable and effective lifestyle interventions in low income and nutritionally at risk pregnant women. According to CDC Pregnancy Risk Assessment Monitoring System data reports that span more than 15 years, at least 50% of the pregnant women supported by WIC are overweight or obese [20] and only 30% achieve appropriate GWG [21]. Moreover because WIC has an established national framework and supports approximately 15% of pregnancies in the US each year [22], WIC has a unique opportunity to disseminate a weight management program to millions of pregnant women.

"*e*-Health" weight management interventions deliver treatment to people who face barriers to traditional clinic-based treatments and include the use of smartphones. Studies have shown that internet interventions that include counselor support and individualized recommendations produce clinically significant weight loss [23-26] with effect sizes similar to intensive lifestyle interventions delivered in-person [27]. With smartphones, people are "mobile" and less reliant on computers for Internet access [28]. This is significant since 77% of adults in the U.S. own a smartphone [29] and low-income households are the most likely to rely solely on mobile devices for

internet access [30]. Smartphones include built-in sensors and paired devices that collect and transmit objective data such as body weight or activity in real-time. They also provide several methods that allow for delivery of near real-time feedback about behavior [31] which is important since behavior change theories, such as learning theory [32], postulates that temporally contiguous, data-driven feedback results in superior behavior change. Smartphones allow for intervention delivery to be intensive and personalized to the needs and adherence of individuals through its varied multimedia functions and access to social media applications. This clearly indicates that smartphone-based interventions should easily reach under-served individuals with limited access to financial and healthcare resources, including the delivery of weight management programs via smartphones in pregnant women. However, there is a dearth of clinical trials testing efficacious, well-designed, culturally relevant and appropriately powered interventions aimed to promote healthy GWG in economically disadvantaged pregnant women. Intensive lifestyle interventions targeting pregnancy weight gain [33-35] or postpartum weight loss [36, 37] in economically disadvantaged women, have been met with poor success. Collectively these trials cite the inherent difficulties of engaging a population that is challenged to meet the basic needs of life which result in low levels of intervention adherence and poor retention rates [37-41]. Thus, there is a clear need for culturally relevant and health literacy appropriate interventions for pregnant women who face disadvantages in financial and healthcare support. Capitalizing on the unprecedented access of WIC to an economically disadvantaged and health disparate population, the overarching goal of this research is to adapt the innovative, smartphone-based, patient-centered, pragmatic and scalable weight management intervention SmartMoms®, shown to foster healthy GWG, for dissemination to pregnant women served by WIC. If SmartMoms® is efficacious when embedded in the Louisiana WIC program, it will provide the first indication that WIC services could be expanded to meet an important public health need and serve as a conduit for delivering a scalable intervention to pregnant women across the country. Furthermore, given the long-term follow-up of children in the WIC program, this study also provides the framework for future investigations into the effects of prenatal obesity (BMI), GWG and lifestyle interventions on health outcomes in children.

4. RESEARCH DESIGN

This is a multi-site randomized controlled trial, testing the effectiveness of the smartphone-based behavior modification program 'SmartMoms®' in pregnant women within the Louisiana WIC program. Equal number of participants will be randomized to either the intervention (SmartMoms) or the control condition (Usual Care). Although the SmartMoms® intervention itself lasts 24 weeks (only during pregnancy), women will be enrolled in this study for approximately 18 months; from the 10-16th week of pregnancy until 12 month postpartum follow-up. Study outcomes will be assessed at three time points during pregnancy (early, mid and late, see Table 3) and three visits postpartum (1, 6 and 12 months).

5. STUDY POPULATION

5.1. Participants

The target population is 432 healthy pregnant women certified to receive WIC services during the current pregnancy, who will be will be enrolled from WIC clinics in the 9 WIC regions across Louisiana. Participants will be randomized to either:

- Intervention: SmartMoms (n=216)
- Control: Usual Care (n=216)

An equal number of women in each group (n=72) will be normal weight (BMI 18.5-24.9 kg/m^2), overweight (BMI 25.0-29.9 kg/m^2) and obese (BMI 30.0 - 40.0 kg/m^2).

5.2. Inclusion Criteria

- Pregnant female less than 16 weeks gestation at S1

- 18-40 years of age
- BMI between 18.5 -40 kg/m^2 using weight measured at the prenatal WIC certification visit
- Expecting a singleton pregnancy
- Certified to receive WIC services during the current pregnancy
- Has Smartphone with internet access
- Willing to be identifiable to other study participants in this study program

5.3. Exclusion Criteria

- Smoking
- Drug or alcohol use
- Non-pregnancy related illness (HIV, cancer, heart disease, type 1 or type 2 diabetes)
- Hypertension (SBP >160 mmHg or DBP >110 mmHg) at S1
- Current mental health issue or eating disorder
- Inability to complete a behavioral run-in task
- Plans to move out of the state in the next 18 months

Figure 1. WIC Region Map

6. RECRUITMENT

The clinic team receives demographic reports from the WIC clinics in each of the 9 regions (Figure 1). Pregnant women who attended a prenatal WIC certification visit and met basic demographic report criteria will be provided study information and will be invited to speak with the clinical staff. The clinical staff will explain the study and the study procedures to interested participants. WIC staff may also refer interested participants for more information. Interested women will complete an electronic webscreener to assess initial eligibility. Women who meet the basic criteria will be offered the opportunity for study screening.

7. SCREENING

Interested participants will provide informed consent prior to the initiation of study procedures. Height, weight, % body fat, and blood pressure will be measured (**See Table 3)**. Participants will provide contact information and will answer questions for study staff to understand potential barriers for study participation (transportation, meal preparation responsibilities etc.). For a behavioral run in, 24h diet recall and accelerometry will be administered to be completed prior to Visit 1 completion. If the 24h diet recall and accelerometry are not completed, the participant will not be eligible to enroll.

8. RANDOMIZATION

The randomization schedule will be prepared by the study biostatistician and kept in a password protected file. Randomization to the SmartMoms® or Usual Care group will be performed after Visit 1. At Visit 1, the participant and study staff will review a document that outlines behavioral requirements for each group and affirms responsibilities during the study. Once the participant understands the requirements and signs the informed consent form, randomization will occur via REDCap that will stratify on the basis of maternal enrollment BMI. The interventionist will then notify the participants and deploy equipment.

Every effort will be made to keep the intervention team and the assessment team separate. Interventionists will be located at Pennington Biomedical and Research Specialists collecting outcome data will be local to the WIC

clinics around the state. This plan will minimize the likelihood of contamination within a WIC clinic. Blinding will only be revealed to the external Medical Monitor to ascertain relatedness of a serious adverse event or safety alert. All investigators will be blinded to the treatment assignment until the end of the study.

8.1. SmartMoms Intervention (Healthy Beginnings curriculum)

8.1.1. Overview

Participants in the intervention group receive SmartMoms®, a Body Trace scale (cellular connected) and a Fitbit. The intervention consists of a ~24-week intensive behavior modification program that targets healthy GWG through self-monitoring of weight and activity data, automated prescriptive feedback from SmartMoms®, personalized feedback from counselors and an evidence-based behavioral intervention delivered throughout pregnancy (**Figure 2**). All interactions and treatment recommendations between the participant and counselor occur via the multi-media functions of the Smartphone. The counselors, who have experience in dietary and behavioral counseling, will be equally trained on standardization of the intervention delivery and will work under the direct supervision of the study investigators. After enrollment, the lifestyle counselors will contact the participant to assist with accessing SmartMoms®, pairing the devices, learning how to use the equipment and interpreting the weight and step graphs. The following paragraphs show a more detailed description of the components of the intervention.

Figure 2: The theoretical framework of SmartMoms

8.1.2. Behavior Therapy

The behavioral part of the intervention will be delivered in virtual sessions beginning in pregnancy after randomization and continuing until delivery. Intervention lessons called SmartTips© (**Table 1**) will be delivered in short (2-4 minute) videos transmitted to the smartphone in the morning. SmartTips© may also be transcribed to text versions and both the text and videos may be available.

Table 1. SmartMoms® SmartTips
Weight Graph and Weight Gain in Pregnancy
Time management and overcoming barriers to success
Meal planning, grocery shopping and your WIC Food Package
Meal prep and healthy cooking
Portion control and eating patterns

Behavior chains
Controlling food cues and hunger
Building social support
Emotional eating
All you need to know about GDM
Protein and fat
Fluids and fiber
Carbohydrate and sugar
Prenatal Vitamins
Social eating (baby shower, church)
Importance of being active
Mindfulness and relaxation techniques
Managing food cravings and snacking
Healthy eating for moms on the go
Stress and sleep
Postpartum depression
Preparing for labor and birth*
Breastfeeding
Optimizing health postpartum
Congratulations & Graduation!
*** American Academy of Pediatrics; +Centers of Disease Control**

8.1.3. Body Weight Tracking

SmartMoms® participants receive a Body Trace scale, which automatically and wirelessly transmit body weight data to a cloud server. SmartMoms® accesses the Body Trace API and automatically obtains the weight data and plots it on the IOM weight graph personalized for the participant to objectively quantify dietary adherence in SmartMoms®. The weight graph is immediately available for viewing. The graph is also available for the interventionist to view in the Clinician Dashboard (**Figure 2**). The weight graph will be created from a dynamic GWG model to determine the trimester-specific increase in energy intake required by each participant to adhere to the IOM GWG recommendations. If weight exceeds the required target and is "out of the zone" for a given period of time (e.g., 3 of 5 days) participants will be provided with automated feedback and treatment recommendations bolstered on behavior change theories (e.g., learning theory, the transtheoretical model of behavior change, motivational interviewing etc.) to modify diet and/or physical activity behaviors and modify weight to comply with the goals. If the participant weight is in the zone, congratulatory messages are received also with strategies to maintain continued success.

8.1.4. Diet Component

Preventing excess calorie intake during pregnancy and avoiding the 'eating for two' philosophy is the cornerstone of successful weight management efforts in pregnant women [42]. SmartMoms® participants will receive a personalized weight graph that will help them gain weight along an appropriate trajectory as determined by the 2009 IOM guidelines [2]. Together with the weight graph, the dietary intake recommendations in accordance with the 2010 USDA Dietary Guidelines for Americans is promoted [43]. The SmartTips© promote a balanced diet and intake of nutrient-dense foods including whole grains, fruits, lean protein sources, nuts and seeds. SmartMoms® participants will not track food intake on a daily basis however, counselors can request participants use their Smartphone to track their intake including taking pictures of their foods [44-46] to determine what types of foods they are eating and their food intake patterns. This approach has been found to be more accurate and less burdensome than food records. These data will be used to help the participant modify her food intake and adhere

to the weight gain target. Adherence to a healthier diet will be supported through the meal plans and shopping lists, written and recorded recipes and cooking demonstrations. These materials will be posted to SmartMoms® and/or closed Facebook group. We will provide a participation statement for the Facebook group and explain the privacy limitations in the Informed Consent. Additionally, we will work with PBRC Communications and IT Departments to ensure the appropriate security measures are in place for the group.

8.1.5. Physical Activity Component

The SmartMoms® intervention promotes the increase of physical activity to 150 minutes/week as recommended during pregnancy [47, 48]. A major focus of the physical activity component is on increasing lifestyle activities, such as taking the stairs instead of the elevator, building in walking whenever possible, and replacing more sedentary activities with more active options. Physical activity data is collected and tracked via an activity tracker (Fitbit). SmartMoms® retrieves the participant steps from the FitBit API and plots the step data against the personalized physical activity goal of each participant. The step graph is sent to the participant's smartphone automatically and is simultaneously available for counselor view on the clinical dashboard. Physical activity will be encouraged each week through the 'exercise of the week' clips and 8 live exercise sessions featuring pregnant women scheduled throughout the intervention.

8.1.6. Gamification Component

Participants will earn points for recording weight/activity data, achieving healthy weight milestones, watching videos, participating in sessions (such as cooking or exercise classes), commenting on Facebook and YouTube, winning friendly group competitions, and other tasks important to the Healthy Beginnings program. Incentive items can be earned through the redemption of points for smaller valued items or points may be saved to purchase higher valued items (eg. jogging stroller). Points required for each item will be based on the goal of 70% adherence to the intervention as this level of adherence was required to produce significant weight management results in our past study [37].

8.2. Usual Care

Analogous with previous trials embedded in the WIC program [37, 49, 50], participants assigned to the Usual Care Group will receive all aspects of the standard WIC program plus a brief orientation to the study. To boost retention, Usual Care Group participants will receive weekly health information related to pregnancy, birth and infant health via a closed Facebook group (**Table 2**). We will provide a participation statement for the Facebook group and explain the privacy limitations in the Informed Consent. Additionally, we will work with PBRC Communications and IT Departments to ensure the appropriate security measures are in place for the group. This information is adapted to the target population as refined by WIC mothers before.

Table 2. Weekly Usual Care Health Information
Importance of prenatal vitamin
Healthy Sleep Habits*
Preparing for Labor and Birth*
Healthy Attachment
Recommended Immunization Schedules*
How to Prevent Tooth Decay in Your Baby*
How to Take Your Child's Temperature*
The Importance of Meditation for Kids*
All you need to know about GDM
Get Fit, Stay Healthy*

Feeding Kids Right Isn't Always Easy*
Childproofing Your Home*
Tips for Healthy Families*
Birth to 6 Months: Safety for Your Child*
How Do Infants Learn?*
Car Seats: Information for Families*
Welcome to the World of Parenting!*
Postpartum depression
Breastfeeding Your Baby: Getting Started*
Choosing a Pediatrician*
Back to Sleep, Tummy to Play*
How Do Infants Learn?*
Preparing for Baby*
Parenting your Infant*
Congratulations!
*** American Academy of Pediatrics; +Centers of Disease Control**

9. ASSESSMENT SCHEDULE AND PROCEDURES

The planned schedule of procedures is shown in **Table 3**. Following the initial screening visit, there are 3 visits in pregnancy (early, mid and late) and 3 visits postpartum (1, 6 and 12 months). Study visits will be conducted at participating WIC clinics. Visits may also be performed at participants' homes, medical care provider offices, or other locations to maximize the opportunity of data collection for women who report difficulty in returning to the clinic. To assist with clinic visit retention, intervention staff will reach out to participants through contact outlets (e.g. telephone call, text message, Facebook group message, video conference) to remind them of upcoming clinic visits throughout the study for both the SmartMoms (Healthy Beginnings) and the Usual Care groups.

Table 3. Schedule of Procedures

	Pregnancy				Postpartum		
	Screening	V1 Early	V2 Mid	V3 Late	V4 1 month	V5 6 months	V6 12 months
(Weeks of gestation)	<16,0	10,0-16,6	24,0-27,6	35,0-37,6	+2,0-6,6	+22,0-25,6	+48,0-56,6
Height	X						
Weight	X	X	X	X	X	X	X
% Fat by BIA	X	X	X	X	X	X	X
Behavioral Run in	X						
Blood pressure	X	X	X	X	X	X	X
Questionnaires		X		X	X	X	X
24h diet recall	X			X		X	X
Physical activity (5-7 days accelerometry)	X			X		X	X
WIC Data Abstraction				X			X
Birth Certificate Data Abstraction					X		

RANDOMIZATION

9.1. Visit 1

Participants will have their weight, % body fat, and blood pressure measured. Questionnaires will also be administered. After reviewing the behavioral requirements for each group with study staff, participants will be randomized to either the SmartMoms or Usual Care group. Participants will be provided with a prenatal vitamin to be taken throughout their pregnancy.

9.2. Visits 2-6

At each visit, participants will have their weight, percent body fat, and blood pressure measured.

At V3, V4, V5, and V6, questionnaires will also be administered. At V3, V5, and V6, diet (24h dietary recall) and physical activity (accelerometry) will be administered to participants to be completed over the next 5-7 days. At the end of pregnancy and at 12 months postpartum, the WIC chart will be abstracted. After delivery, the birth certificate (long form) which captures birth and prenatal outcomes will be obtained.

10. MEASURES AND OUTCOME ASSESSMENTS

10.1. Anthropometrics and Body Composition

Body weight and % body fat is obtained using the same calibrated electrical scale (DC-430U Dual Frequency Total Body Composition Analyzer, Tanita Corp, Arlington Heights, IL). Height is measured with a calibrated wall-mounted stadiometer. If the two trials differ by more than 0.5 kg for weight or 0.5 cm for height, a third measure is obtained. Blood pressure is obtained using portable, manual blood pressure devices. Some visits are conducted outside as per Louisiana Department of Health COVID-19 guidelines so anthropometrics and blood pressure may not be collected under standard conditions in these cases.

10.2. Maternal Dietary Intake

The Automated Self-administered 24-hour Recall of National Cancer Institute will be used to obtain an assessment of dietary intake (calories, macronutrient) and diet quality [51]. Participants will be trained to complete the assessment using paper guides and short training videos (e.g. https://www.youtube.com/watch?v=QcXZWmzUWws) prior to enrollment and throughout the study as needed. At each assessment period, the recall will be performed twice through a website as previously done in the WIC population [50].

10.3. Maternal Physical Activity

Maternal physical activity will be measured with a triaxial accelerometer (ActiGraph) over approximately 5-7 days. The accelerometer will be worn on the non-dominant wrist unless contraindicated. Days with wear time of more than 6h for sleep and 8h for awake will be used in analysis. Raw data are analyzed with the ActiLife® software. Outcomes will be activity minutes, sleep minutes, steps, METS and vector magnitude (counts per minute).

10.4. Questionnaires

The prenatal packet administered at Early and Late pregnancy will include the Pregnancy Physical Activity Questionnaire [52], Depression Anxiety Stress Scales-21 [53], Quality of Life Inventory, Household Chaos Questionnaire[54], and Infant Feeding Styles Questionnaire [55]. The postpartum packet administered at 1, 6 and 12 months postpartum will include the prenatal questions, a modified physical activity questionnaire and the Breastfeeding Questionnaire [56, 57]. After the conclusion of the SmartMoms intervention, participants will be provided a qualitative, anonymous questionnaire through REDCap to provide their acceptance of the intervention

on a 6-point Likert scale (e.g extremely dissatisfied to satisfied) to allow the participant to express how much they agreed or disagreed with a particular component of the intervention.

10.5. Data Abstraction

At the end of pregnancy and at 12 months postpartum, the WIC chart will be abstracted. After delivery, the birth certificate (long form) which captures birth and prenatal outcomes will be obtained.

11. PARTICIPANT SAFETY AND CONFIDENTIALITY

11.1. Risks to participants

This Human Subjects Research meets the definition of a Clinical Trial. This study does not involve major risk to study participants. To minimize the potential risks of the assessment methods and outcome variables, investigators will frequently monitor the study to assure that no volunteer suffers any adverse effects from participating in the research. Risks of complications will be reduced by carefully selecting only healthy participants to enroll in the study. The inclusion and exclusion criteria were created to ensure pregnant women, a vulnerable population, would have minimal risk for completing the study protocol.

Potential risks associated with the study procedures include (listed alphabetically):

- **% body fat by BIA.** There is no known risk to having % body fat measured by bioelectrical impedance analysis. The BIA is non-invasive and safe for use during pregnancy.
- **Accelerometry.** There is no known risk associated with measuring physical activity with an accelerometer or FitBit. The accelerometer fits comfortably on the participant wrist. In rare cases, the device(s) may irritate the skin; if this occurs, the device(s) can easily be removed should the participant become uncomfortable.
- **Blood pressure testing.** Participants may experience temporary discomfort during blood pressure recordings due to the pressure of the cuff inflating on their arm.
- **Body weight.** There is no known risk to participants who measure/record their body weight.
- **Calorie controlled diet**. There are no known risks associated with the recommended calorie intake and calorie-goals in this study. The macronutrient composition of the diet is consistent with the recommendations for pregnant women from national organizations, including the USDA and IOM. We will provide all subjects with a prenatal vitamin to ensure proper intake of iron, calcium and folate to support fetal growth. Subjects will be counseled to gain weight during pregnancy in accordance with the 2009 IOM guidelines.
- **Increased exercise.** The proposed exercise dose is consistent with the recommendations for pregnant women of national organizations (30 minutes of moderate intensity activity per day for five or more days per week). Since subjects will be thoroughly screened, including with the PARmed-X for PREGNANCY, we expect risk to be minimal. There is the possibility of adverse events such as minor musculoskeletal problems, but risk is minimized by excluding potential participants with contraindications to exercise.
- **Maternal food intake.** Food intake will be estimated with by a 24h dietary recall. There is no known risk to participants for recalling their dietary intake.
- **Questionnaires.** There are no anticipated risks from completing self-report questionnaires. If signs of minor stress or fatigue are apparent, participants will be given time to take a break from completing the questionnaires. It is estimated that the questionnaires will take from 15 to 30 minutes to complete. The questions contained in some of the questionnaires may make people feel uncomfortable since they ask about topics such as how they feel about their body size. Responses to the questions will be coded to protect confidentiality, and participants may choose to not answer questions. Participants will be offered to have someone read aloud the questions and answers to ensure participant has equal opportunity to complete the questionnaire packet.

- **Smartphone use.** Parts of this study may involve using a Smartphone. There is a possibility that using it for this study could increase data usage. Participants are responsible for the increased cost, not the study.
- **Facebook group.** As part of the study, participants will be added to a closed Facebook group (abiding by Facebook's strictest settings for group privacy, membership approval and posting permissions) for the respective study group. These groups are governed by Facebook's privacy policy and terms of service. As with any social media platform, there is a potential of loss of privacy and breach of information.

11.2. Data Safety Monitoring Plan

The PI will be responsible for annual reporting to the PBRC Institutional Review Board. As part of the data and safety monitoring plan, the PI, study investigators, biostatistician and project manager will review participant safety data including adverse events and safety alerts in 6 month periods. The team will also review participant accrual rates, retention and completion rates and data completeness. Remedial action, including amendments to the protocol, will be actioned as deemed appropriate by the study team. The team meetings will be recorded with a copy of the data and safety report and summary of the findings filed with the IRB.

All serious adverse events (SAEs), adverse events (AEs) and safety alerts will be reviewed by the study medical monitor (Dr. Daniel Hsia) or his designee on an ongoing basis. Any significant health problems that come to our attention during the study will be referred to the participant's usual source of medical care, with her permission. Any action resulting in a temporary or permanent suspension of the study (e.g., IRB actions, or actions by the PI/investigators) will be reported to the appropriate officials.

11.2.1. Adverse Events

An **adverse event (AE)** is defined as any untoward medical occurrence which may or may not be associated with participation in the study, including but not limited to:

- A clinically significant new diagnosis or medical problem reported by the participant.
- An event that requires a non-routine visit to a medical care provider.
- An event that occurs as a result of a study procedure.
- Unanticipated untoward medical events that are not plausibly pregnancy related but may or may not be study related

A **serious adverse event (SAE)** is defined as an untoward medical occurrence, whether associated with study participation or not, that results in one of the following:

- Death: maternal death and/or fetal death, including miscarriage, therapeutic abortion because of increasing signs of maternal or fetal compromise, and stillbirth
- Life-threatening event: Life threatening events in the mother or fetus are defined as those that in the view of the research staff and PI put the individual participant at imminent substantial risk of dying, or if continued participation in the study might have resulted in death.
- Hospitalization (initial or prolonged): Maternal hospitalization or acute outpatient evaluation (e.g. in an emergency room or labor and delivery triage unit) alone is not sufficient to qualify as a serious adverse event. Hospitalization or acute outpatient evaluation for the following would not be considered a serious adverse event: term delivery, preterm premature rupture of membranes (pPROM), pyelonephritis, bedrest, contractions, ruling in or out preeclampsia, and preterm labor. Any medical or surgical procedure performed (e.g., surgery, transfusion) itself is not the adverse event; instead, the condition that leads to the procedure is the adverse event.
- Preterm delivery prior to 32 weeks gestation
- Disability or permanent damage: If the adverse event resulted in a substantial disruption of the mother's ability to conduct normal life functions, i.e., the adverse event resulted in a significant, persistent or

permanent change, impairment, damage or disruption in the participant's body function/structure, physical activities and/or quality of life. The recommendation for bedrest does not constitute an SAE.
- Medical Intervention to prevent permanent impairment or damage
- Other serious important medical events also qualify. When an event does not fit the other outcomes, but may jeopardize the participant and may require medical or surgical intervention or treatment to prevent one of the other outcomes, this will also be reported as an SAE.

11.2.2. Adverse Event Reporting

Pennington Biomedical Research Center is an AAHRPP accredited institution and, above all else, is committed to ensuring and maintaining the safety of its participants. Due diligence will be applied to ensure that study subjects are not exposed to undue or untoward risk. Any significant health problems that come to our attention during the study will be referred to the participant's usual source of medical care, with her permission. We will cooperate fully with her physician by providing relevant medical records.

Adverse events will be documented during the scheduled visits, evaluated by the Medical Monitor for severity and relatedness, and reported according to the reporting policy requirements of the IRB of the Pennington Biomedical Research Center. For each sign, symptom or adverse event, the following information will be recorded:

- A brief descriptor of the adverse event
- Start and stop dates
- Intensity (mild / moderate / severe)
- Whether the AE was "serious" or not (as defined below)
- Causal association with the intervention assigned (none / doubtful / possibly / probably / very likely)
- Outcome (resolved / resolved with sequelae / improving / still present and unchanged / death)
- Action taken with respect to the intervention (none / intervention temporarily discontinued / medical therapy required / intervention permanently discontinued / other).

Unanticipated problems involving risks to participants or others include incidents only if the incident is unexpected, related or possibly related to participation in the research, and indicated that subjects or others are at a greater risk of harm than was previously known or recognized.

11.2.3. Additional Safety Monitoring

Additional safety monitoring is included in this study. Identification of the following would generate a safety alert and require specific action if noted during any study visit:

- Contraindications to moderate to high intensity physical activity during pregnancy
    - Incompetent cervix/cerclage
    - Persistent 2nd or 3rd trimester bleeding
    - Placenta previa after 26 weeks' gestation
    - Premature labor that requires hospitalization and treatment with medications to stop contractions
    - Ruptured membranes
    - Preeclampsia / gestational hypertension
    - Severe anemia defined as a hemoglobin < 8 or hematocrit < 24

****If any of these conditions are reported, study staff will notify the PI and interventionist(s) that the participant has developed a contraindication to moderate- to high-intensity physical activity in pregnancy. The physical activity component(s) of the intervention may need to be modified. The presence of any of the conditions may not

require a change in any dietary component(s) of the intervention. Participants for whom a change to intervention component(s) is indicated should not be considered withdrawn from the study.

- High blood pressure
  - If measured blood pressure is ≥ 160/110, i.e. systolic blood pressure ≥ 160 mm Hg and/or diastolic blood pressure ≥ 110 mm Hg, study staff will consult with the study MI or his designee. Staff will contact the participant's provider as recommended by the study MI.
  - If measured blood pressure is ≥ 140/90, i.e. systolic blood pressure ≥ 140 mm Hg and/or diastolic blood pressure ≥ 90 mm Hg, study staff will instruct participants to contact their provider regarding the elevated measure to arrange appropriate follow-up. Additionally, study staff will consult with the study MI or his designee to arrange follow-up as appropriate.
  - At least one blood pressure reading must meet criteria when two readings are taken, and at least two blood pressure readings must meet criteria when three readings are taken.

- Weight loss during pregnancy after randomization – <u>All participants</u>
  For all participants, weight safety alert values will be obtained from the weight measured at the clinic visit.
  - For women who are normal weight at enrollment, alert values will be any weight loss from enrollment weight.
  - For women who are overweight at enrollment, alert values will be weight loss of 4% or greater of enrollment weight.
  - For women who are obese at enrollment, alert values will be weight loss of 6% or greater of enrollment weight.
  - Safety alert procedures:
    - For the first weight loss alert, the research staff will notify the participant, and **ask the participant to return to clinic for a study visit weight within 2 weeks.** Repeat weights should be collected at the same location at which the original safety alert weight was collected. The intervention team will be notified, and if the participant is enrolled in the Healthy Beginnings program, the intervention team will discuss her energy balance activities, provide weight management counseling, and modify the intervention if appropriate.
    - If the repeat weight indicates the same or greater upon 2 week assessment, study staff will consult with the study MI or his designee. Staff will contact the participant's provider as recommended by the study MI. Additional modifications to the intervention may be indicated (i.e. decrease exercise, increase caloric intake). If the weight upon reassessment no longer meets the alert value criteria, the participant will continue current study activity.

- Weight loss during pregnancy after randomization – <u>Healthy Beginnings participants only</u>
  For participants in the Healthy Beginnings program, weight monitoring values will also be obtained from the Bodytrace scale and based on either change in weight from the beginning of the intervention or a change in weight from week to week. It is important to note women can remain in the Institute of Medicine recommended weight range and not gain weight for a week or longer, even women with normal weight. Thus, no weight gain for short periods of time (1-4 weeks) can be acceptable.
  - For women who are normal weight at enrollment, weight monitoring values will be weekly weight loss from the first Bodytrace scale weight for two consecutive weeks.
  - For women who are overweight at enrollment, weight monitoring values will be weight loss of 4% or greater from the first Bodytrace scale weight or 4% or greater weekly weight loss.

- For women who are obese at enrollment, weight monitoring values will be weight loss of 6% or greater from the first Bodytrace scale weight or 6% or greater weekly weight loss.
- Monitoring and safety alert procedures:
  - The first Bodytrace scale weight monitoring value will trigger close monitoring by the intervention staff. The intervention team will discuss her energy balance activities, provide weight management counseling, and modify the intervention if appropriate including strategies to increase food intake, decrease weighing frequency, and other toolbox options.
  - If a second Bodytrace scale weight monitoring value occurs within 2 consecutive weeks and after intervention monitoring and adjustments, a safety alert will be documented. Staff will contact the participant's provider as recommended by the study MI. Additional modifications to the intervention may be indicated (i.e. decrease exercise, increase caloric intake). If the weight upon reassessment no longer meets the alert value criteria, the participant will continue current study activity.

11.2.4. Stopping rules

This study does not involve major risk for participating. Nevertheless, we will follow the 2009 Recommendations of the American College of Obstetrician and Gynecologist, Committee on Obstetric Practice [47] to determine if temporary and permanent discontinuation of the intervention of a participant is required due to the safety concerns. Modifications to the intervention or complete but temporary discontinuation will be determined on a case-by-case basis.

- Criteria for **Temporary Discontinuation** of the Intervention
  - Severe anemia
  - Intrauterine growth restriction in current pregnancy
  - Other complications identified by the Medical Monitor or the participant's provider
- Criteria for **Permanent Discontinuation** of the Intervention
  - Premature labor in current pregnancy
  - Ruptured membranes
  - Preeclampsia
  - Persistent second or third trimester bleeding
  - Other complications identified by the Medical Monitor or the participant's provider

11.3. Confidentiality

All personnel involved in the design and conduct of this research project will receive the required education on the protection of human subjects prior to the start of the study. An individual record will be kept for each subject. This record will contain identifying data, demographic information, medical history, and results of physical examination and medical tests. Study samples and data sheets will be coded with an identification number for each subject. All data will be treated with confidentiality and the subjects' names and identities will not be disclosed in any published reports. Clinic records are maintained in locked file cabinets in a locked file room. Access to these areas is limited to the clinical support staff, director of the WIC facilities, and the PI. Electronic data storage is similarly restricted with only authorized persons having access to databases containing confidential clinical records, i.e. those containing name or other potential identifying information. The coded participant list identifying participants by name will be stored separately from the number coded records/questionnaires/data. Study results will be reported as group data and/or by participant identification number only. Study results may be presented in publications or at meetings/conferences, however participant identity will not be disclosed. A participant may request their personal health information or their personal study data/results at any time during the study and will be given copies.

11.4. Informed Consent

Informed consenting is only permitted by the clinical research specialist or project manager or other qualified person (determined by the PI) who has completed CITI training in human subjects' research and has completed study familiarization training by the Principal Investigator. Confidentiality is assured at all times as well as the right not to participate or to withdraw at any time without prejudice. Interested participants will sign and date the informed consent forms and will be given a copy to retain for their records. Names and telephone numbers of contact persons on the investigative team, including a 24h number are given to the participant for use if future questions arise at any point throughout participation in the study.

11.5. HIPAA Compliance

The Pennington Biomedical Research Center complies with the federal 1996 Health Insurance Portability and Accountability Act (HIPAA). Specifically, PBRC protects the privacy and confidentiality of medical records and information contained in medical records of persons who are subjects of research projects, including all protected health information (PHI) as defined by the HIPAA Privacy Regulations. PHI of research subjects and the use or disclosure of such information is governed by PBRC research policies, as well as Common Rule, FDA regulations, and other applicable laws.

PBRC and the PI protect the privacy of research subjects and their PHI collected during a research project. PBRC will not use or disclose existing PHI or PHI created during a research project, unless:

- The subject signs both (a) a HIPAA Authorization for use and disclosure of PHI using an approved Authorization Form or other form containing all the elements of legally effective HIPAA authorization and (b) the informed consent to participate in research form approved by the IRB, or
- The IRB grants a waiver to the requirement of obtaining a signed HIPAA Authorization Form, or
- The IRB-approved protocol uses properly de-identified PHI
- The IRB-approved protocol uses the limited data set and the PI signs a limited data use agreement with the entity that maintains the designated record set.

12. DATA MANAGEMENT

12.1. Data Collection

Pennington Biomedical uses a study-specific data management system in RedCap (81) which allows for real-time, web-based data entry for community-based studies. All collected data are entered into the central RedCap (81) database that undergoes continuous quality assurance by the PBRC Research Computing Core. All data are stored on a server backed-up daily and the Research Computing Core oversees data management.

12.2. Sample Size Consideration

To observe a 14% increase in the incidence rate of GWG (**Hypothesis A**), and accounting for 15% attrition, a total of 432 participants with 1:1 allocation between the two groups (SmartMoms® and Usual Care) and equal stratification across the three BMI categories (n=144) is required to detect a significant difference. The sample size estimates assume β=0.8 and α=0.05 to detect the specified increases in the incidence rate of appropriate GWG. The incidence rates of appropriate GWG for the Usual Care group were derived from women receiving WIC benefits in the 2013 Louisiana Pregnancy Risk Assessment Monitoring System data (95). The estimated effect size is based on our pilot trial data where the incidence rate of appropriate GWG for overweight women was 12.3% for Usual Care versus 43.8% in SmartMoms®; and for obese women 0% for Usual Care and 42.9% in SmartMoms®. However since the pilot trial was not in an exclusive under-served population, we conservatively estimate that the SmartMoms® intervention will increase the incidence rate by a minimum of 14% across each BMI category.

This study is also powered to detect BMI group changes in incidence rates. Assuming an overall average change in incidence rate of 14%, 125 participants in each BMI group (accounting for 15% attrition) is sufficient to detect an incidence rate that is at least 20% different between BMI groups.

In addition, we will also investigate the rate of GWG per week (**Hypothesis B**). Per the 2009 IOM guidelines, each BMI category is allocated a different rate of GWG per week (79). We will investigate the deviation between the observed rates of GWG and rates deemed appropriate by the 2009 IOM. Our pilot data from the 'Expecting Success' study showed that both overweight and obese women in the SmartMoms® gained an additional 0.06 kg/week above the recommended amount, which was approximately 3 times higher in the Usual Care groups (0.21 and 0.16 kg/week for overweight and obese women respectively). With our planned sample size of 432 participants, we have more than 80% power to detect change a change as small as 0.12 kg/week between SmartMoms® and Usual Care and within each BMI category and over 99% power to show overall differences in rates of weekly GWG.

12.3. Data Analysis Plan

Statistical analyses will be completed using SAS/STAT® software, Version 9.4 of the SAS System for Windows (Cary, NC, USA) by a Biostatistician. All tests will be performed with significance level α=0.05 and using intent-to-treat analysis. Outcomes will be assessed for normality (where appropriate) with the Shapiro-Wilk test. If transformed data is still not normally distributed, then non-parametric analyses will be conducted on these outcomes. LARS (least-angle regression) will be used for the covariate selection methodology. Covariates will include, but may not be limited to, the infant sex, gestational age at delivery as well as and the maternal age, weight at screening, parity, race/ethnicity, and gestational diabetes status. Treatment and BMI category will be included in all models. Intent to treat analysis will be the primary analysis type. Both completers and multiple imputation (Markov chain Monte Carlo method, preferred) may also be performed if there is a large amount (>10%) of missing data. However, we will extract the mothers' WIC record and therefore for participants who fail to return to clinic, weight measurements will be acquired from the planned chart abstraction. This should greatly decrease the amount of missing data from loss to follow-up.

Hypothesis A: Higher incidence rate of appropriate GWG

Initial results will be expressed contingency tables with incidence rate and either treatment or BMI category. Tests for associations between these variables will be based on Pearson's Chi-squared statistic. Further results will be based on a generalized linear mixed effect model with a binary distribution and a log odd link function modeling the incidence rates. The model will use random effects to account for a site effect and within-subject correlation over time. Results from this model will be reported as odds ratios of least square means, with p-values based on z-tests. Two different sets of models will be used. The first set of models will contain only treatment and BMI category, while the second is will also contain the covariates based on LARS. Pairwise post-hoc comparisons of the category variables will be corrected for multiple comparisons will be made when necessary.

Hypothesis B: Small Deviation in Weekly GWG

Overall deviation rates will be reported using a linear effect mixed model, using random effects to account for site and within-subject correlation. The response is the deviation of the weekly GWG rates from the IOM guideline rates. Models will be reported using both the simple model with treatment and BMI category and with covariates selected by LARS. Adjusted means of the deviations will be obtained using the least squared means. Two-sample t-test will be used to compare adjusted mean deviations.

Hypothesis C: Improvements in Physiological and Behavioral Factors

Each physiological and behavioral factor will be investigated independently from each other. Linear mixed effect models, like the ones listed in 2B, will be used to test differences between the treatment groups with least square

means. The response for each of these models will include both repeated measures and percent change from baseline approaches.

13. SUBJECT PAYMENT

Participants will receive $25 for completion of each study visit (V1-V6) or up to $150 in total at the completion of the study to help offset transportation costs and their time. Participant payments will be received via check requested from the Pennington Biomedical (LSU) payroll department or charging card in accordance with standard procedures.

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