Author’s response to reviews

Title: The Kusamala Program for primary caregivers of children 6-59 months of age hospitalized with severe acute malnutrition in Malawi: study protocol for a cluster-randomized controlled trial

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1) The protocol is well-written, detailed and describes a relevant and interesting study.

Response: We thank the reviewer for these comments as well as their important detail-oriented feedback provided below.

2) Allocation concealment: It seems from Figure 2 that this is ensured, but should be explicitly accounted for.

Response: Yes, this is an essential consideration for this trial. The allocation concealment has been described as follows:

“A biostatistician (CB) completed the computer-generated random allocation sequence for each study week and put the sequence in sealed envelopes to be opened at the start of each week by a nurse at the NRU. NRU staff (apart from NRU nurses) and those doing screening, recruitment, enrollment, and data collection will be blinded.” – page 15, lines 323 – 328
3) L139: "This design will also prevent an overlap ...." Does this mean that new children will not be enrolled (t-1), while previously enrolled children are being given the intervention? If yes, could this result in spill-over between intervention groups?

Response: This is an important consideration, and we thank you for raising this point. We have therefore added the sentence:

“Recruitment and enrollment will not overlap with the delivery of intervention sessions, although it is possible that children from different groups will be in the NRU at the same time depending on the duration of their inpatient treatment.” – page 6, lines 146 – 148

4) Blinding: It is described that NRU staff including data collectors are blinded to group allocation (p 15), but it is not described who will assess the main outcome using MDAT. Are data assessors different from the 5 nurses trained to deliver intervention? This doesn't seem to be described? It may help to explain where the intervention is taking place, relative to where children are being screened, recruited, enrolled and examined?

Response: Yes, the data assessors will be different from the nurses trained to deliver the intervention. We have added the following:

“Data collection will be done by three different enumerators who have been trained on all relevant assessment tools and questionnaires, including the MDAT.” – page 15, lines 332 – 333

With regards to the description of the intervention location and where children are assessed, we have added these two sentences:

“Each of the four days (t1 – t4) of the Kusamala Program involves 45 minutes of counselling done in the back bay of the NRU, which is separated by a wall from the rest of the ward.” – page 9, lines 198 – 200

“Baseline data collection will be done privately in the NRU, either in the procedures room or in the back bay depending on availability of these locations.” – page 15, lines 335 – 337

5) Figure 1 give the impression that children may be

Response: It seems as though this comment is missing. We think this comment may have been about the number of children not receiving the intervention if they have been allocated to intervention groups, and have therefore removed this from the figure because it would be against the protocol of this study.
6) It is described, that any adverse events will be recorded (p 18), but it is not clear what adverse events could be expected from this low risk intervention?

Response: This is a good point, as we described elsewhere in the paper that this is a low-risk intervention. We have clarified this sentence to be:

“It is expected that there will be no adverse events as a result of this low-risk intervention, yet if any adverse events do occur they will be recorded […]” – page 18, lines 399 – 401

7) Discussion: It is mentioned that the trial will examine the feasibility of implementing the intervention at an nutrition rehabilitation unit (p 19), but it is not clear from methods description how feasibility will be assessed. Assessment of program fidelity is mentioned, but other aspects of feasibility might be relevant?

Response: Thank you for bringing this to our attention. We conducted a separate qualitative study to understand feasibility of the intervention in an NRU setting by interviewing relevant personnel (e.g. nurses), yet in this protocol we have not included a specific measure of feasibility. We therefore have elected to remove this mention of assessing feasibility. The sentence has been modified as follows:

“In addition to ascertaining the effectiveness of the Kusamala Program to improve participant outcomes, this trial will also participant engagement and adherence and delivery of the Kusamala Program.” – page 19, lines 430 – 432

8) It seems very relevant to test impact of a short and easily administered program. However, it might be optimistic to expect effects of a 4-day intervention on child development outcomes at 6 months? It will be interesting to see the findings from this trial!

Response: We agree that this may be optimistic – but with so few interventions applying psychosocial stimulation have been evaluated in this particular population, it is difficult to predict the expected effect on child development. One of the reasons that this type of intervention is not commonly applied is because it may seem unfeasible for implementation, and we hope that a four-day intervention will be feasible for a real NRU setting. We too look forward to seeing the results as well! Thank you so much for your comments.