Reviewer's report

Title: The feasibility of using the Mother-Generated Index (MGI) as a Patient Reported Outcome Measure in a randomised controlled trial of maternity care

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Reviewer: Samantha Lain

Reviewer's report:

BMC article review:

This study is part of a large RCT in pregnant women. This side study measures the acceptance of and validates the use of a patient-reported outcome measure, the MGI. The MGI was posted to study participants and completed without assistance from researchers. It is important to validate a tool that is completed by participants without guidance from researchers however this study needs some refining.

Please find my comments below:

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Major compulsory revision:

1. Abstract needs work, feels like an afterthought.
   - MGI is not defined anywhere in abstract.
2. The Method is not the trial - it's the validation of the MGI. Methods need complete rewriting.
3. Results: state correlations to other tools, doesn't matter if its significant correlation, it was all low-medium, need to give actual correlation coefficients for each tool - that's the result.

Results section:

4. Were the women that did not respond at 6 weeks different at baseline to the ones that did respond? Do you have any information as to why they did not respond?

5. Were there differences in % respondents between intervention & control? What are the characteristics of women that completed MGI? Are they different to overall characteristics of participants? Presumably Table 1 is in the original study manuscript? Rather than just replicating - could you add more information relating to the kinds of women who completed the MGI at baseline & at 6 weeks.

6. How did women differ who did not complete stage (or should it be Step?) 2 and step 3.
Discussion section:

7. What questionnaire/tool did the authors expect the MGI have the highest correlation with? That is what the validation is for - did the women understand the MGI & give the same or similar answers to another tool that has been validated to collect those data, or if the results of the MGI do not correlate with that/those tools is it because the women did not complete it properly or needed a researcher to explain it to them.

Excellent completion rates of a tool does not really matter if it is collecting something different to what you want/think your collecting.

Minor revisions:

Background section:

8. Be consistent with terminology: 'professionally driven proforma' and 'respondent-driven PROM' in abstract background but not in study background. I found the terminology in abstract much clearer.

Consistent terminology again: are the women primigravid (have they been pregnant before? Had miscarriages?) or nulliparous? Used both terms in the background.

Methods:

9. What was done if there was disagreement about the themes of narrative responses between researchers?

Results:

10. There is too much detail about the written comments. Tables 3 & 4 could be combined - I don't think that much detail is necessary for a validation study. The most important points are which of these comments would not be picked up in any other questionnaire/tool. As these comments are much more difficult to collate than objective answers to questions in a tool - the main point of text is if it picks up something that would not be picked up by the questions asked.

All of these separate comments could be in a descriptive study of outcomes from the RCT rather than in a study validating the MGI.

Discussion:

11. It doesn't really matter that the correlations are highly statistically significant - it's the low to moderate correlation that's important. We can be very sure that the true correlation is low to moderate. The MGI did not have great correlation with some of the other tools - but that's because they are collecting different things - the EQ-5D is collecting about health status, the MGI is collecting information about quality of life.

12. The authors say within a 'culturally diverse population' - table 1 shows about 92% of trial participants are white.
13. So no other RCT has posted out QoL follow up to participants to complete themselves? Is that what the authors are saying?

**Level of interest:** An article of limited interest

**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.