**Author’s response to reviews**

**Title:** Mood and Quality of Life Changes in Pregnancy and Postpartum and the Effect of a Behavioral Intervention Targeting Excess Gestational Weight Gain in Women with Overweight and Obesity: A Parallel-Arm Randomized Controlled Pilot Trial

**Authors:**

Abby Altazan (abby.duhe@pbrc.edu)

Leanne Redman (Leanne.Redman@pbrc.edu)

Jeffrey Burton (Jeffrey.burton@ochsner.org)

Robbie Beyl (robbie.beyl@pbrc.edu)

Loren Cain (loren.cain@austin.utexas.edu)

Elizabeth Sutton (suttonef@mwri.magee.edu)

Corby Martin (corby.martin@pbrc.edu)

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**Author’s response to reviews:**

Complete letter is attached as supplementary materials.

The reviewers’ comments were extremely valuable and have helped to greatly improve our work. We hereby provide a resubmission of our manuscript and provide detailed responses to the critiques including the section title and line number in the revised manuscript for each response that requires an edit in the manuscript.

**Editor Comments:**

1. Since all readers are not familiar with SmartMom programme, please consider some explanations on this program in the introduction.
Thank you for this suggestion. The SmartMoms intervention was described in greater detail in Introduction (Pages 4-5, Lines 79-99) to help familiarize the reader and give additional context to the Expecting Success primary outcome results.

2. METHOD: How authors randomized participants, please explain in the method section.

Thank you for this suggested addition. Participants were randomized by unblinded staff using envelopes that were prepared before study initiation by the biostatistician. Further description was added to Methods, Study Design and Intervention section (Page 7, Lines 137-143).

3. The intervention also was not explained in the method section. What did authors exactly do in the Smart Mom in person and Smart Mom by phone? How many sessions did the Smart Mom in person had and how many calls or text messages received the group of Smart Mom by phone. Who did all these recommendations in person or on the phone? Who was responsible for the usual care from mothers (midwife or other health care providers?).

Thank you for pointing out that the intervention could be further explained. The intervention is entirely described in the primary outcome paper (Redman et al 2017, JMIR MHEALTH AND UHEALTH), but we agree that we needed to incorporate key details about the intervention in Methods, Study Design and Intervention section (Pages 7-8, Lines 145-162), namely that there were 18 lessons for both the In-Person and Phone groups and that interventionists interacted with participants in face to face sessions (for In-Person group) and within the application and other remote contact at least once per week (for Phone group). Also, additional text was added to indicate that the usual care group participants were not provided any services from interventionists but relied on usual care from their obstetricians (Page 7, Lines 145-146).

4. Please write the allocation concealment in this study.

In line with the other additions about randomization and random group assignment, a biostatistician prepared the randomization envelopes prior to study initiation and the numbered envelopes remained sealed until they were pulled by unblinded staff. Further description was added to Methods, Study Design and Intervention section (Page 7, Lines 137-143).
5. Any blinding, please explain who?

Interventionists and clinical staff were different and were not in contact about the study participants. Clinical staff were blinded to group assignment and conducted all assessment outcomes. Interventionists interacted with the SmartMoms® intervention participants in the In-Person and Phone groups and thus were unblinded by necessity. Additional text was added to the Methods, Clinical Assessments section (Page 9, Lines 186-187) and Methods, Psychological Assessments section (Page 10, Lines 204-205).

6. Did mothers completed all questionnaires themselves or by interview?

Clinical staff provided the paper-based questionnaires to participants and they completed the questionnaires themselves in private. Additional text was added to the Methods, Psychological Assessments section (Page 10, Lines 204-206).

7. In the method, authors did not mention that how many women recruited for each group?

Thank you for pointing out that this was unclear. We clarified that we had to drop some individuals from this analysis because they did not have psychological assessments after baseline and added the numbers for each comparison group to the Results, Participant Characteristics section (Page 12, Lines 246-255).

8. What was the logic for sample size of 54 for three groups? With withdrawing during study only 11 women remained in one group and I need to know what was the power of study at the beginning of it and how much declined after completion of data collection.

The study was originally powered on a larger sample size but was conducted and completed as a pilot and feasibility study to follow 54 mother-infant dyads. The outcomes presented here were secondary measures and not part of the original power analysis. In Table 2, the effect sizes based on standard deviation show that most of the effects are small according to Cohen’s effect size criteria (Cohen 1988 Statistical power analysis for the behavioral sciences). We calculated post-hoc observed power on the group comparisons described in Table 2 and found that the lowest
calculated post-hoc observed power was 768 for SF-12 physical component scores from baseline to 1-2 months postpartum. The majority of comparisons in Table 2 had post-hoc observed power of 2000 or more. We recognize the small sample size, but feasible larger numbers (n=100, 200, etc) still would not achieve adequate power and may not meaningfully affect the conclusions. Thus, this is novel preliminary data that provides insight to mood and quality of life throughout pregnancy and into the postpartum period. The existing text was moved to the beginning of the limitations for clarity and additional text was added to the Discussion section (Page 20, Lines 403-407).

9. Results: again it is not clear that how many were recruited for each group and 54 stands for which group? 50 completed

Thank you for pointing out that it is not clear how many are included in this analysis. Fifty four women enrolled in the study with four dropping due to miscarriage and 50 women completed the primary weight outcome assessments (Redman et al 2017, JMIR MHEALTH AND UHEALTH). Only 43 women had psychological assessments after baseline so additional text was added to the Results, Participant Characteristics section (Page 12, Lines 246-255) to describe the number of participants included in this analysis.

10. In table 1 we need to see the Mean ±SD of first visit in pregnancy, as weight alone does not have value.

We added the gestational age in weeks at the baseline visit in Table 1. Baseline visits and randomization were completed before 13 weeks 5 days gestation.

11. In table 1, when you have just two groups, why did you use ANOVA for continuous data?

The p-values based on the ANOVA and t-test for this setting are equivalent. ANOVA was chosen so that there would be consistency when testing differences in the model with three groups [Usual Care, SmartMoms® (In-Person), SmartMoms® (Phone)] or with two groups (Usual Care, SmartMoms® Intervention).
12. In the method section there was three groups (usual care, smart Moms in person or SmartMoms via smartphone, but in the result section I could see only two groups, why?

Both the SmartMoms® In-Person and Phone intervention groups were successful in attenuating gestational weight gain as compared to the Usual Care group and overall gestational weight gain was shown to be equivalent between the SmartMoms® In-Person and Phone intervention groups (p=0.04 equivalence) and this was added to the Methods, Statistical Analysis section (Page 11, Lines 219-225). We analyzed the data as intervention vs usual care and as In-Person vs Phone vs usual care and saw similar results; but decided to combine the groups into a single SmartMoms® intervention group to decrease the type I error rate and provide a better variance estimate.

13. According to the results of this study, even one case of postpartum did not happen. Do not authors thing that it was related to the small sample size and the intervention.

We do agree that no incidence of postpartum depression was related to the small sample size.

14. Actually this study designed to behavioral change (for mental health and physical health) for overweight or obese women; however, I could not see any comparison of weight gain before and after intervention between intervention groups and control groups.

Thank you for this comment. We described the weight gain results from the primary paper in the introduction initially, but after reviewing your and other suggestions, we added the overall gestational weight gain and prevalence of excess gestational weight gain results from this subset of 43 women. The findings are similar to the primary paper findings and help to show the differences in overall weight gain between the SmartMoms® intervention and the Usual Care groups. An additional section was added to the Results, Gestational Weight Gain section (Page 13, Lines 263-270)

Reviewer Reports

Reviewer 1: This manuscript describes the effect of a behavioral intervention to prevent excess weight gain in pregnancy and to quantify changes in mental health and physical quality of life.
The paper is on the whole well written. However, there are a number of areas where clarification is required.

1. The authors state that in a previous paper the tool was effective for weight loss. However they do not show in the results the magnitude of the weight changes between the tool and usual care in the current study.

As mentioned above in Editor Comments #14, we described the weight gain results from the primary paper in the introduction initially, but after reviewing your and other suggestions, we added the overall gestational weight gain and prevalence of excess gestational weight gain results from this subset of 43 women. The findings are similar to the primary paper findings and help to show the differences in overall weight gain between the SmartMoms® intervention and the Usual Care groups. An additional section was added to the Results, Gestational Weight Gain section (Page 13, Lines 263-270)

2. In the introduction the authors state weight restriction tools have been effective and restricting excess weight gain but have had little effect on adverse pregnancy outcome. This seems an important point, if they do not improve health outcomes, then why use them at all?

We think that recent lifestyle interventions may not have shown effects on adverse outcomes due to low behavioral intensity, too few interactions with intervention staff, and/or starting too late in pregnancy. We think that technology based interventions may have the potential to deliver a higher intensity and interaction program to individuals and therefore have the potential to move the needle on adverse outcomes (Redman 2017 JMI R MHEALTH AND UHEALTH). Indeed, more evidence is needed to confirm whether or not a link exists between gestational weight gain and adverse outcomes, and future research should include intervention intensity, diet quality during pregnancy related to weight gain, physical activity behaviors, and other metabolic and behavioral parameters.

3. In the methods there is no sample size calculation so it is unclear if this research was adequately powered (there are only 11 in the placebo group). Please could the power calculation be added to the methods.
As mentioned above in Editor Comments #8, the study was originally powered on a larger sample size but was conducted and completed as a pilot and feasibility study to follow 54 mother-infant dyads. The outcomes presented here were secondary measures and not part of the original power analysis. In Table 2, the effect sizes based on standard deviation show that most of the effects are small according to Cohen’s effect size criteria (Cohen 1988 Statistical power analysis for the behavioral sciences). We calculated post-hoc observed power on the group comparisons described in Table 2 and found that the lowest calculated post-hoc observed power was 768 for SF-12 physical component scores from baseline to 1-2 months postpartum. The majority of comparisons in Table 2 had post-hoc observed power of 2000 or more. We recognize the small sample size, but feasible larger numbers (n=100, 200, etc) still would not achieve adequate power and may not meaningfully affect the conclusions. Thus, this is novel preliminary data that provides insight to mood and quality of life throughout pregnancy and into the postpartum period. The existing text was moved to the beginning of the limitations for clarity and additional text was added to the Discussion section (Page 20, Lines 403-407).

4. Could you add the actual cut-offs used to define overweight and obesity.

Thank you for the suggestion. Definitions for overweight and obesity and how it was determined for participant eligibility was added to the Methods, Clinical Assessments section (Page 9, Lines 190-193).

5. How was gestational age determined, was this via ultrasound or using the date of LMP, could this be added to the methods.

Thank you for requesting clarification for gestational age determination. The methods for determining gestational age were added to Methods, Participants section (Page 9, Lines 174-176).

6. Where in the US was the study carried out? How were the women compensated.

The study was conducted in Baton Rouge, Louisiana, United States and text was added to Methods, Study Design and Intervention section (Page 7, Lines 131-132). Also, participants were compensated financially for their time and to offset transportation costs. They were also provided
small incentive items with the study logo throughout the study. Additional text was added to clarify compensation to Methods, Participants section (Page 9, Lines 181-183).

7. Was the income data maternal income or mother plus partners income?

Income data was collected as total household income self-reported by the participant. Naming was clarified in Methods, Clinical Assessments section (Page 10, Line 198) and in Table 1.

8. In table 1, what is pre-gravid BMI, when was this measured. Was this estimated by the mothers or is actually baseline BMI? Should the postgraduate be education rather than work.

The BMI described in Table 1 was actually baseline BMI which we term enrollment BMI. We have renamed pre-gravid BMI to enrollment BMI and described in detail how it was measured and calculated in Methods, Clinical Assessments section (Page 9, Lines 190-193). In addition, postgraduate work was changed to postgraduate education in Table 1.

9. The results needs to include how the weight gain differed between treatment and usual care.

As mentioned above in Editor Comments #8 and Reviewer 1 #1, we added a section in the results that describes prevalence of excess weight gain and overall gestational weight gain between the groups Results, Gestational Weight Gain section (Page 13, Lines 263-270).

10. In the discussion the authors state the sample size was too small to assess the extent of lifestyle intervention on mood etc and another larger study is needed. if this is the case then what is the value of this current study, if it is not adequately powered to find anything and you find nothing then it could just be the sample size is too small rather than lack of actual effect.

As mentioned above in Editor Comments #8 and Review 1 #3, we concluded using the effect sizes in Table 2 that most of the effects are small according to Cohen’s effect size criteria (Cohen 1988 Statistical power analysis for the behavioral sciences). We calculated post-hoc observed
power on the group comparisons described in Table 2 and found that the lowest calculated post-hoc observed power was 768 for SF-12 physical component scores from baseline to 1-2 months postpartum. The majority of comparisons in Table 2 had post-hoc observed power of 2000 or more. We recognize the small sample size, but feasible larger numbers (n=100, 200, etc) still would not achieve adequate power and may not meaningfully affect the conclusions. Although the study was not powered on the secondary outcomes in this analysis, this is preliminary data that provides insight to mood and quality of life throughout pregnancy and into the postpartum period that is novel and has not been shown before in clinical studies. The existing text regarding the limited sample size was moved to the beginning of the limitations for clarity and additional text was added to Discussion section (Page 20, Lines 403-407).

Reviewer 2:

The manuscript "Mood and Quality of Life Changes in Pregnancy and Postpartum and the Effect of a Behavioral Intervention Targeting Excess Gestational Weight Gain in Women with Overweight and Obesity: A Parallel-Arm Randomized Controlled Trial" discuss and show results from a evaluation of maternal mood and quality of life during pregnancy and puerperium. It is a new knowledge that must be shared with the scientific community. Is well designed and the analysis were very well performed.

1. For me, the manuscript is ready for publish. Nevertheless, I have a little small suggestion. The authors could explain or try to explain why the intervention group had no differences from the controls and should analyze the two parts of intervention group (presential and phone) separately.

Thank you for these comments. We were able to clarify that the SmartMoms® In-Person and Phone intervention groups were shown to be equivalent in attenuating gestational weight gain as compared to the Usual Care group and added text to Methods, Statistical Analysis section (Page 11, Lines 219-225). We analyzed the data as intervention vs usual care and as In-Person vs Phone vs usual care and saw similar results; but decided to combine the groups into a single SmartMoms® intervention group to decrease the type I error rate and provide a better variance estimate. To address the other comment about why there were observed no intervention effects, one plausible speculation would be that the SmartMoms® intervention was aimed at appropriate weight gain as opposed to traditional weight loss interventions that have shown improvements in mood and quality of life in non-pregnant adults. In addition, some observation studies have shown that physical activity, specifically, in pregnancy may positively affect mood and quality
of life so future interventions that incorporate structured exercise plans may have more success. Additional text was added to the Discussion (Page 19, Lines 377-381).