Author’s response to reviews

Title: Preparing for a Clinical Trial to Test a Postpartum Weight Retention Intervention among Low Income Women: Feasibility of a Protocol in a Community-Based Organization

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Dear Reviewers,

It was exciting and humbling to have reviewers who are so integral to the work I am doing provide such thoughtful comments to strengthen the manuscript. Thank you so much for your time and attention, and for your seminal contributions to the field.

In speaking with my research team, we have decided to describe this study as a feasibility study. We were attempting to understand whether our trial could be implemented as intended. As was encouraged in feasibility trial literature and by my statistical team, we aimed to include 10% of our projected necessary population for the trial in this feasibility study, hence our n=17. Our focus group work is now in press as we methodically worked to best understand our population
and their needs prior to testing the intervention. We performed an initial sample size calculation for the clinical trial based on the literature, powered for the primary endpoint of postpartum weight change, driven by a desire to detect a 2 lb difference in mean weight change with double standard deviation (4) between control and intervention participants. The data from this feasibility study lead to an alteration in our plan for recruitment as standard deviations were much broader as weight change variability was seen (SD 8-10). To detect a 4 pound difference in weight change at one year post delivery using the standard deviations acquired (8), we would require a control population of 85 and an intervention population of 85 (instead of 63 in each group). Assuming 40% attrition, which was a conservative estimate based on other community and faith-based based intervention studies, we now project a sample size of 240.

Here are additional changes by reviewer comment:

Reviewer 1

1) Abstract, Lines 33 - 35 - I think what you want to say here is something more like, "Other secondary outcomes were the change in psychosocial and clinical measures from baseline to one year following delivery." The baseline measure is not an outcome.

Thank you. This was done. Lines 35-36

2) Lines 59-62 - Given the now fairly large number of intervention and observational studies that have been carried out on the topic of postpartum weight retention including some with low income audiences and with non-white samples, it is appropriate to cite reviews and meta-analyses here. But the authors need to be sure to cite the most recent and comprehensive reviews. In that regard, the Amorim et al. Cochrane Review was updated in 2013. It is Issue 7, Art. No. CD005627. In addition, since the authors claim is that none of the previous intervention studies look place in a community-based setting (a statement about which I am skeptical), they need to cite specific references to support this claim.

The background is now entirely updated. Lines 52-88
3) Line 70 - Cite a reference for the Theory of Planned Behavior. I say that because this theory evolved from the Theory of Reasoned Action (that includes the constructs the authors mention in the paper), but adds two constructs: perceived behavioral control and perceived power, according to Mark Edberg in the "Essentials of Health Behavior," 2007.

I used the original TPB constructs as described by Ajzen et al in 1985 (attitudes, subjective norms, perceived behavioral control). You are correct that the perceived behavioral control construct was not a part of the theory of reasoned action from which TPB is an extension and also developed by Ajzen. The foundational work of this study (from observational work to focus work to this feasibility study), was based on those three constructs described by Ajzen alone. Lines 96-97

4) Lines71-78 - A reference is not included for the study that describes the 4 intervention components. Please include. Reference 12 that is used earlier in the paper describes the development of the measures for some of the psychosocial constructs and their relationship to gestational weight gain.

This manuscript is in currently in press and I just reviewed the proofs to review. I was hoping it would be through by this paper but I do not yet have a DOI.

5) Lines 80-81 - I think it would be clearer to say that you are studying 5 of the 8 conceptually distinct outcomes that Parker et al. include in their model. Those you are not studying are appropriateness, fidelity and implementation cost. Why did you not choose to include these?

Due to time and funding we were limited in our scope. Part of this more appropriately-named feasibility study (we are changing how we explain what we did thanks to our second reviewer), was trying things we didn’t end up using in the clinical trial, so we felt that focusing on cost and fidelity would not be an effective use of time at this juncture. Lines 114-118
6) Lines 85-86 - The conceptual model in Figure 1 is very rudimentary and lacks important details such as the specific behavior changes that are the target of intervention. Also do the authors think that any of the secondary outcomes are on the pathway to achieving the primary outcome? If so, this should be shown on the model. I’d think that breastfeeding and diet composition would be. The model would be more useful, if it specified which intervention components were aimed at which theoretical constructs and which behaviors.

We decided not to include the conceptual model and instead use the text to explain the targets, constructs, and behaviors.

7) Line 109 - The "one of 3 initial classes" is confusing. It sounds like there were 3 different classes and women only had to attend one. But now that I have read the whole paper, I think that what you mean is that an initial class was offered at each of the 3 sites from which study participants were ultimately recruited. Whatever the case, this needs to be clearer.

I made this clearer—yes, we have three cohorts from 3 sites, and a class was offered at each.

8) Lines 142-143 - How do you know if the scripts were followed? Do you have any measures of fidelity, an implementation outcome specified by Parker et al.?

Great question! During this pilot, I observed all the workshops. We ended up developing a checklist, but for this study I only have qualitative observations that the script was followed.

9) Data analysis section, Lines 152-156 - In your data analysis you are comparing "those who began the pilot and those retained in follow-up one year later," according to the manuscript. Those retained are a subset of those who began, so the two samples are not independent. The manuscript does not indicate that paired t-tests were used, which I believe would be the
appropriate t-test. However, the other issue is that the total n is then 9 which is a small number for statistical analyses. A statistical consultant should give an opinion on these issues.

The total n is very small, with statistical analysis between those who dropped out at one year and those who were retained (independent samples). We are limited with what we can accomplish with this small size, but I thought it important to highlight the differences between those retained and not for assessment of feasibility. I corrected the table 1 to demonstrate these differences.

10) Results section - Given the small and changing sample sizes, rather than just giving percentages, I strongly suggest giving both the numerator and the denominator for each percentage in the Results section. For examples in line 160 - "... with 30% (5/17) by six weeks, 35% (6/17) at 6 months, and 47% (8/17) attrition at one year."

This was done. I agree. Lines 209-211

11) Line 182 - Foundation does not need to be capitalized here.

Agreed. Lines 238 and 243

12) Line 194-195 - The problem with saying that the proportion of women with depression did not change over time is that the sample size changed quite a bit across time. So I guess that depression was not related to staying in the study.

I further clarified that the depression percentage was a point prevalence. In our small study, it does not seem to be associated with staying in the study. It was highly prevalent at the beginning and prevalence persisted no matter who was retained. Lines 250-252
13) Lines 216-218 - In my view, the authors are describing an important decision that they made on the basis of this study, at this point in the manuscript. But the statement is very confusing. It sounds like you made the initial class longer. Be clearer in stating the decision made and give more detail on how many more classes and/or home visits we added, if that is what the investigators did.

We provided further explanation. Lines 276-278

14) References - I am not sure whether the authors are following the journal's style for references or not. But I am pretty sure that page numbers need to be included in each reference and in reference 12, no page numbers were included. They are 332-343.

I really appreciate the level of detail in this review! I have never been given page numbers before!

15) Figure 1 - This figure is so rudimentary that it is not worth including as it is. If it can be expanded with more detail as described above, then it could be included.

Our team agreed that we should leave it out and develop the text further.

Reviewer 2:

1) I am not fully convinced that this study should be considered a pilot study - I would refer as a feasibility trial. I am fully aware that the terms "pilot" and "feasibility" study are often used interchangeably in published research to indicate a study done in anticipation of a full-scale clinical trial, to test out different components of the methods or to provide information that will help with the trial's design. However, pilot studies are often seen as miniature version of the
main study to test whether the components of the main study can all work together. It will therefore resemble the main study in many respects (design and recruitment). In this case the authors mentioned that this pilot is a prep work for the full-scale RCT. I assume the study will consist of two armed-trial with random allocation. Right? However, the design applied was a quasi-experimental study (pre-and post-test). My understanding is that a feasibility study is a piece of research done before a main study in order to answer the question "Can this study be done?". I think that it is the case of this study. Therefore, I would replace the word trial from the title by feasibility.

Our team agrees about the often interchangeable use of pilot and feasibility study. Since we study additional implementation outcomes beyond just feasibility, I tried to better explain what we were doing and I did change the title to better reflect the “can it be done” nature of the study.

2) In the abstract (if space allows) it would be informative to add more details about the intervention (duration) and scale of the study (N or sample size).

This was done. Lines 37-41, 149-151, and 276-286

3) Methods: Authors should provide more detailed information about the intervention activities. For example topics covered in the healthy eating and feeding sessions, types of exercise aid give, intensity of the exercise regime prescribed, frequency and duration of each home visit (face-to-face) contact, etc. By Knowing the intensity of the intervention the readers would feel more convinced about the feasibility and acceptability for the proposed intervention.

I agree and I further explained the intervention. It was my hope that another study on the focus group work would have been published by now. It is in press and I just reviewed the proofs. Lines 99-122
4) The author mentioned that focus group was performed. Were the results from the focus group published? If so, the authors should provide the reference. If not, more details should be given in the manuscript (key findings). It would be useful to define low income and provide details about ethnic profile.

100% of the women were WIC-eligible as a way to define low-income status. I provided more details that were in the focus group manuscript in press. Lines 99-122, 142-143 and Table 1

5) In your focus group did you find ethnic differences in terms of barriers and attitudes towards healthy eating and physical activity? Was the intervention design culturally tailored?

We found some differences in past experiences shared, particularly sentiments discussed from a newer immigrant from a rural community who used to walk and eat fresher food, and now doesn’t. We heard about the varying need for white rice to “complete a meal”. We therefore had all materials and communications in Spanish and English, our project coordinator was bilingual and herself Hispanic. We also offered a food guide that had commonly bought Hispanic foods and substitutes. All scripts and handouts were vetted by the academic-community partnership research team.

6) If the team is planning to conduct a full scale RCT, willingness of participants to be randomized should have been included as one measure of acceptability. Was this covered in the focus group discussions? Did the team discuss what the population and staff considered an acceptable 'control' e.g. delayed intervention, no intervention?

We discussed this at length in focus group and in our academic-community team research meetings. We also asked the question during this feasibility study. In our ongoing clinical trial, we therefore have an intervention group and an enhanced control group which was proposed by the community health workers—even the control participants therefore receive a baby carrier, and the health texts, meal planning, and nutrition handouts in paper form. The inclusion of an enhanced control group was still scientifically rigorous but allowed for the key stakeholders to have their voices heard.
7) Pilot/feasibility study can be used to inform the sample size calculation (mean and sd of primary outcomes). This should be mentioned as one of the aim of the present study. I appreciate that there is little guidance in the literature re how large a pilot/feasibility study should be. Often using 10% of the sample required for a full study, may be inadequate for pilot studies. To the best of my knowledge feasibility trials usually included 20-50 participants per arm. Did the authors considered any rational for the sample size for this "pilot" study? Authors should include clear criteria to judge whether progression to the definitive study is justified. Again there are no set progression criteria defined in the literature to use, but they should aim to address whether the uncertainties that were set out to be resolved in the preliminary studies have been determined. In the discussion (line 203-204) the authors mentioned that "the level of penetration and attrition during the pilot was unacceptable". Therefore, it is important to define the threshold used to define poor recruitment rate, poor attrition rate, low adoption and adherence to the intervention, etc. One critical issue in all trails is recruitment/enrollment. It seems that only 3 (out of 8) geographic sites contributed to recruitment. This should be considered when planning the large scale trial. In the discussion the authors should prove that measures are in place to guarantee successful recruitment in a given time frame for the study.

We did use the tenet that 10% of anticipated sample required for our study should be included in the pilot. It is an assessment of our protocol. Since other community based intervention studies showed 40% attrition, we were aiming to have no more than that. We made critical decisions regarding recruitment and retention as described when we reached 47% attrition. We also changed who was responsible for recruitment to avoid the lack of referrals that occurred from some sites and to speed up number of potential participants enrolled (lines 216-219, 262-268). The study team felt comfortable with the adjustments made prior to progression to the RCT.

8) My systematic review has been updated. I suggested citing the updated version: Adegboye Amorim AR, Linne, Y

Thank you so much for this!

Sincerely,

Charmaine Wright MD