Reviewer's report

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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Reviewer: Angela Taft

Reviewer's report:

Falb K et al
Cluster RCT of an HCP delivered intervention to reduce IPV and mitigate associated health care risk in Mexico City

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:

Major compulsory revisions

Background:

1. 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 counselling 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 counselling intervention in FP clinics.

As yet, you have not hypothesised 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.
2. 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.

Methods/design:
3. 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?

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

Intervention description
4. 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?

5. 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.

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

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

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

Minor essential alterations

Ethics
9. How did you manage the discovery of nurses own victimisation?

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.

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?

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

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests