Reviewer's report

Title: Findings from the SASA! Study: a cluster randomised controlled trial to assess the impact of a community mobilisation intervention to prevent violence against women and reduce HIV risk in Kampala, Uganda

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Reviewer: Angela Taft

Reviewer's report:

There are very few well-designed studies of interventions to reduce the impact of IPV on HIV infections taking into account their socio-economic determinants, particularly the difficult area of gender inequality. This team of authors represent some of the leaders in the field and this study will make an important contribution to the further development of research and community-based prevention strategies to tackle the intersection of these two serious problems. Pragmatic cluster trials are very complex interventions and have a very high degree of difficulty. They are especially difficult in an unstable nation state and the five years which this study reports illustrates the difficulty well. It is therefore very important that readers have as clear a picture as possible of the conduct of the study, should others wish to adapt or replicate the design, process and analysis. Whilst there are sure to be other papers from this study, the primary outcomes paper should give as clear and full an account as possible. Protocol publication and trial registration were important steps in this process.

This is an ambitious, important and challenging study. The greatest difficulty our statistician (who has analysed several published cluster randomised community-based trials) and I had, was to understand the rationale for and methods of analysis you have used.

Minor essential revisions important to fully understanding the study

Methods:
L240 – You say you used an ‘unpaired analysis’ to maximise power – understandable and ITT. What follows is difficult to understand as you then say the log of each site prevalence went into an ANOVA model including terms for ‘site-pair’ etc. Can you explain more clearly why you have done this?

The next paragraph is also quite opaque and it would be helpful if you could be clearer. Why did you not use regression analysis and adjust for cluster? How have you used the baseline data?

Results:
As this is a cluster RCT, you should report descriptions of the characteristics of clusters and CAs rather than, or as well as, the individual respondents – whether religion, SES etc. varied by cluster and no of CAs and their sex per cluster. It
would also be helpful to know about intervention exposure per community/cluster.

L321-6: You report low levels of variation between clusters – this is not reported in Table 1 and would be a useful resource for others. We find it very useful to have ICCs reported in order to calculate sample sizes in similar studies.

Discussion

L 402 You say that the repeat X-S design allows you to control for baseline imbalances – please describe how this was done and describe these differences in the methods section

L 430 you note Intra-Cluster variation for physical IPV – please describe this in the results section when describing the cluster effects.

There is a strange anomaly in Table 2, where male acceptability of physical VAW in the control groups grew from 24% at baseline to 86%. Similarly female acceptability that a woman can refuse sex went from 36% to 73%. Please comment on this in your discussion.

General comments and discretionary revision

Your abstract is succinct and the introduction and rationale are well described. The methods which are sound, especially the survey training and implementation suitable to such a sensitive topic, are well described and echo your protocol well. You pre-specified your desired outcomes and as far as possible sought to minimise bias where possible in a pragmatic trial. Your sample size and rationale is also well described.

Methods

Study population

L. 94/5. For those not well versed in HIV, can you give other African comparisons when you state that Uganda has a high prevalence of HIV/AIDS – what is it and compared with what? The 6% prevalence among A-N clinics does not sound high, especially considered alongside the IPV prevalence among ever-married women from the DHS. Why not give the HIV prevalence among married women or just among women?

Evaluation design

Please give a brief description of the randomisation method and who conducted it.

SASA! Is an inspiring and challenging study and congratulations for the enormous effort that went to implementing it and achieving important effects.

Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the
statistics.

**Declaration of competing interests:**

'I declare that I have no competing interests’