Reviewer’s report

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

Version: 2 Date: 09 Sep 2019

Reviewer: Reviewer 2

Reviewer's report:

PEER REVIEWER ASSESSMENTS:

OBJECTIVE - Full research articles: is there a clear objective that addresses a testable research question(s) (brief or other article types: is there a clear objective)?
Yes - there is a clear objective

DESIGN - Is the current approach (including controls and analysis protocols) appropriate for the objective?
No - there are minor issues

EXECUTION - Are the experiments and analyses performed with technical rigor to allow confidence in the results?
No - there are minor issues

STATISTICS - Is the use of statistics in the manuscript appropriate?
No - there are issues with the statistics in the study

INTERPRETATION - Is the current interpretation/discussion of the results reasonable and not overstated?
Yes - the author's interpretation is reasonable

OVERALL MANUSCRIPT POTENTIAL - Is the current version of this work technically sound? If not, can revisions be made to make the work technically sound?
Maybe - with major revisions

PEER REVIEWER COMMENTS:

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.

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 ?
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.
Statistical analysis section need to be revised by a biostatisticians, inferential statistics is needed for
table 1. Tests used for table 2 need revision and better interpretation
Title of table 2 is too long.

ADDITIONAL REQUESTS/SUGGESTIONS:
The Methodology section need to be revised in term of sample and randomization procedures
Statistical analysis section need to be revised.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

No

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional
statistical review?
If an additional statistical review is recommended, please specify what aspects require further
assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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