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

"SmartMoms in WIC"

NCT04028843
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*Finalized at 5/17/2024 research team statistical analysis meeting

Amendments to Statistical Analysis Plan

Prepared by Robbie Beyl, PhD (Biostatistician)

In May of 2024, the research team met to go review the plan for statistical analysis. Several amendments were recorded to ensure the accuracy and transparency of our planned approach. No study data or unblinding information was used to inform these changes which are outlined below in detail.

Section 1.3
Amendment May 2024:
Wording clarification to ensure that gestational weight gain is expressed as incidence of appropriate study-observed GWG per week according to the 2009 Institute of Medicine guidelines, in addition to the three different measures, including study-observed GWG, weekly GWG, and deviation from guidelines.

Section 1.4
Amendment May 2024:
Details on prespecified subgroup analysis was moved from section 3 to this location to indicate these hypotheses were established a priori.

Section 1.4.1 and 1.4.2
Amendment May 2024:
Sections removed as they are not part of the primary analysis.

Section 2.1
Amendment May 2024:
The sample size was changed to enroll at least 330. The COVID-19 pandemic occurred in the early stages of data collection for the trial (i.e., 9 months after the first participants was screened). This resulted in several statewide restrictions, including lockdowns (with the initial "Stay at Home Order" issued on March 22nd, 2020), after 87 participants had been screened and 26 participants were in the primary data collection phase of the trial. Study visits were continued for participants who were already in the screening process or enrolled in the trial. It was necessary for visits to be modified to allow for collection of data to occur in a manner that ensured compliance with COVID-19 mandates (e.g., social distancing, wearing of PPE, etc.) for the participant and study staff. Restrictions required recruitment to cease for 5 months (March 2020 through July 2020). Research activities resumed when Louisiana progressed to Phase 2 of the reopening plan – however, multiple restrictions were still in place that required adjustment of study procedures (detailed in the amended protocol). To adjust to and address the unforeseen circumstances arising from COVID-19 (including to comply with the time constraints set by the funding institute), the trial steering committee decided in October 2022 to end enrolment by December 2023. Based on trial enrolment through 2022, enrolment rate was estimated to be at least 11 participants per month for the following year, and as a result, it was assumed that the trial could achieve a sample size range of between N=339 and N=360. See below in section 2.3 for more details.

Section 2.2
Amendment May 2024:
The randomization section edited to denote that regions were used as the blocking information for the randomization scheme as compared to clinics since multiple clinics per regions were used for enrolment.

Section 2.3
Amendment October 2022:
The sample size was updated to a minimum of 330. The initial estimated effect size for the SmartMoms® intervention was based on preliminary data in the Expecting Success trial. The incidence of appropriate GWG for people with overweight was 12.3% for Usual Care versus 43.8% in SmartMoms®, and in people with obesity, it was 0% for Usual Care and 42.9% in SmartMoms®. However, the Expecting Success trial was not conducted in an exclusively underserved population, so we needed to conservatively estimate the SmartMoms® intervention effect to ensure this study would be well powered. The incidence of appropriate GWG for the Usual Care group was derived from individuals receiving WIC benefits in the 2013 Louisiana Pregnancy Risk Assessment Monitoring System data. The table below was created to show the incidences needed for 80% power in each of the BMI categories. All the estimates were tenable since they were lower than the SmartMoms® trial estimates. This study aimed for a total sample of 432 originally to allow for unknown variability that may have caused the observed rates to be different than the ones used for the power analysis. Sample size was reassessed in response to the COVID-19 pandemic. Based on the feasible recruitment estimates, the sample size was lowered to a minimum of 330. No new data were used to obtain the changes in power.

Table 1. Sample Size Estimates

BMI Category	Usual Care Appropriate GWG Incidence Rate	SmartMoms® Appropriate GWG Incidence Rate				
Normalweight	36.9	50.9	51.4	51.9	52.4	52.9
Overweight	23.9	37.9	38.4	38.9	39.4	39.9
Obesity	25.2	39.2	39.7	40.2	40.7	41.2
Overall	28.7	42.7	43.2	43.7	44.2	44.7
Sample Size		432	405	372	350	330

Section 3.0
Amendment May 2024:
Section was rewritten to clarify that treatment group differences within each BMI category is an a-priori subgroup analysis we would consider.

Section 3.1
Amendment May 2024:
Description of methodology used to assess distributional assumptions was reduced to allow for which test is most statistically appropriate to be used.

Section 3.3
Amendment May 2024:
Based on recommendation from other statistical analysis experts in maternal health, a priori variable selection for determining covariates will be used. Gestational age at randomization, BMI category at randomization, and categorically defined parity will be the only covariates to be included in the model. Exploratory analysis will examine relationships of the outcomes with other

covariates. Variable section is now a priori, no variable section methods are needed. This section has been removed.

Section 3.4 – removed now
Amendment May 2024:
Mediation and moderator section has been removed since these are intended to be exploratory analyses

Section 3.4
Amendment May 2024:
No missing data will be imputed, and the missing data section is adjusted accordingly. Data is missing not at random (MNAR) for participants that have early deliveries, and a sensitivity analysis will be conducted to include data from the visit during mid-pregnancy for individuals that had missing data at the late pregnancy visit time point. See section 4.1 for more details.

Section 3.6 – removed now
Amendment May 2024:
Details about how tables and figures will be expressed in tables have been removed to not limit how results can be presented in order to comply with journal guidelines.

Section 4.0
Amendment May 2024:
The description of the analysis was moved to this section as it was originally written for each individual hypothesis. There are no changes in analysis, but details were moved from this general analysis section to remove repetitive sections of the analysis descriptions.

Section 4.1
Amendment May 2024:
To better match the wording of the analysis that will be used, the details of intent-to-treat analysis approaches, including description of the included analysis populations were spelled out.

Section 4.2
Amendment May 2024:
Each of the study outcomes are explicitly defined to provide transparency and clarity on exact definitions.

Section 4.3.1 – now removed
Amendment May 2024:
Hypothesis analysis description was reduced since a general description of the analysis is written in section 4. No changes are made to the actual analysis.

Section 4.4 – now removed
Amendment May 2024:
Removed the secondary objective section since it is not part of the primary results.

Section 4.5 – now removed
Amendment May 2024:
Removed the mediator and moderator section since it is not part of the primary results.

Statistical Analysis Plan
Prepared by Robbie Beyl, PhD (Biostatistician)

1 INTRODUCTION

1.1 Preface

This study is developed to address an important public health issue; maternal obesity and gestational weight gain (GWG) and in a population that is most vulnerable to the societal influences of overconsumption of energy dense foods and sedentary behaviors. Capitalizing on the Louisiana Special Supplemental Nutrition Assistance, Women, Infants, and Children (WIC)'s unprecedented access to an economically disadvantaged and health disparate population, the overarching goal of this research is to adapt an innovative, patient-centred, pragmatic and scalable weight management intervention called SmartMoms® shown to foster healthy GWG, for dissemination to pregnant individuals 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 individuals across the country.

1.2 Purpose of the Analyses

The analysis will be conducted to test if the participants in the SmartMoms® group differ in terms of GWG as well as pregnancy and birth outcomes as compared to participants in the Usual Care group.

1.3 Study Aims and Endpoints

The overarching goal of the study is to test the effectiveness of SmartMoms®, a patient-centred, pragmatic and scalable intensive lifestyle intervention, to foster healthy GWG in low-income pregnant individuals in the WIC program, a health disparate, racially diverse and underserved population.

Hypothesis 1: The incidence of appropriate study observed GWG per week according to the 2009 Institute of Medicine guidelines [1] will be higher in the SmartMoms® group as compared to the Usual Care group.

Hypothesis 2: Study observed GWG seen in the SmartMoms® group will be less as compared to the Usual Care group. This will be assessed using the following three measures: study observed GWG, weekly GWG, and deviation from the 2009 Institute of Medicine guidelines.[1]

1.4 Subgroups

Per the 2009 Institute of Medicine guidelines, each BMI category is allocated a different rate of GWG per week [1]. Therefore, intervention effects within each body mass index (BMI) category (normal weight, overweight, obesity) will be determined as a subgroup analysis. The study sample sizes are powered to detect differences within each subgroup.

1.5 Exploratory Aims

We designed the research program such that our primary objectives, described above, are the foundation of a rigorously designed study with mechanistic hypotheses. Such a study design requires focus and derivation of hypotheses that are strongly supported by preliminary data and adequate study power. Through this process, we identified many promising hypotheses that did not meet our rigorous criteria for being a primary outcome. Pregnancy and birth outcomes are of great significance but have less supporting evidence and we therefore classified them as exploratory outcomes.

2 STUDY METHODS

This study will be using a parallel-arm design with one intervention arm (SmartMoms®) and one control arm (Usual Care). Each participant will be followed for approximately 24 weeks (from week 16 until delivery). Measurements on the primary outcomes will be collected in clinic visits occurring at early (10,0 to 16,6 weeks gestation), mid (24,0 to 27,6 weeks), and late (35,0 to 37,6 weeks) pregnancy.

2.1 Study Sample

At least 330 pregnant individuals certified to receive WIC services during the current pregnancy (had to be certified by October 31, 2023) will be enrolled from WIC clinics across the nine Louisiana Department of Health (LDH) regions.

Eligible participants will satisfy the following inclusion criteria:

1) Aged 18-40 year,

2) BMI 18.5-40.0 kg/m^2,
3) Expecting a singleton pregnancy,
4) No current mental health issue or eating disorder,
5) Not planning to move out of the area in the next 18 months.

Participants will be excluded for:
1) History of or current smoking, drug or alcohol use,
2) Significant non-pregnancy related illness (HIV, cancer, heart disease, diabetes),
3) Inability to complete the behavioral run-in task.

2.2 Randomization

Individuals will be randomized 1:1 to either the SmartMoms® or Usual Care group. Prior to randomization, 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 confirms understanding of study requirements, randomization will occur via a phone call with intervention staff. The randomization schedule will be prepared by the study statistician and use a permuted block strategy with stratification for LDH region (1 through 9) and BMI category (normal weight, overweight, obesity) to ensure balance within each stratum between individuals in the SmartMoms® or Usual Care groups. The Research Electronic Data Capture (REDCap) will be used to conceal the allocation sequence to intervention staff until randomization occurs.

2.3 Sample Size and Study Power

Study hypotheses will be assessed using appropriate statistical tests, input variables and endpoints, and therefore, power calculations and sample size estimates are presented for the study aims. Estimates of the study power are derived from our preliminary data and from existing literature. The 1:1 randomization scheme within each BMI stratum is applied to ensure that the study is also sufficiently powered to compare intervention effectiveness within BMI groups which is important for the program announcement (PA-18-135).

The sample size estimates assume $\beta=0.8$ and $\alpha=0.05$ to detect the specified differences between incidence rates of appropriate GWG. All sample sizes are inflated to account for 15% attrition. Intent-to-treat (ITT) analyses will be used. Participants are required to have at least one follow-up clinic weight to compute GWG (incidence rate, study observed, per week, and deviation). We plan to enrol at least 330 participants, with relative balance within each BMI stratum. We have sufficient power for our primary comparisons of GWG as well as comparisons within BMI groups. Due to the Covid-19 pandemic impacting trial procedures and enrolment, the goal of this study is to enrol at least 330 participants. That is, the study will continue to enrol individuals until either the end of the enrolment period (December 2023, with participants having to be certified to receive WIC benefits by October 31, 2023, to be eligible) or until all three BMI categories have 110 enrolled participants. Enrolment in any given BMI category will continue past 110 if the other BMI categories have yet to meet the enrolment goal.

2.3.1 Sample Size Estimates for Specific Aims

Hypothesis 1: The incidence of appropriate study observed GWG per week according to the 2009 Institute of Medicine guidelines[1] will be higher in the SmartMoms® group as compared to the Usual Care group.

The estimated incidences of appropriate GWG for the Usual Care group were derived from data based on pregnant individuals receiving WIC benefits in the 2013 Louisiana Pregnancy Risk Assessment Monitoring System.[2] The estimated effect size for the SmartMoms® intervention is based on preliminary data from our Expecting Success trial where the incidence of appropriate GWG for pregnant individuals with overweight was 12.3% for Usual Care versus 43.8% in SmartMoms®; and for pregnant individuals with obesity, 0% for Usual Care and 42.9% in SmartMoms®. However, since Expecting Success[3] was not conducted in an exclusively underserved population, we conservatively estimated that the SmartMoms® intervention would increase the incidence by a minimum of 16% across BMI categories. The resulting overall incidence would be similar to our observation in Expecting Success (Table 1). To observe a 16% difference in the incidence between SmartMoms® and Usual Care while accounting for 15% attrition, at least 330 participants with 1:1 allocation between the two groups and equal stratification within each BMI stratum is required.

Table 1. Sample Size Estimates

BMI Category	Usual Care Appropriate GWG Incidence Rate	SmartMoms® Appropriate GWG Incidence Rate				
Normalweight	36.9	50.9	51.4	51.9	52.4	52.9
Overweight	23.9	37.9	38.4	38.9	39.4	39.9
Obesity	25.2	39.2	39.7	40.2	40.7	41.2
Overall	28.7	42.7	43.2	43.7	44.2	44.7
Sample Size		432	405	372	350	330

In additional to overall differences in incidence of appropriate GWG, this study is also powered to detect incidence differences within each BMI stratum. Assuming an overall difference in incidence of 16%, 110 participants in each BMI stratum are sufficient to detect a difference of at 26% in incidence within each BMI stratum (Table 2).

Table 2. Power For Detecting Differences Within Each BMI Stratum

Difference in Incidence	Power
23%	0.70
26%	0.80
29%	0.88

Hypothesis 2: Study observed GWG seen in the SmartMoms® group will be less as compared to the Usual Care group. This will be assessed using the following three measures: study-observed GWG, weekly GWG, and deviation from the 2009 Institute of Medicine guidelines.[1]

We will investigate study observed GWG, weekly GWG, and deviation between the observed rates of weekly GWG and rates deemed appropriate by the 2009 IOM. Based on our pilot data (Table 3), pregnant individuals with overweight and obesity in the SmartMoms® group had comparable deviation rates (gaining an additional ~0.06 kg/week above the recommended amount) whereas the Usual Care group had a greater deviation rate that was seen in both BMI strata. With our planned sample size of at least 330 participants, we have more than 80% power to detect a difference of at least 0.16 kg/week between the SmartMoms® and Usual Care group and within each BMI category, and over 99% power to show overall differences between groups in study observed GWG.

Table 3. Weekly GWG in Expecting Success

BMI Category	Usual Care Weekly GWG Deviation Rate (kg/week)	SmartMoms® Weekly GWG Deviation Rate (kg/week)
Overweight	0.208	0.063
Obesity	0.160	0.060

3 STATISTICAL PRINCIPLES

Statistical analyses will be carried out by the study biostatistics team within the Louisiana Clinical and Translational Science (LA CaTS) biostatistical core under supervision of the principal statistician Dr Robbie Beyl, who also developed the statistical analysis plan. Analyses will use R (version 4.3.1). The primary methodology will be linear models and linear mixed-effects models to account for within-person correlations arising from repeated measures over time. Further details about the covariance structures are described below. Results will be given in the form of within- and between-group effect estimates derived from the model, as applicable. Unless otherwise stated, significance will be set at alpha ≤0.05. No adjustments for multiplicity will be performed for secondary and exploratory outcomes; these results will be reported as point estimates with corresponding 95% confidence intervals that will not be adjusted for multiplicity. We will highlight that caution is warranted in interpreting these effects and the results should not be used to infer definitive treatment effects.

3.1 Distributional assumptions

Preliminary statistical testing will be performed to investigate homoscedasticity and normality of model residuals. Visual inspections will initially be performed, followed by more tests when departures from normality are present.

3.2 Covariance structures

The variance-covariance structure of the repeated effects will be dependent on the variability among all participants. A preliminary test will be conducted to assess significance of the homogeneity of variances for between-group differences. The within-participant variability will be modelled with an unstructured covariance matrix. Correlation patterns will be assessed with Akaike's Information Criterion (AIC) to make final selections.

3.3 Covariates

The models will include the following covariates: gestational age at randomization, BMI category at randomization, and parity defined categorically as nulliparous vs non-nulliparous.

3.4 Missing data

No statistical imputation of missing values will be conducted (data as observed) per contemporary guidelines.[4]

3.5 General reporting conventions

Descriptive and summary statistics will be generated for baseline characteristics and outcomes of interest. Continuous variables will be summarized using mean and standard deviation (SD). The frequency and percentages of observed levels will be reported for all categorical measures unless otherwise specified.

3.6 Timepoint of analyses

At the completion of all pregnancy visits and confirmation of infant deliveries, chart audits and data quality checks will be undertaken. Once all pregnancy data in the database is checked against the charts, the pregnancy dataset will be locked and the planned analysis to test hypotheses related to pregnancy outcomes as outlined above only will be undertaken.

4 ANALYSIS

4.1 Analysis Populations

Analyses will rely on ITT methodology. The primary analysis will use data from the visits during early and late pregnancy. For participants that had missing data at the late pregnancy time point, we will conduct a sensitivity analysis in which we use data from the visit during mid-pregnancy to calculate outcomes related to GWG per week for these individuals; that is, the incidence of appropriate study observed GWG per week according to the 2009 Institute of Medicine guidelines, as well as weekly GWG and deviation from the 2009 Institute of Medicine guidelines.[1]

4.2 Outcomes Measures

Per the 2009 Institute of Medicine guidelines,[1] each BMI category is allocated a different rate of GWG per week, which we will base our BMI-specific definition of GWG outcomes on (Table 4).

Table 4. 2009 Institute of Medicine Guideline Ranges for Weekly GWG

BMI Category	Inadequate	Adequate	Excessive
Normalweight	<0.35 kg/week	0.35 kg/week to 0.50 kg/week	>0.50 kg/week
Overweight	<0.23 kg/week	0.23 kg/week to 0.33 kg/week	>0.33 kg/week
Obesity	<0.17 kg/week	0.17 kg/week to 0.27 kg/week	>0.27 kg/week

Study observed GWG is defined as the difference between clinic weight assessed during late pregnancy and clinic weight assessed during early pregnancy.

Weekly GWG is defined as study observed GWG divided by the number of weeks between the early and late pregnancy study visits, with number of weeks calculated based on the number of days between study visits divided by 7.

Incidence of appropriate study observed GWG per week is defined as the number of participants that have weekly GWG in the adequate category according to the 2009 Institute of Medicine guidelines as opposed to inadequate or excessive (Table 4).

Deviation from the 2009 Institute of Medicine guidelines will be defined as the absolute difference in weekly GWG outside of the range bounds (Table 4). Participants within the bounds will not be included in this analysis.

Adverse perinatal outcomes will be abstracted from the birth certificate records obtained from the state. The Louisiana Electronic Event Registration System (LEERS) collects all official records related to birth and includes information from prenatal and delivery records. These records will be requested from the state by the study investigators using records related to participant, incident pregnancy, and participant-reported delivery information.

Information will be abstracted from the LEERS records on adverse perinatal outcomes, including on the diagnosis of gestational diabetes, gestational hypertension/preeclampsia, and medically indicated Cesarean section (maternal outcomes) as well as neonatal intensive care unit admission and birth weight that will allow for calculation of small for gestational age or large for gestational age (neonatal outcomes). Specifically, we will define medically indicated Cesarean section as deliveries via Cesarean method of delivery with attempt of labor or if prior to 39 weeks with any medical indication. Small for gestational age (SGA, <10th percentile) and large for gestational age (LGA, >90th percentile) will be defined using birth weight for gestations greater than 19 weeks and less than 45 weeks based on the Alexander criteria specific for neonatal sex and rate.[5] Preterm birth will be defined as any birth occurring prior to 37 weeks gestation; the calculation of gestational age at delivery will be determined as the difference in days between delivery date and the estimated date of conception divided by 7, with the delivery date abstracted from the birth certificate record and the date of conception calculated as 280 days prior to the participant self-reported due date.

From these outcomes, a maternal and neonatal composite will be calculated. Specifically, for each participant, the number of adverse maternal outcomes (as listed above) will be summed; from this, a binary maternal composite will be derived with any participant who has a non-zero sum indicated as having a maternal adverse outcome and those with a zero-sum having no maternal adverse outcome. A neonatal composite will be derived analogously based on the adverse neonatal outcomes (as listed above).
Other study measures (e.g., baseline characteristics) are briefly defined below.

Gestational age at randomization in weeks is defined as the number of days since the date of conception divided by 7, with the date of conception calculated as 280 days prior to the participant self-reported due date.

Parity is defined categorically as either nulliparous or non-nulliparous based on participant self-report.

Race/ethnicity is based on self-report and includes the options ‘Hispanic’ (if participant reports any Hispanic, Latino/a, or Spanish origin), ‘Non-Hispanic White’ (if participant reports no Hispanic ethnicity and indicates White race), ‘Non-Hispanic Black’ (if participant reports no Hispanic ethnicity and indicates Black or African American race), and ‘Mixed or Other’ (if participant reports multiple races or ethnicities, or a race other than White or Black).

Marital status is defined based on self-report and includes options ‘Married/Living with Significant Other’ (if participant reports to be married or living with significant other) or ‘Not Married’ (if participant reports not to be married, or to be separated, divorced, or widowed).

Educational attainment is defined based on self-report and includes options ‘Some college education’ (if participant reports a college degree, postgraduate work, or 1-3 years of college, business, or technical school) or ‘No college education’ (if participant reports some high school or a high school diploma or GED).

4.3 Analyses of Study Aims

Hypothesis 1: The incidence of appropriate study observed GWG per week according to the 2009 Institute of Medicine guidelines[1] will be higher in the SmartMoms® group as compared to the Usual Care group.

The categorical outcome of study-observed GWG per week attainment will be analyzed using a general linear model with a fixed effect for group (SmartMoms®, Usual Care) with a binary distribution and a log odd link function modeling the incidence rates. Covariates will include BMI category (normal weight, overweight, obesity) at randomization, parity (nulliparous, non-nulliparous), and gestational age at randomization. Results will be reported as adjusted odds ratios (OR) and/or relative risks (RR) as appropriate. The analysis will also be conducted and reported within each BMI category.

Hypothesis 2: Study observed GWG seen in the SmartMoms® group will be less as compared to the Usual Care group. This will be assessed using the following three measures: study observed GWG, weekly GWG, and deviation from the 2009 Institute of Medicine guidelines.[1]

The continuous outcome of study observed GWG will be analyzed using a linear mixed-effects model including fixed effects for time (early pregnancy, late pregnancy), group, and the interaction thereof, with participant as a random effect to account for within-participant repeated measures as well as BMI category (normal weight, overweight, obesity) at randomization, parity (nulliparous, non-nulliparous), and gestational age at randomization as covariates. The continuous outcomes related to study observed GWG per week assessed only during late pregnancy (i.e., weekly GWG and deviation from the 2009 Institute of Medicine guidelines) will be analyzed analogously using a linear model with a fixed effect for group and the same covariates. The analysis will also be conducted and reported within each BMI category.

Exploratory: The incidence of adverse perinatal outcomes will be less in the SmartMoms® group as compared to the Usual Care group.

These outcomes will be analyzed analogously to the categorical outcome of study observed GWG per week attainment using a general linear model with a fixed effect for group (SmartMoms®, Usual Care) with a binary distribution and a log odd link function modeling the incidence rates, as well as BMI category (normal weight, overweight, obesity) at randomization, parity (nulliparous, non-nulliparous), and gestational age at randomization as covariates.

5 REFERENCES

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