Reviewer’s report

Title: A study protocol for testing the feasibility of a randomized stepped wedge cluster design to investigate a Community Health Intervention through Musical Engagement (CHIME) for perinatal mental health in The Gambia

Version: 0 Date: 22 May 2019

Reviewer: Charlotte Hanlon

Reviewer's report:

Review, May 2019

Testing the feasibility of a randomized stepped wedge design to investigate a community singing-based intervention for perinatal mental health in The Gambia

I found this to be a well-written paper describing an innovative proposal to examine the feasibility of a trial of singing groups to reduce antenatal distress in Gambia. The approach to cultural adaptation of the intervention was explained well and indicates in-depth understanding of, and respect for, the context. The feasibility questions and outcomes have been described well. There were some areas where further clarification would be helpful.

1) The study is described as a feasibility study for a stepped wedge trial. However, I wasn’t clear about the process. It reads as if there is going to be an intervention and control group at the same facility, but I presume that is not going to be the case because of the risk of contamination. I expected that the randomisation would be at the clinic level and would be in terms of which clinics were randomised to get the intervention in step 1 vs step 2. If this is the case, please can you make that clearer. If this is not the case, then I am not sure it is a stepped wedge trial.

2) Related to my first query, assuming it is a stepped wedge design, I understand that all pregnant women will be recruited at the baseline of the study and then will have repeated measures of their mental health, thus allowing the clinics to act as their own controls. If so, how will you manage the fact that the women will be further along in the pregnancy gestation by the time they get the intervention? (if they are in the clinics randomised to the 2nd step).

3) Please can the investigators justify why they selected a stepped wedge design rather than a cluster RCT?

4) The investigators propose to include all pregnant women, but some will not have any depressive symptoms and so it will not be possible to see any improvement. Is the intervention being conceptualised as preventing poorer mental health as well as alleviating current symptoms? If so this should be made explicit and this should be
reflected in relevant design aspects. If the intention is to have a universal intervention that does not require screening of depressive symptoms (which could have benefits in terms of personnel training + acceptability and avoiding stigma) then this rationale should be mentioned.

5) Relatedly, what about women who have severe depressive symptoms? Shouldn't there be an element of stepped care whereby more severely unwell women are identified at the beginning and fast-tracked for psychiatric nurse review (to consider risk management, potential prescription of antidepressants, potential admission, need for more intense follow-up and monitoring)? Is it ethical to keep severely depressed women in the groups without additional care when the evidence base indicates that this type of intervention is most likely to benefit women with mild-moderate depressive symptoms, but not severe?

6) The investigators face a difficult challenge because of the inclusion of women speaking two different languages. Without a validation study, it will not be possible to combine scores from these different groups, given that cut-offs tend to vary when translated into different languages/adapted across cultural groups. Even with a validation study it is going to be difficult. Can this feasibility study be used to investigate and inform how the investigators might need to handle this issue in the main trial?

7) To what extent is there a need for an intervention for distress that may well be transient? Is it worth trying to also measure level of disability which would help to make the case for the health system relevance of the intervention?

8) Can the investigators include an evaluation of the reliability of the application of the fidelity measures?

9) If women are not literate, would there need to be a witness to confirm that the information was explained as per the information sheet?

10) In terms of the concern that women may link adverse events to participation in the intervention, perhaps it would be wise to provide clear information about the nature of the intervention at baseline to try to avoid any misunderstandings. Involving MoH to convince women after the event may back-fire (and the specifics of any SAE/AE needs to be considered in order to decide relatedness or not, so it is not possible to have a global statement on this).

11) Is there any religious connotation to singing in this setting and will this mean that any women are systematically excluded (if they do not endorse that religious faith)? Could this be monitored in the feasibility trial?

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