Title: Healthy Options: Study protocol and baseline characteristics for a cluster randomized controlled trial of group psychotherapy for perinatal women living with HIV and depression in Tanzania

Version: 0 Date: 24 Jul 2019

Reviewer: Deepa Rao

Reviewer's report:

Thank you for the opportunity to review this paper. The paper describes an important study, and with substantive revisions, would make an excellent contribution to the literature. Overall, the paper seems torn between a report of baseline results and a protocol paper. If a report of baseline results, the authors should describe their research questions/hypotheses in the introduction and report on these results. For example, based on literature, one might wonder if self-efficacy is related to HIV stigma in this population of pregnant women. Then, as a baseline results paper, a detailed description of the analyses would be presented in the methods. Further, if this is a report of baseline results, then the words 'design' and 'methods' should be taken out of the title. The paper seems more appropriate as a protocol paper. If the authors settle on this as a protocol paper, some points below are suggested, including more detail on the follow-up procedures (at what point are the women assessed at follow-up?) and data analysis (mixed effects models?) that will be performed for the primary and secondary outcomes.

Title:
If a protocol paper, remove 'baseline results' and change to 'baseline characteristics' in title. The term 'characteristic' is used at the end of the introduction and that term seems more appropriate than 'result.'

Intro:
1. Add background/citation on statement 'lower access to formal education' and risk for depression. Statements that follow are limited to income/employment opportunities.
2. Add background on secondary constructs (e.g. social support, self efficacy, hope, stigma, food insecurity, adherence, etc) to provide justification for their inclusion as measures. Are these variables associated with perinatal depression and HIV comorbidity? Background is good in depressive symptoms and IPV.
4. The phrase 'symptoms comparable with MDD' seems unclear, especially in later use in the paper. Is there a reason why the authors did not simply state 'depressive symptoms'?

Methods
1. There is mention here of an "original list of facilities" from which included facilities were chosen at random. How many facilities were eligible for inclusion on the initial list?
3. The intervention appears to take a stepped care approach, with additional CBT offered after delivery. If this is a protocol paper, a diagram of the participants trajectory through the study would be helpful.
4. Good to add to the data collection section with a description of the consent, screening process, and other data collected at screening. Since this is a protocol paper for the entire study, good to describe in
detail the other procedures for intervention and follow-up surveys.
5. STATA should have a version number and reference.
6. Were the sample size estimations based on previous work? How did you figure 80% of participants screened might enroll, 30% might drop-out, and the effect size?
7. What are the research questions/hypotheses for the larger study? What type of analysis will be conducted on the primary outcome?

Results:
1. If 90.7% of the participants screened met inclusion criteria, what percent were excluded based on not meeting inclusion criteria? A flow diagram of inclusion would be helpful here.

Discussion:
1. At the start of this section, the authors state "The present cluster randomized controlled trial will compare two strategies for the treatment of symptoms…" The methods section outlines a stepped care model, rather than a comparison of PST and CBT. Please clarify.

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?
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

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Please indicate the quality of language in the manuscript:

Needs some language corrections before being published
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