Author’s response to reviews

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

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Author’s response to reviews:

Thank you for your suggestions and recommendations. We have now addressed both points below. Reviewers’ comments are in italics and all changes in the manuscript have been highlighted.

1) Add "study protocol" to the title.

This has now been added. We have also developed an acronym for the intervention “CHIME” (Community Health Intervention through Musical Engagement) which has been added to the title abstract and study aims.

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
2) Add some benchmark or threshold levels for each feasibility criterion, which in turn would inform the authors/reader if a future study is indeed feasible.

Thank you for this suggestion as we agree this is a helpful addition. We have now added a few sentences with benchmarks in the Analysis section.

“Descriptive statistics will be summarised to understand the demographic variables relating to the recruited population. Descriptive statistics and plots will be used to assess the distribution of the measurement tools, repeated at baseline and follow up and by each arm. We will also examine the distributions of scores in the different language groups to see to what extent item scores and overall distributions differ or are similar. Correlations between our two measurement tools will be calculated. To determine if the intervention is deliverable we will record the number of sessions that the Kanyeleng groups delivered, aiming to deliver two-thirds of the sessions, and the duration of each session, aiming to last between 45-75 minutes. We will also perform a qualitative evaluation, using the video and audio recordings, to determine intervention fidelity at the four sites. Both RAs will watch the video and audio recordings of the 1st and 4th group-singing sessions at each clinic and complete a checklist to determine if all the necessary elements - as outlined in the training workshops - were included in the intervention. Reliability of the fidelity measure will be ascertained by measuring inter-rater consistency. We will also calculate the proportion of clinics approached that consented, aiming to reach over 50% recruitment rate, and recorded any scheduling problems in keeping with the stepped wedge timeline. Recruitment, adherence and completeness of data will be calculated for both groups. We aim to achieve a 60% recruitment rate and no more than 30% attrition in both arms. To determine if the intervention was culturally appropriate and well received by the community and health workers we will collect qualitative data from post-intervention interviews and perform a thematic analysis”