Author’s response to reviews

Title: Reporting Quality of Pilot Clinical Trials in Chronic Kidney Disease Patients on Hemodialysis: A Methodological Survey

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Author’s response to reviews:

RE: PAFS-D-18-00216
Feb 13, 2019

Dear Sameer Parpia,

Thank you for considering our manuscript entitled, “Reporting Quality of Pilot Clinical Trials in Chronic Kidney Disease Patients on Hemodialysis: A Methodological Survey” for publication in Pilot and Feasibility Studies.

We have revised the manuscript as per the reviewer’s suggestions and believe it is greatly improved.

Best Regards,
Reviewer #1 Comment #1: Editor report:

I have one query for the authors to address before this manuscript can be accepted. It relates to the 'unvalidated' item - is the pilot in preparation for a future definitive trial.

Two items in the checklist address this issue - items 2a and 22a. Both items allow an explicit statement of the pilot being in preparation of a future trial.

Page 11 lines 39-47 of the discussion states that this is an unvalidated item:

"With respect to the study characteristics collected, the non-validated item (not a CONSORT item) of whether the manuscript explicitly stated the pilot study to be prelude to definitive study, may not have been reported as this might be assumed by authors given that is the purpose of pilot studies."

I would prefer this text was moved out of limitations to around line 10 of page 11 (to the end of the paragraph about reporting of items) and the two items that address this made more explicit. For example, (or words to this effect):

"With respect to the study characteristics collected, the two items (items 2a and 22a) concerning whether the manuscript states that the pilot study is a prelude to a definitive study, may not have been reported well as it might be assumed by authors as a given that this is the purpose of a pilot study. However this should be explicitely reported for every study as recommended by the guidelines."

Response: We thank the editor for their helpful comments.

We have revised the manuscript as follows:
These items are critical to the development of a larger, definitive trial that is rigorously designed and well-powered, which should be the primary purpose of a pilot study [9]. The low levels of reporting for these items is consistent with our finding that only 17.4% of included studies indicated that they were a prelude to a larger trial, as well as the findings of a previous study on reporting completeness in pilot trials in behavioural interventions (13%) [14]. The manuscripts may not have explicitly stated the pilot study to be prelude to definitive study (CONSORT 2a and 22a) as this as might be assumed by authors given that is the purpose of a pilot study, however, this should be explicitly reported for every study as recommended by the guidelines.