Reviewer's report

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

Version: 1 Date: 27 Sep 2017

Reviewer: Christine Olson

Reviewer's report:

Review of MSS#BMWH-D-17-00289R1, Preparing for a Clinical Trial to Test a Postpartum Weight Retention Intervention among Low Income Women: Piloting a Protocol in a Community-Based Organization

The objective of this study is "to pilot a PPWR (postpartum weight retention) intervention in partnership with a community-based organization (CBO) serving low-income families with social support." Postpartum weight retention is an important public and women's health issue and the authors are using an appropriate approach to addressing it. The overall issues with the study and the paper are a very rudimentary conceptual model of the targets for intervention, the intervention components, and how they relate to the primary outcome and secondary outcomes, an initially small sample size with high levels of loss to follow-up, potentially inappropriate statistical analyses, and a general lack of detail on potentially important findings and what they mean for the design of the clinical trial.

Additional Comments to Authors:

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.

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.
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.

4) Lines 71-78 - 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.

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?

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.

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.

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.?

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.
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."

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

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.

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.

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.

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.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
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