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?

Authors:
Marta Palmeirim (marta.palmeirim@swisstph.ch)
Amanda Ross (amanda.ross@swisstph.ch)
Brigit Obrist (brigit.obrist@swisstph.ch)
Ulfat Mohammed (ulfatamour87@gmail.com)
Shaali Ame (shaaliame@yahoo.com)
Said Ali (saidmali2003@yahoo.com)
Jennifer Keiser (jennifer.keiser@unibas.ch)

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Author’s response to reviews:

Dear Editorial Board

We refer to your e-mail sent to us on 20th of September and would like to thank you and the additional external reviewer for going through our manuscript again and providing further comments and suggestions. We hope that the review process is now finalized. We have addressed all the points raised.

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)

PS The email addresses of the corresponding author are fine

Reviewer 3:
GENERAL COMMENTS:
The overall impression is positive regarding this study. The idea is novel and important and will have impact on the validity of consent form used in clinical trials. The Introduction was clear and informative and objectives were well written. The authors obtained ethical clearance and consent form and aimed to assess the comprehension of participants regarding items in the consent form. I have no points to mention regarding not meeting best practice.
We thank the reviewer for this positive feedback.

REQUESTED REVISIONS:
• The randomization section need to be clarified the following is not clear "The first group of parents (10-15 people) to arrive were immediately interviewed (i.e. were assigned to either the control group or to the pamphlet only group, depending on whether they had been given a pamphlet beforehand or not". The control group were 65? Thank you for pointing this out. As it is, it reads that only 10-15 caregivers in total were included in this group. We have now adapted the sentence to make it clear that the first 10-15 caregivers to arrive to every information session (we held several information sessions) were included in the control group.

• Sample size description need clarification. It was mentioned in the abstract that the sample is 254 however in the methodology section this what was found "the final sample size was 180 participants (90 per arm). In order to reach this sample size, 364 children were consented and screened. Due to time restrictions, all caregivers who provided consent could not be interviewed. A mean of 62 participants per group were included in this study, which allowed to detect a difference of 25% to 45% with 80% power" clarification is needed. Again, many thanks for bringing our attention to this. 180 is the sample size of the clinical trial in which this study was embedded; we have now added this to this section of the manuscript.

• Statistical analysis section need to be revised by a biostatisticians, inferential statistics is needed for table 1. The statistics section has been revised by a biostatistician (Amanda Ross co-author). We have also gone through the tables to check that the relevant statistics are provided. Table 1 is a list of multiple choice questions, and so does not bear any statistics. Table 2 provides information on the proportion of caregivers who receive the pamphlet or information session by group. Here the numbers and proportions are provided but there is no justification for doing hypothesis tests since we know absolutely from the outset that the groups are different. Table 3 contains the results of the questionnaire and inferential statistics are provided here.

• Tests used for table 2 need revision and better interpretation We suspect that this refers to Table 3. We have added a footnote to this table to explain the tests.

• Title of table 2 is too long. We have shortened it.

ADDITIONAL REQUESTS/SUGGESTIONS:
• The Methodology section need to be revised in term of sample and randomization procedures. We believe this has been improved now.

• Statistical analysis section need to be revised. We have now revised this section. See comment above.