Author's response to reviews

Title: Evaluating a health care provider delivered intervention to reduce intimate partner violence and mitigate associated health risks: a randomized controlled trial in Mexico City

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Author's response to reviews: see over
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Dear BMC Public Health Editors:

On behalf of the authorship team, we are pleased to submit the requested revisions for the study protocol manuscript, “Evaluating a health care provider delivered intervention to reduce intimate partner violence and mitigate associated health risks: study protocol a randomized controlled trial in Mexico City”. We believe this study represents an important contribution to identifying potentially effective comprehensive health care response interventions in a middle income country. Since the time of initial submission, our study has completed the baseline, three month follow-up assessment, and we are currently in preparations for the fifteen month follow-up (endline) survey.

All requested revisions have been made in track changes and are detailed in a point by point response in the following pages.

We look forward to your feedback.

Respectfully,

Kathryn Falb
Claudia Diaz-Olavarrieta
Jimena Valades
Roosebelinda Cardenas
Giselle Carino
Paola Campos
Jhumka Gupta
Reviewer #1

The authors thank Reviewer #1 for their helpful comments.

I think the title is a bit misleading. The fact that the paper is a description of the study design should be indicated.

We have updated the title to now read, “Evaluating a health care provider delivered intervention to reduce intimate partner violence and mitigate associated health risks: study protocol for a randomized controlled trial in Mexico City”

Background:

The authors say that the nurses were given a self-efficacy test and 45% of nurses disagreed with the statement that they did not feel prepared. In English, there is very little use of double negatives. My interpretation of this is that 45% of nurses were prepared. Perhaps it should be changed to say only 45% of nurses were prepared… the quoting of the actual statement is unnecessary.

The reviewers interpretation is correct and we have revised the sentence for clarity. It now reads, “Furthermore, nurses were given a self-efficacy test and knowledge test related to IPV as part of piloting the intervention and results showed that only 45% of nurses (n=187) were prepared to make appropriate referrals for women experiencing IPV.”

Study Setting:

What is the difference between Type I and II clinics?

The main difference between Type I and II clinics is that Type II is slightly larger than Type I and may employ additional doctors or nurses. Neither are as large as Type III nor offer as many services. We have added additional information about this in the study setting section.

Saying “I and II” is better than “II and I”.

This has been changed in accordance with the reviewer’s suggestion.

There is a sentence (2nd paragraph) that begins …These clinics, chiefly located in low and middle income areas… It isn’t clear if the authors in using the word “These” are referring to Type III clinics or Type I and II clinics.

The authors are referring to Type III. We have revised the sentence to read, “These Type III clinics, chiefly located in low and middle income neighborhoods, serve primarily a low income population, and are thus eligible for the Seguro Popular.”

The last sentence in the paragraph referred to above, says “Approximately, 2,336,564 residents use the services…” Usually if there is a number that precise, you don’t see the word approximately with it. Perhaps try saying that “More than 2,336,000 residents use the services… annually.

Thank you for pointing this out. We have updated the sentence with these suggestions.
Randomization, Sample Size and Power Analysis:

The authors need to explain how that got from 57 to 42 clinics. Why didn’t they randomize all 57? This paragraph could and should be re-written for clarity. Why is the sample size 900? Is that what they need to have 80% power? It doesn’t say that. What metric are the authors using to estimate change?

The authors have re-written this paragraph for clarity and have added additional information. It now reads: “Approximately 900 women from 42 health clinics were calculated to be sufficient sample size in order to achieve 80% power to detect a 15% difference in IPV frequency between treatment versus control arms at the $\alpha<0.05$ statistical significance level. A conservative intraclass correlation of 0.07 was assumed for clustering at the clinic level. This total sample size takes into account an attrition rate of 45%. The study proposal has budgeted for tracking participants that are relatively more difficult to track in order to reduce attrition.

Health clinics were first stratified by city zone (e.g. Center, North, East, West, South). Of the 57 health clinics that met inclusion criteria, 42 were randomly selected and randomized to treatment or control conditions, based on sample size calculations. To select the 42 health centers, all centers were assigned random numbers in Excel and sorted from smallest to largest; health centers were selected based on city zone and in order of their random number. Randomization was completed in STATA.”

Study Population, Recruitment and Retention

Information in Table 1 should be incorporated into the text and the table eliminated.

The information has been incorporated into this section and the table was deleted.

When I read that the study is using the abuse assessment screen, I thought they meant “The Abuse Assessment Screen.” http://www.dbhds.virginia.gov/documents/scrn-pw-aas-eng.pdf. But apparently they don’t since the AAS has only 5 questions and they are talking about 11 questions. So then, I don’t know what instrument they are talking about. They say it is validated. For what group of individuals? The screening instrument should be included in the manuscript.

We agree the screening instrument should be included in the manuscript and is Figure 1. The abuse assessment we refer to is a set of standard questions used by IPPF in Latin American countries. We have included this in the manuscript and have added citations.

The authors refer to “Box 1.” I presume they mean figure 1. This should be clarified.

We have updated Box 1 to say Figure 1.

Do they ask the women if it is okay to phone them? I worry about anything that may trigger the partner to violence.

The authors agree safety is a concern when phoning participants and all research assistants were trained on how to respond to different scenarios to ensure participant
safety. We have added the following sentence, “All participants agreed that it was okay to call them and research assistants were trained to ask if it was a safe time to talk and did not mention violence or the study if another person answered the phone.” This was also mentioned in consent forms as well.

Intervention description:

I liked the point that women were more likely to be comfortable asking for services if there is a specific name.

Thank you for this comment. We found this to be an important finding from our pilot work.

The reasoning behind training only nurses who work the morning shift is unclear. It may be obvious if you know the system, but it isn’t to this reviewer.

We have added the following clarification to the description of nurse selection: “Nurses from all 42 health clinics were invited to participate in the training based on the following criteria: morning shift nurses (due to the walk-in basis of appointments and afternoon shifts not occurring at all clinics) and not a field nurse (due to their limited time at the health clinics).”

Quantitative Assessments & Analytic Pan:

Information in Table 3 should be incorporated into the text and the table eliminated.

We have eliminated the table and have included this opening sentence in the quantitative assessment section, “Our primary outcome is past-year IPV and our secondary outcomes include past-year reproductive coercion, use of community-based resources, safety planning measures, and quality of life.”

Quantitative Assessments & Analytic Pan:

This paragraph needs to be re-written for more depth.

We have added additional information in the qualitative assessment section.

Process Evaluation:
If they are testing nurses every three months, are they considering test-retest bias?

We have added the test-retest bias as a limitation to this process evaluation in the manuscript.

Are the mock clients anonymous? I presume so, but if yes, it should be stated explicitly.

Yes, mock clients are anonymous and we have clarified this in the description.

Cost Analysis:
In doing the cost analysis, is the cost to the system for taking care of abused women considered? Is the cost to the women for pain, suffering, humiliation considered in this?

The authors wholly agree that costs of taking care of abused women, as well as their own pain, suffering, and humiliation are important considerations in costing analyses. Unfortunately, there is insufficient information in the Mexico City or Latin American context to have appropriate estimates of these costs in order to inform a more precise cost-effectiveness analyses.

Discussion:

As data collection has already started, it is likely too late to implement this suggestion. Having something that requires a bit more of the women initially helps weed out people who may eventually drop out. (No response to this comment is needed.)

We agree this is an important consideration and is the rationale for the exclusion criteria of study participation if women intent to relocate within two years of the baseline. However, more understanding and assessment to reduce attrition would be helpful.

The word impact is a noun not a verb.

Thank you for pointing out this error. We have revised the word “impact” throughout the manuscript when appropriate.
Reviewer #2

This study attempts an important and challenging task - to rigorously assess nurses' capacity to identify IPV and assist women with risk mitigation in large community health clinics in a middle income country. It is a very commendable and important goal. The study is underway and this paper reports the protocol of the study as completed to date and what steps are to follow to assist those wishing to replicate it and those wishing to sustain and improve the intervention. As the study is a cluster randomised intervention trial, there are several important points in this protocol which need clarifying to assist with these latter objectives. Best practice for cluster RCTs of interventions is to follow Consort guidelines for RCTs and for Cluster RCTs.

With this in mind, I make the following recommendations, which I hope will help readers understand better the design and conduct of the trial:

The authors thank Reviewer #2 for their helpful feedback.

Major compulsory revisions

Background:

The majority of screening only trials have been ineffective (see recently published Cochrane review, Taft et al, 2013). The references you give are for pregnant or post-partum women and for interventions significantly beyond screening and referral only. Tiwari had a nurse-delivered ‘empowerment’ counselling session designed for Chinese pregnant women in a hospital antenatal clinic. Kiely et al had additional individually tailored counseling interventions above and beyond screening specially adapted to each of their outcomes for low income African American pregnant women. Miller et al reduced only pregnancy coercion with a specially designed family planning counseling intervention in FP clinics.

We agree with your assessment of screening trial effectiveness in terms of reducing violence and have added the Taft reference to our background section, which examines screening only interventions and excluded interventions that also had an advocacy or counseling component (O’Doherty, et al, 2014). However, all studies included came from high-income countries (Taft, et al, 2013). The authors had originally included references to the other studies by Tiwari, Kiely, and others as they are above and beyond screening only studies and include components of counseling or improving referrals., which is more consistent with the current study.

As yet, you have not hypothesized or described in sufficient detail (a) how your intervention will reduce your primary outcome a reduction in severe IPV and (b) what aspect is comprehensive.

We have added additional details about how the intervention will reduce severe IPV: “Through this objective, nurses will be equipped to provide counseling and information for women experiencing IPV, linking women to resources in their community, creating safety plans to reduce risk of severe violence, and to mitigate any adverse health risks.” Additional details about the comprehensive nature of the intervention are found in the intervention description of the manuscript.

Please include the referenced measures you will use for your primary and secondary outcomes (as you have in the trial registration). Please specify more clearly what is primary and what secondary. In the final paragraph of the background e.g outcome (a) is both past-year severe
IPV (measured by what scale) and also injuries. These should be separated. Similar with (c) use of resources or safety planning. Etc.

We have added references to the measures we will be using in the outcomes sentence in the introduction. We have also clarified that the primary outcome is severe IPV, measured by the WHO Multi-County Study on Domestic Violence and Women’s Health. The authors have added a clause to separate the secondary outcomes.

Methods/design:

Please clarify your randomisation method and for which outcome your sample has been powered and on what reduction (with reference). Your attrition rate is very sensible. Why did you use an ICC of 0.07?

We have added additional information in the re-written section on randomization and sample size, per Reviewer #1 comments. This new section also includes information regarding the outcome our sample has been powered. We have used the attrition rate of 0.07 as it is a conservative estimate.

You have done some substantial piloting work which is to be commended.

Intervention description

Please tell us what proportion of the nurses working in clinics the 187/144 represent and what proportion are in intervention and what proportion in control clinics?

Thank you for pointing out this needed clarification. After submission of the protocol manuscript, ten additional nurses were trained. We have updated the numbers and identified the proportion from treatment or control arms. In total, we trained 197 nurses, of which 45% were staff of treatment clinics and 55% were staff of control clinics.

Please give much more description of the training methods and topics and who delivered this as this is the core of your intervention. Please give a reference for the IPPF materials.

We have added information on the training in the intervention section per the reviewers suggestion: “All training activities were conducted by the research team, IPPF training consultants, and invited guests from local organizations and government offices who specialize in this area. Specific topics in the training included an introduction to IPV, legal considerations in Mexico City, methods to screen for violence and assess for health implications such as reproductive coercion, safety and ethical considerations, referral methods and linkages to other organizations in the community.”

Data collection

You have not outlined how data will be collected and by whom - how will you manage blinding of staff?

We have added the following in this section: “Data was collected through a computer-assisted survey which has been shown to improve response rates to sensitive behaviors. Participants completed the survey in a private space in the clinic and were able to listen
to the questions in Spanish through headphones and answer on the keyboard. Research assistants were available during this period in case the participant had any questions. Given that clinics were randomized and not individuals, research assistants were not blinded to whether they were in a treatment or control clinic.” As this is a large scale cluster RCT, the investigators felt it would be difficult to blind research assistants, which is a limitation of the study.

Analysis

In this section you suggest that IPV reduction is your primary outcome and all others secondary. If so, can you confirm above?

We have clarified that past-year IPV is our primary outcome in this section: “Through this objective, nurses will be equipped to provide counseling and information for women experiencing IPV, linking women to resources in their community, creating safety plans to reduce risk of severe violence, and to mitigate any adverse health risks.”

Will you follow CONSORT and will your analysis be by ITT (in most cases, complete case analysis?)

Yes, the analyses will be conducted by ITT although we may also use per protocol to explore the effectiveness of the intervention for women who adhered to their assigned group. The ITT analysis is specified in the quantitative data analysis section.

Minor essential alterations

Ethics

How did you manage the discovery of nurses own victimisation?

Yes, this is an important consideration and a few nurses did reach out to research assistants during the initial phases of the study. Their responses were overwhelmingly supportive of the study. We have included an additional clause in the following sentence to address this point, “Research staff and nurses participating in the study are encouraged to report any emotional distress, including if they were struggling with experiences of victimization in their own lives, to principal investigators.”

Discretionary changes

Like many of us, your paper has taken time to be written. Please check tenses as they vary within paragraph, so we will know what has been completed and what remains.

At the time of this revision, the research team has completed the baseline, three month follow-up survey, and is in preparation for completing the endline survey in the coming months. We have updated the tense throughout the manuscript to reflect this as well updated the trial status.
Discussion

This section like the rest of this paper is well written and organised.

You note very real limitations and it is wise to note the sometimes non-significant findings at 12 months which at 24 months becomes significant after women have adjusted to all the changes they have made to their lives.

Sometimes it is the capacity of referral agencies to respond to a significant increase in referrals which can limit a study. Are there any challenges for you?

Thank you for this comment. We have added this as a limitation when discussing referral to community agencies in the discussion.

You have outlined a thorough process evaluation strategy and you have a very strategic context with MOH commitment to the issues.

Thank you for your comments.