Reviewer's report

Title: A mixed methods feasibility study of the Kusamala Program at a nutritional rehabilitation unit in Malawi

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Reviewer: Natalie Ives

Reviewer's report:

This study is reporting the results from the internal pilot of a cluster randomised controlled trial. To understand this paper better, I had to read the published protocol for the full trial. In order for this to be a standalone paper, this paper would benefit from including more information on the full trial rather than just making reference to the published paper.

The study has three objectives:

1. Determine engagement and adherence rates of participants to the Kusamala Program

2. Obtain data on outcomes to re-estimate the sample size

3. Gain insight into barriers and enables to the implementation of the Kusamala program.

Participants - The authors list some criteria for participants not being enrolled, but I cannot see mention of these in the protocol paper.

This is a cluster trial in that the participants make up clusters within the same hospital, so selection bias could be a real problem, since staff will know what the last cluster were randomised too, so may select participants based on guessing what the next cluster may be allocated too. Since this is cluster trial, need to ensure no selection bias, it is not entirely clear how the participants were selected and allocated to the treatment groups, was this sequential?

Results - Order of results should follow the objectives.

The authors present outcome data with 𝑝-values for the MDAT z-scores, and discuss the results in terms of there being no significant differences. I am not sure is appropriate to present
outcome data for an internal pilot beyond that needed for the sample size re-estimation, but that may be a personal preference.

If presenting outcome data, then this should be at the end of the results, or just in a table, with the summary data presented with no p-values. Any text on the results should just describe the data and no statistical analysis should be undertaken. Statistical analysis is not appropriate.

The sample size re-estimation section should provide information on the calculations for the full trial, so the reader knows how the parameters have changed. From the results, I don't know if the re-estimation means the sample size needs increasing or not. This is later in the discussion, but since this is one of the objectives, this section needs expanding.

The discussion is very long. It could be stream-lined to focus on how the internal pilot has informed the continuation of the full trial, and any changes made. Some of the content of the discussion would be better placed in the results.

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