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: 0 Date: 15 Jul 2019

Reviewer: Julia Stoll

Reviewer's report:

This is a well-written and elaborated study about an important research issue concerning many independent research fields.

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

Was the pamphlet you used only written information? 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? You comment on "the still low literacy levels" in the "Discussion" section and could probably also mention this study limitation there.

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

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.

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.

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.

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

Yes

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

Yes
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:

Acceptable

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