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: 13 Oct 2017

Reviewer: Amanda R Amorim Adegboye

Reviewer's report:

COMMENTS:

This is a well-written and interesting paper. Happy to see that the research team is taking the appropriate steps to design a community-based intervention to tackle a relevant public health problem (postpartum weight retention and subsequent overweight/obesity associated with childbearing) and health inequality by targeting low income women. Well done!

I have a number of minor comments, which I believed if addressed would enhance the quality of the manuscript.

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.

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).
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 given, 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.

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.

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?

If the team is planning to conduct a full scale RCT, willingness of participants to be randomised 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?

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 trials 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.

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

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

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.
No

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.
Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.
I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:
Acceptable
Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

none

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal