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, 17 July 2019

Dear Editorial Board

We refer to your e-mail dated 15 July 2019 and would like to thank you and the external reviewers for carefully studying our manuscript and for offering constructive comments and suggestions. In the meantime, we have addressed all the remaining points. To readily assist you in tracking our changes made, we use track-changes (line numbers refer to the manuscript with track-changes).

We would be delighted to have our manuscript published by BMC Medical Ethics.

Marta Palmeirim and Jennifer Keiser (on behalf of all authors)

Editor's comments:

- Besides the suggestions raised my the two reviewers, my main concern is the quality of the English writing. The manuscript should edited by a native speake
We have carefully re-checked all English use in our paper.
Reviewer's comments:

Reviewer #1:
1. The purpose, methods, and results of the study were clear.
   We are very glad to hear that.

2. At times the quality of the English writing compromised the comprehensibility.
   Sorry, we tried to improve the English writing throughout the paper.

3. Table 2 is confusing and should be re-organized, or at least the bolded question "How well did you understand it?" should be moved up so it is apparent that "not at all" is an answer to that question and not the previous one.
   Thank you for this very pertinent suggestion; we have made this change.

4. The limitations and potential confounds of the study were discussed well, which were particularly important to note given the setting in which the study was conducted.
   We thank the reviewer for noting this.

Reviewer #2: This is a well-written and elaborated study about an important research issue concerning many independent research fields.
We thank the reviewer for his encouraging words and the suggested improvements to our manuscript.

However, I would like to address some points that might be adapted or discussed:

1. Was the pamphlet you used only written information?
   The pamphlet included a mixture of text and images. It has been added as supplementary file.

2. Did you assess the literacy of the caregivers or have you only asked if the caregivers have read or understood it, as it appears to the reader?
   That is correct, we only asked if caregivers had read and understood the pamphlet. Unfortunately, we did not assess the literacy of caregivers in this study, which would have been very interesting (we will do so in our next planned study, though). However, we find that these two questions are not necessarily dependent on each other since the fact that one can read the pamphlet does not mean they actually will. We asked them and hoped they provided an honest answer. Still, we agree that it would have been very useful (and could explain why the pamphlet had no significant effect on knowledge in this setting) to know whether they could read or not.

3. You comment on "the still low literacy levels" in the "Discussion" section and could probably also mention this study limitation there.
   Thank you very much for raising this excellent issue. We have added this to the discussion section (line 320-321).

4. It would be great to have the pamphlet as "Supplementary Material" or give a more comprehensive description in the "Information session and pamphlet" section.
   We have added it.

5. It seems to me as if you included all the participants in the "Pamphlet-Group" independent of
whether they have actually read the pamphlet or not. Is this correct? If so, it may be better to exclude those who (admittedly) have not read it or consider this in your regression model, if possible. Otherwise, you are mixing the control group (no information at all) with the "Pamphlet-Group", which creates an overlap that might influence your results. That is a good point and we discussed this issue before performing the analysis. However, we concluded that, in a real life context, many people receiving the pamphlet would not actually read it and we did not want to exclude this “reality” from our results. Excluding them from the analysis could have improved the effect of the pamphlet but in a real life situation that is not what would have happened.

6. In the "Discussion" section, you comment on why the pamphlet may not have been as successful as the information sessions. One further reason may be that the caregivers in the "Pamphlet Group" had no possibility to ask questions. This is an extremely important point we had not thought of – we have now added it to the discussion (line 241-243).

7. Your control group received no information at all. In your "Background" section, you write that many studies "rely on lengthy and complex ICFs alone to transfer all relevant information to participants". Creating such a control group might have been another option by, for example, conducting the interview (questionnaire) after the caregivers signed/declined to sign the ICF. You may, for example, suggest this for further research in the "Discussion" section. You have pointed out something very important; in fact, in this study, parents in the control group received the ICF at home and had the chance to read it, or not. This was not clear throughout the manuscript so we have adapted it for clarity. Many thanks for this comment. Changes were made on lines 96, 114-116 and we have substituted the term “no information” when addressing the “ICF only” group by “control” group – since ICF only is the most common method.