Author’s response to reviews

Title: Informed consent procedure in a double blind randomized anthelminthic trial on Pemba Island, Tanzania: do pamphlet and information session increase caregivers knowledge?

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Author’s response to reviews:

Palmeirim et al. “Informed consent procedure in a double blind randomized anthelminthic trial on Pemba Island, Tanzania: do pamphlet and information session increase caregivers knowledge?” (manuscript no: METH-D-19-00077)

Point-by-point response

Basel, 14 August 2019

Dear Editorial Board

We refer to your e-mail dated 12 August 2019 and would like to thank you and the external reviewers for going through our manuscript again and providing further comments and suggestions. We have now address all these points, please find the responses below.

Once again, we would be delighted to have our manuscript published by BMC Medical Ethics.

Marta Palmeirim and Jennifer Keiser (on behalf of all authors)
Sarah Wood, J.D., Ph.D., LL.M. (Reviewer 1):
It remains difficult to thoroughly assess the article with the English as is and some of the wording is pejorative at times.
One of our authors (Amanda Ross) is a native English speaker and she has re-read the whole manuscript to make any improvements she found necessary and pertinent.

Additionally, a few other clarifying statements should be added to fully address the issues previously raised by the second reviewer. I have provided some examples below, which are not exhaustive.
• Misuse of apostrophes, e.g., lines 59, 70.
We have corrected the use of apostrophes.
• Missing articles and conjunctions, e.g., lines 74 and 80.
This was corrected
• Line 84: The sentence beginning with "Moreover" needs to be reorganized for clarity.
We have reorganized this sentence. Thank you for pointing it out.
• Line 90: Same as above; as written this is not clear.
We tried to make it clearer.
• Line 105: A sentence on the literacy issue should be included. It was not assessed, which must be disclosed.
This is clearly mentioned as a limitation in our discussion section (lines 306-307).
• It should also be reported how many caregivers used thumbprints instead of signing.
We feel that this is beyond the scope of this article
• Line 134: Information on the questionnaires is not clear. It appears from the attachment they were completed by staff via an interview. If so, state this so the reader is not worried that the literacy issue further confounded the data.
Many thanks for this important observation; we have added a sentence about it.
• Line 140: How were caregivers' ages estimated?
The interviewers just looked at the person and estimated their age since it is not only considered rude to ask but also very often people don’t know their age.
• Line 149: Who were the interviewers? In what language were participants and caregivers interviewed?
Again, thank you for pointing this out – we have added a sentence with this information.
• Line 187: This paragraph needs to be edited. "All reported to drink water from" doesn't make sense when you have different percentages of reported answers.
Thank you for pointing out this mistake - we have now corrected the sentence.
• Line 191: The issue of literacy must again be mentioned and the wording of the paragraph could again be improved.
We have added a sentence to this paragraph to clarify that we did not assess literacy levels. We have also made changes to the paragraph as suggested.
• Line 224-225: The wording comes across as pejorative. Avoid saying they "did not understand it properly."
We have addressed this issue.
• Lines 230-232: Same issue as above.
We do not see what you believe sounds pejorative in this section. We are merely trying to explain why this method is not appropriate in this specific setting and we are certain culture plays an important role;
this does not mean it is better or worse, just different from what we may have expected.

- Line 246: Keep the wording factual - we don't know if the engagement with caregivers was "proper," but we do know information sessions were small and allowed for increased engagement with caregivers. We have adapted this sentence accordingly.
- Line 310: Again, "properly" should be removed and replaced. We have replaced the word “properly” with “truly”.