Reviewer's report

Title: A Pilot Randomised Controlled Trial of Cognitive Behavioural Therapy for Antenatal Depression

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Reviewer: Angus MacBeth

Reviewer's report:

The area of antenatal psychological interventions is under-developed and thus a contribution to the field is to be welcomed. The authors present results of an RCT which is correctly pitched as a pilot study, and the evidence suggests a larger scale RCT is both feasible and justifiable. The results are presented in a way that clearly demonstrates the pragmatic nature of implementing an RCT in a routine health service setting. I have some comments on the manuscript that are very much offered in a spirit of constructive criticism, and which if addressed would serve to fine tune the paper.

Main revisions requested are around the context for the study, and some queries regarding methodology.

Minor Essential Revisions

I would be inclined to rephrase abstract to: "effectiveness of psychological treatment in improving depression".

Introduction p.5. I wonder if the authors could highlight in their review of postnatal interventions that they are largely discussing psychological treatments

It isn’t a major point but I would like to see the authors highlight that the evidence base in antenatal depression is largely for non-specific psychological interventions, rather than CBT (despite the NICE guidelines). This argument is in the current draft but needs a little highlighting, thus giving clear justification for the RCT.

The authors are incorrect to state this is the first RCT of CBT for antenatal depression as Cho and colleagues have published a modest RCT in Korea (Cho et al. Antenatal Cognitive-behavioral Therapy for Prevention of Postpartum Depression: A Pilot Study. Yonsei Med J. 2008 August 30; 49(4): 553–562.). There are sufficient differences between the studies to ensure the current paper is a relevant contribution to the field, but the authors should acknowledge the previous study.

It would be useful, albeit constrained by manuscript word limit, to have some brief description of how the CBT intervention was modified, obviously with the reference to O’Mahen et al. 2012 for further detail.

Who collected the process and outcome data? Were they blind to treatment
allocation? I see that several measures were computer measures – did the participants complete these in their own time, or was completion prompted by the research team?

I presume the secondary outcomes were only collected at 15 and 33 weeks post randomization?

Results:

The PAI scores seem to be missing from Table 4 so it is difficult to ascertain from the text whether the differences in attachment are significant. Results are generally clear and easily interpretable.

The authors are upfront about recruitment issues, but they could perhaps be a little clearer that their drop out from the n=154 identified by records, and the 36 who were randomized is a significant attrition rate. They are correct to identify the significant loss of potential participants due to invitation not being extended. As it is a pilot trial these are reasonable issues to have. They can also reiterate that this is not a typical CBT population and the demographics suggest that this an economically high risk/hard to reach sample.

Discretionary Revisions

In the review of the risk of antidepressant medication to the fetus, Suri et al AMJPsychiatry, 2007, 164, 1206 – 1213) could be cited.

The health service usage, medication and treatment pathway data are interesting, but when added to the therapy data, I wonder if it gives the reader too much data to digest in one reading. It could potentially support a paper of it’s own and be removed from the current paper. Another consideration for the treatment usage data is that the numbers involved really are quite small, and perhaps the findings lose generalizability.

Discussion points are generally well made and relevant. The drop-out due to miscarriage is unfortunately unavoidable and it might be worth noting that women who experience a miscarriage are also at risk of mood difficulties thereafter.

The authors could note that measurement of antenatal anxiety could be a useful addition to a larger scale trial, given the emergent links between anxiety and poor developmental outcomes (e.g. O’Connor et al., BJP 2002).

There are quite a lot of secondary measures, and the study could be seen to be under powered for the number of measures used. However, as the authors are clear that this is a pilot study, this seems a minor concern.

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.
Declaration of competing interests:

I declare that I have no competing interests.