Author’s response to reviews

Title: A protocol for a cluster-randomized controlled trial testing an empowerment intervention to prevent sexual assault in upper primary school adolescents in the informal settlements of Nairobi, Kenya

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Author’s response to reviews:

Dear Editor:

Please see responses to reviewer comments elow. Thank you for the opportunity to revise and resubmit.

Technical Comments:

=Missing=

1. Email addresses of all co-authors in the title page Addressed

2. Author cited Figure 1 but not included in the manuscript - Addressed
BMC Public Health operates a policy of open peer review, which means that you will be able to see the names of the reviewers who provided the reports via the online peer review system. We encourage you to also view the reports there, via the action links on the left-hand side of the page, to see the names of the reviewers.

Reviewer reports:

Daniel Tancredi, PhD (Reviewer 1): Peer Review of PUBH-D-18-02455 "A protocol for a cluster-randomized controlled trial testing an engagement intervention to prevent sexual assault in upper primary school adolescents in the informal settlements of Nairobi, Kenya"

Summary: This is a clearly written description of a generally sound protocol for a sexual assault prevention intervention trial that aims to fill an important evidence gap in the literature, the need to develop and evaluate interventions for adolescents in urban settlements in low and middle-income countries. This reviewer has a small number of concerns for the authors to address.

Moderate concerns:

1. Page 8, lines 13-14. The authors report that schools that refuse to participate at baseline will be replaced with a different school, but then a couple of paragraphs later, in the "Randomization" section, they describe that randomization has already been performed. To preserve the statistical equivalence of the intervention and control schools, one would want to avoid randomizing schools until after ensuring that they would participate. Was that done? If so, then a simple revision would be needed, which would be to change the tense of the sentence in lines 13-14 to say that schools that refused to participate were excluded prior to randomization.

The verb tense has been modified as suggested. The reviewer is correct that (ideally) a commitment from a school would mean that they would participate. But there are a number of challenges for these schools. For example, at one point the Kenyan government (in a surprise move) came in to one of the slums and bulldozed nearly a quarter of the slum – demolishing a number of schools. You can imagine that this kind of environment leads to challenges in holding schools to their promise to participate in a study. A flexible randomization strategy is required. The resulting procedure is not ideal, but it’s internally valid.

If schools can drop out after they have been randomized, then the authors will need to present an approach for dealing with that, including a sound rationale. This is particularly important given that matched pair design that the authors used. I recommend that the authors look closely at their reference #27, the 2009 Statistical Science paper by Imai et al, where the issue of drop-out clusters is extensively discussed, because the potential drop-out of a single cluster from a matched pair is something that can complicate the analysis. Replacing drop-out schools with
other schools may not be desirable in regards to preserving the internal validity of the randomized design. In any case, a rationale presented (and perhaps sensitivity analyses should be proposed) for dealing with drop-out schools.

Thank you for suggesting we clarify this issue. We more carefully discuss these issues in the “Dropout” section on pages 14-15. It turns out only one school ended up dropping out post-intervention. School-level dropout (post-intervention) was not a major concern in this study.

2. Page 13, line 38. The authors should specify the regression framework that would be used for the instrumental variables analysis, picking one of the three options in Reference 36. I would guess that the authors intend to use the structural nested models framework, for example, but there are two other frameworks that could be used.

Regrettably, trainee-attendance records were not well maintained, so an IV analysis was not feasible. We’ve updated out language to say: “An instrumental variable (IV) analysis was also proposed as a secondary analysis to estimate the effectiveness of the intervention [citation], but was not tenable because trainee-attendance records were not well-maintained.”

3. Page 14, line 48. The units of analysis in this study are participant surveys, but for any given outcome, it would appear that only male or only female participants will be involved, so the authors may wish to add this detail.

Language updated accordingly. Thank you.

4. Page 13, line 55. Although a "difference-in-difference" estimand could potentially be estimated from a model that used a logistic-link function, using predictive margins for example, that would not be the natural thing to do. I suspect that the authors may have intended to say they would do, say, a between-group ratio of post:pre odds-ratios analysis. That's what would result from exponentiating the "time*arm" logistic regression coefficient to express it as a odds-ratio. Alternatively, the authors could retain the "difference-in-differences" phrasing, but it would need to be applied to the "log odds" of sexual assault, not the "rates", as described later in that sentence.

The language has been updated to read: “We estimated the effect of the intervention on the rate of sexual assault on the participant level using generalized linear mixed models (GLMM), with each participant’s survey being a unique observation in the model. Note that the analyses were stratified by sex – models were separately run for girls and for boys. The outcome of interest was
binary and thus will be modeled using a logistic-link function. Missing covariate values were addressed using multiple imputation models.

The estimand of interest was a repeated measures quantity, the change of rates of sexual assault between the prior twelve-month period at baseline as compared to the twelve-month period between the first follow-up period and the final follow-up period on the participant level. In our GLMM, repeated measure effects were added to the model for individual girl, school, and matched set. Fixed effects were added for period (i.e., baseline, first follow-up and end of study), intervention level, and an interaction for period and intervention level. The coefficient for the interaction term between period and intervention level was our estimate of interest. The GLMM was chosen in order to facilitate comparisons with other interventions in the What Works to Prevention Violence Against Women and Girls consortium. A GEE model of the main outcome was performed as a sensitivity analysis."

You will note that (i) we clarified the issue the reviewer raised about the term of interest in the model, and IMPORTANTLY (ii) we added the language: “The GLMM was chosen in order to facilitate comparisons with other interventions in the What Works to Prevention Violence Against Women and Girls consortium. A GEE model of the main outcome was performed as a sensitivity analysis.” As part of the WW consortium, we shifted our main reported model from a GEE to a GLMM. We also report the results of the GEE, which produces no material differences in its conclusions.

5. Page 14, line 45-46. The authors say that only complete-cases will be available for analysis because participants who exit the study will be lost, but that is questionable. Wouldn't they still have provided the baseline survey, which could potentially be analysed? Please revise this sentence to make it clear what the rationale is for dropping data from drop-outs. Also, please clarify whether unique identifiers for individuals are available for this study. I presume they are, but it's not clear.

We removed the “complete-case” language and added a section that particularly discusses “Dropout.” See page 14. We added the language: “To deal with observational units that dropout at the endline data collection period the analysis will use baseline covariates to construct an inverse probability-of-missing weighting to address units that dropped out at the endline.”

Yes, unique identifiers are available, we have added a sentence to make that clear.
Minor issues:

6. Page 6, line 28: Should "adolescents and urban settlements" be changed to "adolescents in urban settlements"? It seems from the nicely presented literature review that the gap is with respect to adolescents in urban settlements.

Change made.

7. Page 9, line 27. The 40% decrease appears to be for the "odds", not the "odds-ratio". In other words, it appears the authors are talking about an odds-ratio of 0.60, which corresponds to the odds being reduced by 40%.

Thank you for pointing to that error. We have updated accordingly.

Suggested edits for style:

Page 8, line 28: Change "which" to "that".

Change made.

Page 9, line 2: Change "among large schools" to "in large schools," (note addition of comma).

Change made.

Page 11, line 1: Change "a ratio of approximately 1:15 students" to "a trainer:student ratio of 15".

Change made.

Reviewer 2 (Reviewer 2): PEER REVIEWER ASSESSMENTS:

OBJECTIVE - Full research articles: is there a clear objective that addresses a testable research question(s) (brief or other article types: is there a clear objective)?

Yes - there is a clear objective

DESIGN - Is the current approach (including controls and analysis protocols) appropriate for the objective?

No - there are minor issues
EXECUTION - Are the experiments and analyses performed with technical rigor to allow confidence in the results?

N/A - no experiments or analyses

Statistics - Is the use of statistics in the manuscript appropriate?

Yes - appropriate statistical analyses have been used in the study

INTERPRETATION - Is the current interpretation/discussion of the results reasonable and not overstated?

Yes - the author's interpretation is reasonable

OVERALL MANUSCRIPT POTENTIAL - Is the current version of this work technically sound? If not, can revisions be made to make the work technically sound?

Yes - current version is technically sound

PEER REVIEWER COMMENTS:

GENERAL COMMENTS: This is a well-written and excellently designed protocol on sexual assault among young Kenyan learners. The authors lay out their argument and methodology clearly.

REQUESTED REVISIONS:

I have only minor comments for consideration, though I believe the protocol would be publishable in its current form.

Intro

1. I wondered about adding citations to page 4, line 47 and then later saw a strong paragraph in Discussion about informal settlements. Could this paragraph be better upfront to make the case for the novelty and importance of this work?
We have added a sentence and reference to this paragraph as follows: “Informal settlements are an important setting to study, as they are growing quickly worldwide, and have high rates of violence, infectious disease, and other threats to human health and well-being [15].”

2. Page 5, line 1, should say "settlements are similar to the setting where we plan to conduct this trial." Change made.

3. I think the paragraph on page 5, lines 18-40 could actually be dropped. None of these trials are among adolescents. Would it be more valuable to rather highlight the literature from other settings (primarily UK and US) where school-based interventions worked with young learners around sexual assault?

We left this paragraph in as we believe it is important to highlight other work in sub-Saharan Africa, and also, per the reviewers suggestion, added the following: “Amongst the age group that is the focus on this study, adolescents 10-14, there have been some promising studies in high-income countries, although most have had short follow-up periods and/or only query changes in skills, not actual assault. Examples include an empowerment self-defense based intervention in New Zealand [20] and a skills and knowledge program in California [21].”

4. On page 6, it would be good to highlight limitations of prior versions of the boys' intervention, to make the case for why "significantly revised boys' intervention" was needed. We added a sentence on page 10/11 to the “boys intervention” section to discuss the rationale for revision further.

5. Depending on journal, you might blind the first study design paragraph. Good point, but seeing how this has already gone through (non-blind) peer-review, it does not seem necessary to make this change at this time.

6. The process evaluation plans seem somewhat small to add value to the overall trial. Could consider enriching these with participant observation, in-depth interviews with facilitators, etc.

Agreed, this was funded to only be an impact evaluation with limited to no process measures. This is definitely a limitation.

7. Please check consistency with regards to total schools count - is it 90 or 100? Rationale in sample size seems to point to 90. It was actually 100…we added the phrase “a minimum of 45 schools per arm” to the sample size description.

8. Could selection bias of schools be a potential limitation? Yes, definitely, we added a sentence to limitations as follows: “Furthermore, since school could opt-into the study, there may be bias in the types of schools that chose to participate.”
9. Kindly check tense throughout - sometimes present tense is used and sometimes past. This will depend on the journal. Thanks for catching that, it’s all in past tense now.

10. On page 9, line 52, what are the authors planning to test with the boys sample. And is such a small n per school going to get at that, at least in a preliminary way? We added the clause “in order to better understand their experiences of violence in this setting”. Agreed that we have minimal potential to test anything in this small sample of boys; the study was primary funded to look at girls, and is therefore powered on their outcomes.

11. How long was the training of trainers? Added the following sentence: “The training and field exercises combined took approximately one year to complete before trainers were allowed to teach classes as the main trainer.”

12. Hard to remember the primary outcome, so please remind readers on page 13, line 35 and perhaps line 49. Added at line 35 for clarity.

13. Is the paragraph on page 14, lines 11-35 needed? No, the reviewer is correct, this is a set of secondary hypotheses for secondary outcomes and is not needed. We have deleted it.

14. How will Kenyan co-investigators be involved in the data analysis of qualitative data? Seems important given the specific contextual considerations of informal settlements to involve local staff in this. Yes, definitely, the Kenyan PI actually has a PhD in Anthropology. Sentence added as follows: “Weekly calls with Kenyan investigators will include discussion of the interpretation of the data based on their unique knowledge about this setting and population.”

Note: This reviewer report can be downloaded - see attached pdf file.

Thank you,

The authors