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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Version: 2 Date: 10 Jan 2018

Author’s response to reviews:

Reviewer reports:

Suzannah Creech (Reviewer 1):

1. The authors of this submission are to be commended on undertaking such important and impactful work to improve the lives of women in Tanzania. I hope my comments are helpful as they continue to refine this work.

Thank you for your helpful comments which have facilitated us in improving the manuscript. Please see responses to your comments below.
2. Abstract: lines 31-36, the authors should specify that this work is being undertaken in Tanzania

This is stated in the abstract – fifth line of the Methods section.

3. Abstract: lines 50-58 and continuing onto the next page- the primary and secondary outcomes sound the same to me - physical and sexual IPV in the past 12 months

The primary outcome of the study is a composite of physical and/or sexual IPV – which will allow comparison with other studies, such as the IMAGE study (Pronyck et al, Lancet 2006;368:1973-83).

For the secondary outcomes, we will look at the impact of the intervention on physical and sexual violence separately, as well as emotional/psychological IPV to investigate whether there is variation in the impact of the intervention on the different forms of IPV. In the SASA! Study (Abramsky et al, BMC Medicine 2014;12:122), the intervention had greater impact on women’s experience of physical IPV compared with sexual IPV. Other secondary outcomes being measured are attitudes towards IPV and disclosure of IPV to others.

4. Page 6, lines 16-21, please add detail on the 2030 Agenda for Sustainable Development. E.g. is this a WHO initiative, a UK initiative etc., and please add a citation if possible

We have added in that this is a United Nations initiative which was adopted by countries in 2015 (page 6) – we have cited this and provided the URL for the 2030 Agenda for Sustainable Development in the references (reference 1).
5. Page 6, the authors have a focus on physical and sexual IPV, and rightly so. However, I wondered why they do not increase their focus on psychological IPV? At least in US samples, psychological IPV is known to predict and precede physical and sexual IPV, and several studies have shown that psychological IPV is associated with greater mental health difficulties compared to other types of IPV. Something to consider.

The primary outcome of MAISHA is a composite of physical and/or sexual IPV. However, we are also examining the impact of the MAISHA intervention on emotional/psychological IPV, which is one of the secondary outcomes of the trial.

We have previously published a paper reporting the baseline prevalence of IPV (including emotional abuse and controlling behavior) and associated factors among women recruited into the MAISHA study. We found that all forms of IPV were associated with symptoms of poor mental health (Kapiga et al. BMC Public Health 2017;17:190).

As part of secondary analyses of the MAISHA dataset we intend to explore the impact of the MAISHA intervention on the different forms of IPV and mental health.

6. Page 7, lines 1-7. Can the authors please add greater detail on what a microfinance intervention is, and what a gender and HIV training program is? Please include citations where possible.

The intervention being evaluated in this study is the MAISHA curriculum (a participatory gender training curriculum) delivered to women taking part in a formal group-based microfinance scheme – we have made this clearer in the manuscript. We have provided a brief description of
the group-based microfinance scheme in the section Study setting (page 10). We have also added more detail on the gender training curriculum in the section Intervention (pages 10-12). The curriculum is not yet published as we do not know if it works, so we are unable to cite it. Activities from other curricula have been included in the MAISHA curriculum and these have been cited.

7. Page 7, 43-46, I wondered throughout this manuscript if there was opportunity to refine the research question so that it is more precise - the research question should include the outcome (IPV).

The research question being asked in this study is:

Do women in established formal microfinance loan groups who participate in a participatory gender training curriculum experience lower levels of past year IPV compared with women in established formal microfinance loan groups who do not?

For clarity, this has been added at the end of the introduction (page 8).

8. Page 7, lines 44-58, CRT1 and CRT2 sound the same to me. I do not understand a rationale for why one wouldn't examine the influence of both treatments if they are being conceptualized as treatments in one study. The most rigorous method would examine IPV outcomes across all 4 groups (microfinance + gender training, microfinance + no gender training, no microfinance + gender training, no microfinance + no gender training). I do not think the 4th no treatment comparison group is present however? Perhaps it is the way this presented that is confusing. Something to consider is that the sample for the study is Tanzanian women participating in group microfinance. An alternative way to frame this study may be the following: Among Tanzanian women participating in group microfinance, this study seeks to examine whether a gender curriculum is associated with reductions in IPV in comparison to a no-intervention control group.
I do not believe the microfinance piece is being studied, so I think clarity could be enhanced if that aspect is described as part of the study sample.

We have edited the text to make this clearer (pages 7-8). A social mapping study (unpublished), which was conducted ahead of setting up the MAISHA study, indicated that formal microfinance, usually delivered by non-governmental organizations (NGOs), is widespread across Mwanza city. In addition, women also engage in informal microfinance which involves small loans usually initiated by neighbors (i.e. people who know each other).

The social mapping study also indicated that formal microfinance is not usually delivered to the poorest of the poor and that most women who take formal microfinance loans come from households that are able to meet their basic daily needs and may even have accumulated some assets. It seems that women who do and do not engage in formal microfinance are different populations. We have opted, therefore, to conduct separate cluster RCTs to evaluate the impact on women’s experience of past-year IPV of a participatory gender training curriculum. The first trial (CRT01), described in this paper, will examine the impact of the curriculum amongst women engaged in formal group-based microfinance – by comparing IPV during the past 12 months reported by women in established microfinance loan groups who receive the curriculum with women in established microfinance loan groups who do not receive the curriculum. IPV during the past 12 months will be assessed 24 months following completion of the curriculum.

The second trial (CRT02), described in a separate paper, will examine the impact of the curriculum amongst women who are not engaged in formal group-based microfinance. Women will be recruited in neighborhoods in Mwanza city and invited to form a neighborhood group. The groups will then be randomized to either receive the participatory gender training curriculum or to no further intervention. IPV during the past 12 months reported by women in the groups who receive the curriculum will be compared with women in groups who do not receive the
curriculum. IPV during the past 12 months will be assessed 24 months following completion of the curriculum.

9. Page 8, aim and objectives - the primary and secondary IPV objectives sound the same. There are also added secondary objectives not mentioned before.

The primary objective of the study is to evaluate the impact of the MAISHA curriculum on a composite of physical and/or sexual IPV – which will allow comparison with measures used in other studies, such as the IMAGE study (Pronyck et al, Lancet 2006;368:1973-83).

We also wish to investigate the impact of the MAISHA curriculum on different forms of IPV as this may vary. For example, in the SASA! study, Abramsky et al (BMC Medicine 2014;12:122) found the intervention had greater impact on reducing women’s experience of physical IPV than on reducing sexual IPV. Therefore, the secondary objectives will investigate the impact of the MAISHA curriculum on physical and sexual IPV separately and on emotional/psychological IPV, as well as examining the impact on attitudes to IPV and disclosure of IPV to others.

The following objectives will be addressed through the in-depth qualitative study:

• to learn more about the factors that contribute to women’s vulnerability to violence; and
• to understand how the intervention impacts on the lives of the participants and their families.

10. Page 9, please explain what BRAC is (not sure it was spelled-out previously).

This is explained in the introduction (page 8).
11. Page 10 - Please add detail on the MAISHA curriculum. Who are the facilitators, what are sessions like? What is the content? Are there practice assignments etc… the table is helpful but not sufficient. What is the theoretical framework of the intervention? Why should it improve IPV?

Further detail on the MAISHA curriculum, training of the facilitators etc. have been added in the section Intervention – see pages 10-12.

12. Page 10 - as noted prior - I am not sure it makes sense to conceptualize the microfinance component as part of the intervention. Related to this, I am not sure the authors made a case in the introduction for why this population was selected (women in microfinance groups). This raises concerns regarding how representative the sample is of Tanzanian women.

We have made it clearer in the introduction and in the methods that in this study we are evaluating the impact of a participatory gender training curriculum delivered to women engaged in formal group-based microfinance. The intervention being tested, therefore, is the curriculum – comparing established microfinance loan groups who do and do not receive the MAISHA curriculum.

MAISHA was inspired by the IMAGE study, conducted in South Africa, which evaluated a combined group-based microfinance intervention with a gender training curriculum. Ahead of replicating IMAGE in Tanzania, a social mapping study was conducted. It is clear from this work, there is widespread engagement with microfinance in Mwanza – on both an informal level (with neighbors) and a formal level with development NGOs, such as BRAC. It seems that NGOs do not usually deliver microfinance to the poorest of the poor. Given these different populations of women in Tanzania, we have opted to conduct two cluster RCTs to evaluate the
impact of a participatory gender training curriculum – the first with women in established formal microfinance loan groups and the second with women who are not engaged with formal group-based microfinance.

Data collected at baseline for the two trials (CRT01 and CRT02) have indicated that women taking part in CRT02 are less educated and poorer (lower monthly income) than women taking part in CRT01.

13. Page 11 - outcomes: again, primary and secondary are the same.

See response to comment 3 above.

14. Page 13, lines 17-34. Greater specificity is needed with regard to the measurement of IPV. Sample items and scoring are needed to understand how IPV will be measured (frequency of IPV? Incidents of IPV, yes/no etc). Are all women in the study in relationships? This will need to be factored in as well.

We have added more detail on how IPV will be measured and included a table (Table 2) to show the items being measured.

The average age of women taking part in MAISHA is 39 years. Not all women in the study are currently in a relationship, however, all women have been in a relationship in the past.

15. Pages 14-15. The inclusion of interviews, focus groups and photo voice raise great concern for me - these are all added intervention (see literature on the Hawthorne effect) and in a RCT may contaminate outcomes. The investigators will need to co-vary this out and/or remove these
participants from analyses of primary outcomes given that their participation is so different. Participant burden is a concern here as well.

MAISHA includes a qualitative study and process evaluation to learn more about the factors that increase women’s vulnerability to violence and to understand how the MAISHA curriculum impacts, or not, on the lives of women and their families. This is standard practice in trials, particularly of social interventions. A total of 18 women have been purposively selected from the 1049 women enrolled into MAISHA and invited to take part in in-depth interviews. In addition, 90 women have been invited to take part in focus group discussions. As the 108 (10.3%) women are from both the intervention and control arms, we are confident that this will not bias the findings. We agree that participant burden is a concern and women are informed that they can withdraw from this component of the trial at any time and that this will not affect their participation in the trial. We have found that women are generally very positive about taking part in the in-depth interviews and focus group discussions and welcome the opportunity to discuss their relationships and experiences.

16. Page 15 - participatory observation - again, this is added intervention. If the authors wish to do this as well as the interview etc. mentioned above - the study is best described as a treatment development study and not an RCT. If the authors truly do not know the information that is to be gained from interviews, photo voice and observation, one might argue there is not enough evidence to support randomizing women to MAISHA, vs. no MAISHA.

Participatory observation is being conducted by the social scientists, as part of the process evaluation, to determine whether the MAISHA curriculum is being delivered as intended and to inform potential refinements to the curriculum. Participatory observation is being conducted in the intervention arm – observing both the microfinance meetings and delivery of the MAISHA curriculum – and in the control arm – observing the microfinance meetings.
17. Page 17, line 1, one would expect a detailed statistical analysis plan to be prepared now. Greater specificity would be useful throughout this section.

We have drafted a detailed analysis plan. We will seek advice from the editor as to whether we should include the full plan as an appendix to the paper.

18. Page 22, lines 13-31 - now CR2 is described differently than it was on page 7. Can the authors please attend to this and revise?

Thank you for noting this - it has been revised.

A few remaining concerns to consider:

1. What if all women in a microfinance loan group do not want to participate?

For a microfinance loan group to be eligible for MAISHA, a minimum of 70% of the group must consent to take part in the study (page 10). For each group enrolled, only women in the group who consent to take part, will participate in the MAISHA curriculum (if allocated to that arm) and undergo other study procedures, such as the baseline and follow-up interviews. For clarity, this has been added at the end of the section Eligibility criteria (page 10). All women in the group will continue with their microfinance activities as usual – the MAISHA study team has no involvement or input into the microfinance loan scheme.

2. How might length of participation in microfinance influence findings?
We are working with established microfinance groups, although members of the group will vary in the length of time they have participated in the group. During the baseline and follow-up interviews, we ask women about the length of participation, so this is something we will be able to look at as part of secondary analyses of the dataset.

3. Throughout the study the authors seems to implicitly subscribe to the view that women are victims of IPV and men are perpetrators. Therefore, this intervention and the way it is presented suggests that the responsibility for stopping IPV rests with the victims. The authors probably do not really believe this - however, this will have to be dealt with more thoroughly in the manuscript.

There is considerable evidence from studies indicating that globally, around one third of women who have been in a relationship has experienced violence from a male partner. In Tanzania, 60% of the women enrolled in the MAISHA study reported, at baseline, that they had experienced physical and/or sexual violence from a male partner. Furthermore, 27% reported that they had experienced physical and/or sexual violence in the previous 12 months.

The aim of MAISHA is to empower women by increasing their capacity to defend themselves against IPV and the negative consequences of IPV. However, the MAISHA intervention does not focus explicitly on women experiencing violence; we expect the intervention may have benefits for both women who are in violent relationships (by stopping future violence) and women who have not experienced violence in their relationships (by reducing their risk of violence in the future).

Whilst, we do not believe that responsibility for stopping IPV rests solely with women, studies such as the IMAGE study have shown that interventions that focus on women do, nevertheless, have an impact. Given that it can be more difficult to achieve ongoing access to groups of men,
interventions targeted at women may continue to be an important part of the response to the global IPV epidemic.

Elizabeth Miller (Reviewer 2):

Thank you for the opportunity to review this protocol paper. This is a highly significant study with potential for major impact on the challenging problem of violence against women.

The authors have already provided revisions requested by the editor.

A few additional clarifying questions:

Thank you for your helpful comments which have facilitated us in improving the manuscript. Please see responses to your questions below.

1. What does 'registered retrospectively in August 2015' mean? Appears the first participant was enrolled into this protocol almost a year before registering in clinical trials? Could this delay be explained perhaps in a footnote or endnote?

Clinical trials.gov requires this statement if the trial was registered after the start of enrolment. All necessary approvals, including research ethics committee approvals were in place before the study started. Unfortunately, due to an oversight, the trial registration was not completed before the start of enrolment of participants.
2. The randomization scheme is not clear (pg 14 of the pdf). Is this randomization at the cluster level? What was the unit of randomization and why? Assuming that women interact with each other in the microfinance groups thus one group should be a cluster?

Randomization is done at the cluster level with each microfinance loan group being a cluster. Once six groups have been recruited and completed the informed consent procedures and the baseline interview, randomization occurs. This is a participatory process involving the study team with representatives from each of the six groups to be randomized. Of the six groups, three are allocated to the intervention and three to the control arm by tossing a coin. This process of randomization is repeated until 66 groups are recruited.

3. Please define ‘good attendance’ in the selection of the sites

For each of the microfinance loan groups, good attendance at loan group meetings is ascertained through discussion with the BRAC loan officer and is based on at least 70% of women attending the weekly meetings.

4. Were all 220 groups invited to participate? If not, how were sites selected?

Microfinance loan groups were selected at random to be approached and assessed for eligibility for MAISHA. This was done in consultation with the BRAC loan officers. Of the 220 established microfinance loan groups, 101 were approached, given information about the study and assessed for eligibility. Of these, 35 groups did not meet eligibility criteria. The remaining 66 groups (target sample) were successfully recruited into the study.
5. How is the photovoice being used for this study?

The photo voice method is being used to capture women’s thoughts on, and observations of, healthy relationships through discussion of visual images they have captured themselves in their communities.

6. More description of measures is needed. A measures table would be helpful

More detail has been added to the section Outcomes (pages 12-13) and a table (Table 2) added with details of the measures of IPV being used in the MAISHA study.

7. Please describe strategies used to reduce bias (participation bias of sites as well as social desirability), plans for calculating attrition, and handling of missing data.

Of the 101 microfinance loan groups approached and assessed for eligibility, 66 groups have been enrolled into MAISHA. Efforts were made to ensure that there was good attendance by members at weekly loan group meetings – as groups allocated to the intervention arm would be required to attend the 10 MAISHA curriculum sessions, held either before or after the loan group meeting on alternate weeks. We do not have resources to collect data on the characteristics of non-participating microfinance loan groups, which would allow comparisons between participating and non-participating microfinance loan groups. However, we have ensured that the eligibility criteria are not restrictive. We believe, therefore, the 66 groups enrolled into MAISHA to be fairly representative of formal microfinance loan groups in Mwanza.
As regards attrition, this will be calculated as the number of women who complete the follow-up interview divided by the total number of women who consented to take part in the study (n=1049) and will be expressed as a percentage.

Multiple imputation will be used to simulate missing outcome data at 24 months post-intervention. The imputation model will be informed by empirical patterns in the IPV data at baseline and follow-up.

8. Greater discussion of potential limitations of the study is warranted (the intervention arm gets significantly more group time, more time for interaction, which is likely to increase connectedness and reduce isolation. The limitations of not having an 'attention control' should be discussed.

All women enrolled into the study are members of an established microfinance loan group. The groups in the control arm will continue to meet weekly following BRAC procedures for repaying loans. Groups in the intervention arm will also meet weekly for loan group activities but, in addition, have a longer meeting on alternate weeks over a 20-week period in order to complete the MAISHA curriculum. As a result, they will get more group time and more time for interaction, which is an integral part of the MAISHA intervention – i.e. that women will be provided with the space to learn about and discuss gender and relationship issues and develop new skills to help defend themselves against IPV.

9. There is a need for copyediting throughout due to grammatical and spelling errors: e.g., complementary (misspelling in abstract - not complimentary)

Thank you – corrections have been made.