Reviewer’s report

**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:** 04 Jun 2019

**Reviewer:** Janet Turan

**Reviewer's report:**

This manuscript addresses the important topic of depression in perinatal women living with HIV in a sub-Saharan African (SSA) setting. The article describes the protocol and baseline results of a cluster-randomized intervention study testing a lay health worker-delivered intervention versus enhanced standard care. The manuscript is well written and generally clear about the study design and methods. However, there are a few key points that need additional clarification. Specific comments by section are given below.

**Background:**
1. Overall: I am wondering about the focus on depression and specifically major depression, when many perinatal women may have other mental health issues (anxiety, PTSD, etc.), or even less severe depression, which could also impede PMTCT and other health behaviors. The authors should justify their focus on major depression, and/or expand their background information to include other mental health issues.
2. Page 6, lines 112-120: The literature review on the approach of using lay health workers for mental health interventions in LMICs seems limited and does not include several more recent studies on this topic conducted in various settings globally.

**Methods:**
3. Page 8, lines 179-180: It would be good if the authors can justify their use of a cut-off of 9 or above on the PHQ-9 here where it is first mentioned, with relevant references of studies with women in SSA, if available. Many studies in similar populations use a cut-off of &gt; 10.
4. Page 8, lines 180-181: Did each of these low resource health facilities have a psychiatric nurse for referrals in case of suicidality? This seems unlikely. How are these situations handled? Also, are referrals for treatment of depression by medications available to women participating in the study who potentially needed depression medications?
5. Page 9, lines 186-187: It is appreciated that the researchers allowed women who just received their HIV-positive diagnosis a few weeks to come to terms with their diagnosis before eligibility screening. But how many women were identified in this way and what % of these were able to be located 2 weeks later to determine eligibility? If there was considerable loss to follow-up here, this could be a source of bias in the sample.
6. Page 12, line 266: How was the coefficient of variation of 0.05 used in the sample size calculations determined? It seems that the intracluster correlation coefficient (ICC) should have instead been used in these sample size and power calculations for a cluster-randomized trial. It is often best to
calculate for a range of ICCs, since actual values are rarely known. See for example, Odeny et al., 2018.1

Results:
7. Page 13, line 283-285: I am confused to how 91% of HIV+ pregnant women screened would have screened positive for symptoms consistent with major depression. This is an extremely high rate, even among HIV-positive women in SSA. Was there some sort of pre-screening that identified women who were likely to suffer from depression for study eligibility screening? If so, this needs to be described in the manuscript. Other studies in similar populations have found rates considerably less than 50%, depending on the depression measure and cut-off used.
8. Page 13, lines 292-296: Education and marital status are potentially very important factors. How will the researchers account for these imbalances between the randomized study arms? Also, why are marriage rates so low in this sample? It seems unusual for East Africa. Did the questionnaire only consider formal marriages?

Discussion:
9. Page 16: lines 343-344: Here the authors should discuss how this high rate of symptoms compatible with MDD compares with other studies of pregnant women living with HIV in SSA, as well as reasons why their rate is much higher than that seen in other studies in similar contexts.
10. Page 17, lines 364-365: It seems the issue of depression treatment using psychiatric medications needs to come into the discussion somewhere.
11. Page 17, lines 378-380: Some important baseline characteristics (education and marital status) were not balanced in the intervention and control arms. How will the researchers deal with this in the analyses of the trial data?

References:

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.

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

Quality of written English
Please indicate the quality of language in the manuscript:

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