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)

Version: 2 Date: 20 Dec 2018

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Complete letter is attached as supplementary materials.

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. If this study was three arm randomized controlled trial, please mention this matter in the abstract and method section.
“Three group” was added to the randomized controlled pilot trial description in the Methods abstract section (Page 2, Line 30) and the section in the manuscript Methods, Study Design and Intervention (Page 7, Line 131).

2. There is need to more information about intervention in the abstract. What exactly each group received?

Additional text was incorporated in the Methods abstract section (Page 2, Lines 33-37) to succinctly describe what services the SmartMoms intervention and Usual Care groups received as part of the study.

3. How many women were in each group, please mention in the abstract.

Thank you for this suggestion. The number of participants randomized to each arm were included in the text section where the SmartMoms intervention and Usual Care services are described in the Methods abstract section (Page 2, Lines 33-37).

4. Again, it is not clear that how many groups did you have, please mention two or three groups?

As suggested in Editor Comment #1, we added “three group” next to the study design description in the Abstract (Page 2, Line 30) and Methods (Page 7, Lines 131) to reflect what is already described in the Methods, Study Design and Intervention section (Page 7, Lines 137-140). As described in the Methods, Study Design and Intervention section (Pages 7-8, Lines 146-160) and the Methods, Statistical Analysis section (Page 10, Lines 215-221) the same SmartMoms intervention was delivered to the two SmartMoms intervention groups (the difference was the mode of delivery) and the two groups were shown to be equivalent at attenuating gestational weight gain. As described in the Methods, Statistical Analysis section (Page 10, Lines 215-221), the groups were combined into one SmartMoms intervention group to decrease type 1 error rate and provide a better variance estimate. To more clearly present the rationale for combining into one SmartMoms intervention group, we rearranged the Methods, Statistical Analysis section (Pages 10-11, Lines 214-257).
5. Abstract: Conclusion: “Intensive lifestyle gestational weight gain interventions do not have negative effects on these outcomes”. Why authors did not use “the intervention did not have any significant impact on those outcomes” instead of “did not have negative effects on those outcomes.”

Thank you for pointing out that this was unclear. The sentence was changed to clarify the statement in the Methods abstract section (Page 3, Lines 52-54).

6. Method: about SF-12, please mention that each domain has how many questions and what is the score of each domain?

Thank you for this suggestion. The number of items and scoring of the SF-12 questionnaire are now fully described in the Methods, Psychological Assessments section (Page 10, Lines 204-210).

7. In the method section, please explain that how many women were recruited for each group and what was the logic for this sample size? What was the power of the study?

The response from the previous revision regarding sample size and power was summarized and added to the Methods, Statistical Analysis section (Page 11, Lines 229-239). As mentioned, effect sizes were calculated and show that the effects are small according to Cohen’s effect size criteria. Then, we calculated post-hoc observed power on the group comparisons and found that the lowest calculated post-hoc observed power was 768 for SF-12 physical composite scores from baseline to 1-2 months postpartum.

8. Results: if the characteristics of all participants are accessible (those 54 that recruited) please prepare the first table including women before drop-out.

Table 1 was updated to include the baseline characteristics for all 54 women who were enrolled in the study (Page 13). Considering, all 54 women who enrolled in the study, gestational age at baseline assessments was no longer significantly different between the SmartMoms intervention and the Usual Care groups so the original text was removed (Page 13, Lines 270-271).
9. Please give information about power of study, then readers can understand how much the power of study has decreased after withdrawal.

As mentioned above in Editor Comment #7, the response from the previous revision regarding sample size and power was summarized and added to the Methods, Statistical Analysis section (Page 11, Lines 229-239). As mentioned, effect sizes were calculated and show that the effects are small according to Cohen’s effect size criteria. Then, we calculated post-hoc observed power on the group comparisons and found that the lowest calculated post-hoc observed power was 768 for SF-12 physical composite scores from baseline to 1-2 months postpartum.

10. Please upload the education program for SMARTMOMS as a supplementary material.

Thank you for this request. We have included the table showing the lesson plans for the SmartMoms® Intervention along with an example lesson to illustrate the structure and example content included as part of the SmartMoms® Intervention as Supplementary Material named SmartMoms Intervention Lessons. Additional SmartMoms intervention material may be obtained by request and this was added to the “Availability of data and material” section (Page 23, Lines 468-470).

11. Please deposit your data in the FIGSHARE and get due DOI and add this information to the “Availability of Data”.

As described in the “Availability of data and material” section (Page 23, Lines 470-471) the datasets can be obtained by request. Data analysis for this study is ongoing with additional outcomes not yet published. Pennington Biomedical Research Center has institutional policies that data sharing at this time require transfer agreements. Data transfer agreements can be established with anyone who reasonably requests data included in this manuscript so that requested data can be shared as intended and agreed upon.