Reviewer's report

Title: Assisting informed decision making for labour analgesia: A randomised controlled trial of a decision aid for labour analgesia versus a pamphlet.

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Reviewer: Hilary Bekker

Reviewer's report:

This paper summarises the findings of an evaluation of a decision aid to facilitate women’s decision making about method of analgesia for labour in a real-world, prenatal context. The rationale for the study is good with appropriate patient decision aid research and applied are evidence have been used to inform the study and write-up. A pragmatic approach has been taken to ensure the RCT to assess the decision aid evaluation integrates appropriately with the existing services delivering routine care. There is a good sample size to carry out a range of univariate and multivariate analyses. The authors have used a number of standardised measures to provide information on clinically relevant and decision quality outcomes. However, there is a need for greater clarity in the manuscript to understand fully the findings and their implications both for decision aid research and services supporting women through labour. These are described in more detail below.

Essential Revisions

1. Aim - re-write to identify the research aim, rather than to describe the outcomes you are measuring. At the moment the aim does not link the introduction with the methods.

2. Procedure – make it clear what was assessed when in the study. From the current write-up, it seems as if a questionnaire was completed at women’s antenatal visit and then at 3 months post-partum. Were the same measures used at both points of measurement?

3. Terminology – change the questionnaires names. It is not possible to have the first follow-up questionnaire without an initial questionnaire; for example, pre-labour questionnaire and post-birth questionnaire.

4. Consistency – the terms used to describe your measures in the methods, results and discussion are different, sometimes referring to the specific measure (e.g. participation in decision making) and sometimes a conceptual idea (e.g. shared decision making), sometimes referring to them as an outcome and sometimes a primary or second outcome.

5. Terminology – not sure that it helps the reader understand your findings when they are labelled as primary and secondary outcomes. Why not just describe them as they are: decisional conflict, knowledge, anxiety, satisfaction (with what?), (preference for?) participation in decision making, intended choice, actual choice, certainty of choice, acceptability of leaflet, etc.
6. More detail of measures - you need to provide a little more description of what these are actually measuring than assuming people are familiar with them, and how they were measured.

7. Point of information – anxiety is not a measure of decisional quality, mentioned twice in the methods section, more appropriate as a measure of affect.

8. More detail of analysis – a clearer rationale for the analysis would help your reader understand the different levels of analyses you are carrying out. Something a little more descriptive such as: analyses to assess effectiveness of intervention on decision quality and acceptability of aid pre-labour; analyses to assess effectiveness of intervention post-birth; analyses to assess changes in decision making, etc.

9. Additional analysis – were there any analyses carried out to assess differences in intended and actual choice by intervention group. Theory would suggest that those in the decision aid group had more stable values than those in the routine group. Did you find this?

10. Results – the results are very difficult to follow, changing the previous sections and labelling the results section appropriately should help to make the results more accessible.

11. Results – there is a rogue ‘follow-up’ that needs to be removed.

12. Limitations – three points need further discussion as they affect our understanding of the findings. First, the timing of measures. This issue is touched on by the authors but basically, the decision quality measures were taken well in advance of the decision being made. As this was at a time when the women were not anxious and not particularly conflicted, it is unsurprising there was no difference by intervention. However, this doesn’t mean that the intervention was not effective, just the timing of measures was inappropriate. This point needs to be made clearer. Also, I suspect the component parts of the decisional conflict score would have been more useful for this study, particularly the ‘informed’ and ‘efficacy’ parts. If there are measures of attitude and risk perception and the possibility that they are ‘more realistic’ in the decision aid group, the authors should think of discussing that to illustrate the aid’s efficacy.

13. Limitations second point – I think the authors need to be a little more reflective about the quality of their intervention compared to the control. I suspect that the readability score of the control information is really poor, it could be argued that a good information aid would get the improvements they have shown. This alternative scenario should be raised and addressed. Also, I would question the validity of a resource that is 55 pages long. Perhaps the authors could suggest, from there findings, possible ways of reducing the length of their resource that shouldn’t, in theory, compromise the validity of the decision aid.

14. Limitations third point – a number of the measures adopted by the authors may well be supported by the IPDAS criteria but do not actually measure what the authors wanted them to measure. I think it is important that researchers talk explicitly about what the measure is measuring rather than what it may imply. This is a complex area and other researchers need to understand that, for
example, knowledge isn’t a measure of decision quality or understanding which may or may not increase with the use of a decision aid, it depends on the quality of existing information which is usually poor.

15. Discussion – I suspect clarifying the methods and results will mean the discussion will need revisiting. It is difficult for the reader to appreciate whether this intervention is ‘good’ or not.

Discretionary Revisions

1. Intervention – did the decision aid help the women realise that it was her responsibility to make this decision. If yes, please include. Also, what do the 55 pages have that the standard care does not have. Would help to understand the difference between the two.

2. Standard care – add the readability of the standard care leaflet and comment on how the quality of the information presentation (e.g. risks presented).

3. Terminology – used the term compliance to decision aid. This term is not very ‘patient-centred’, especially when talking about decision aids, would adherence be a better term?

4. Analysis - decision aids appear to encourage more stable values over time (a month or so after the decision event). Some decision aid research has found that decision conflict after the decision event has happened gets less in the aided group, yet rises in the unaided group. If you have decisional conflict assessed at more than one time-point and/or attitude and/or risk perception scores at two time points, a repeated-analysis might demonstrate the aid’s effectiveness?

5. Measures – not explicitly referred to Marteau’s informed choice measure in the main paper but clearly used it to inform your measures. If the results were not useful, these findings should be reported. That is to say, if the measure is not valid in this context, other people need to know that.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests