Author’s response to reviews

Title: A cluster randomised controlled trial to assess the impact on intimate partner violence of a 10-session participatory gender training programme delivered to women taking part in a group-based microfinance loan scheme in Tanzania (MAISHA CRT01): study protocol

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Dear Editor

Thank you for reviewing our paper. We have responded to each of the points you raised below.

1. Ethical approval Documentation. Before we can proceed with your submission, can you please forward copies of all ethical approval for our records. These documents should be sent as email attachments to the following email address, BMCSeriesEditorial@biomedcentral.com.
The MAISHA study has been approved by the Tanzanian National Health Research Ethics Committee of the National Institute for Medical Research (Ref: NIMR/HQ/R.8a/Vol. IX/1512), and the ethics committee of the London School of Hygiene & Tropical Medicine (Ref: 11642).

The MAISHA study was originally designed as three-arm cluster randomized controlled trial and approved by the ethics committees in Tanzania and at the London School of Hygiene & Tropical Medicine. Before the start of recruitment, the trial was re-designed and re-submitted for ethical review. The new design comprised two cluster randomized controlled trials to investigate the impact on women’s experience of intimate partner violence of a gender training curriculum combined with a microfinance intervention and of a gender training curriculum delivered to women and their male partners. The revised trial design was approved by the London School of Hygiene & Tropical Medicine on 7 May 2014 and by the Tanzanian ethics committee on 2 April 2014.

The first participant was recruited into MAISHA CRT01 (described in the submitted manuscript) on 29 September 2014 and into MAISHA CRT02 (described in a separated manuscript under development) on 22 September 2015.

The following ethical approval documents have been submitted to the email address above as requested:

- Letter from the London School of Hygiene & Tropical Medicine ethics committee granting a favourable opinion for the original trial design – dated 8 March 2013
- Letter from the London School of Hygiene & Tropical Medicine ethics committee granting a favourable opinion for the revised trial design – dated 7 May 2014
- Letter from the Tanzanian National Health Research Ethics Committee of the National Institute for Medical Research granting a favourable opinion for the original trial design – dated 2 April 2013
2. Study status. The protocol must be for a study that is ongoing. An ‘ongoing’ study is defined as one where the investigators are still collecting, or analyzing data. Can you please confirm what stage your study is currently at?

MAISHA CRT01 is ongoing. Recruitment of participants (1049 women in 66 microfinance loan groups) is complete. Delivery of the intervention to women in the 33 microfinance loan groups allocated to this arm is complete.

Data collection is ongoing – follow-up of participants in both arms, at 29 months post-randomisation, for the trial outcomes will commence in April 2017.

3. Related Articles. Can you please clarify whether any publications containing the results of this study have already been published or submitted to any journal. If so, can you please provide a list of the related articles.
A paper reporting the baseline prevalence of intimate partner violence and abuse and associated factors among women participating in MAISHA CRT01 has been accepted for publication by BMC Public Health. The paper is cited in the submitted protocol manuscript (reference number 17):


4. Please note that all manuscripts must contain all the following sections under the heading 'Declarations'. The Declarations should follow the Conclusions section, and be before the References.

Abbreviations, Ethics approval and consent to participate, Consent for publication, Availability of data and material, Competing interests, Funding, Authors' contributions, Acknowledgements

The Declarations have been added, as requested, following the Conclusions section.

5. Please provide clarification on whether you wish to publish the appendix information along with your manuscript. If so, please upload it as a supplementary file instead and please ensure that supplementary files are cited within the text. Any items which are not cited may be deleted by our production department upon publication.

The participant information sheet and informed consent form has been removed as an appendix of the paper and will be uploaded as a supplementary file.
6. Figures should be provided as separate files, and each figure of a manuscript should be submitted as a single file.

The three figures have been provided in three separate files with each figure as a single file.

7. Please provide figure titles/legends under a separate heading of 'Figure Legends' after the References. If Figure titles/legends are within the main text of the manuscript, please move them.

Figure files should contain only the image/graphic, as well as any associated keys/annotations. If titles/legends are present within the figure files, please remove them.

The figure titles/legends have been provided under a separate heading of “Figure Legends” after the References as requested.

Each figure contains only the image/graphic as well as any associated keys/annotations. Figure titles/legends have been removed from the figure files as requested.

8. Unfortunately BMC does not accept boxes for publication. Please remove Box 1 and include the information in a different format.

Box 1 has been removed. The information is presented in Table1.
Please do not hesitate to contact me if you need further information.

Sheila Harvey