Reviewer's report

**Title:** Study protocol for a randomized, controlled, superiority trial comparing the clinical- and cost-effectiveness of integrated online mental health assessment-referral-care in pregnancy to usual prenatal care on prenatal and postnatal mental health and infant health and development: The Integrated Maternal Psychosocial Assessment to Care Trial (IMPACT)

**Version:** 2  
**Date:** 29 December 2013

**Reviewer:** Louise Michele Howard

**Reviewer's report:**

This is a potentially important trial as there is little known about how best to address prenatal mental health problems as the authors convincingly suggest in their introduction. Moreover the need for integrated care is also persuasively argued for by the authors. The paper is well written and generally clear.

Their trial aims to provide integrated assessment and care through use of tablets for on line assessments and CBT modules. My main observations about this trial are the integration with the main sources of routinely available care and a potential lack of generalisibility, but these could be addressed by clarifying some details.

a) Integration with maternity/psychiatric care - Research nurses will be referring to other health providers women who are excluded at the different stages for reasons of severity of illness or other risk factors such as thoughts of self harm - how would this work in the real world? Who would check the on line assessments and make referrals? It would be useful to clarify how the intervention would work in practice if this trial found evidence of efficacy. The input of the research nurse also has implications for appropriate economic analysis – how will the nurse (or other health professional in the non-trial situation?) be costed in to the analysis (see below)?

b) Generalisability - My reading of this protocol if I have understood it correctly, is that women with many of the risk factors for mental health problems will be excluded from CBT ie women who are single, or experience partner violence, have a history of childhood abuse, have a low income, have fleeting suicidal ideation, have mild to moderate depression (more than 15 on the EPDS) etc and will be excluded from the study as a whole with fleeting suicidal ideation (as indicated by scoring 1 on Q10 of the EPDS) or having a moderate major depressive disorder. Thus this integrated system is only available for women with low level symptoms with few risk factors as far as I can see which limits generalisability greatly. Justification of this would be helpful. This is also likely to impact on the recruitment rate (see also below).

Major compulsory revisions
1. More detail is needed on the maternity populations served by the 4 primary care centres which will be where women are recruited from. For example, what proportion of women booked for prenatal care are single mothers, on low income, from different ethnic groups etc at these centres?

2. How will data on harms (serious and less serious adverse events) be collected and dealt with?

3. The authors review the literature in the background comprehensively but much of it does not focus on the study population here - when reading the trial design it becomes clear that this is a study population of women with mild levels of symptoms rather than moderate or severe disorder. The literature on adverse postpartum outcomes finds worse outcomes for more severe and chronic disorders and for those with other moderating factors such socio-economic deprivation. The background would be strengthened by focussing more on the studies that use similar populations to that proposed in this protocol, and making it clear that moderators such as deprivation of these potential adverse impacts exist.

Minor essential revisions

1. Depressive symptoms, anxiety symptoms and symptoms of stress are measured - not depression or anxiety disorders. Use of the terms “depression” and “anxiety” is potentially confusing and needs to be replaced by appropriate terminology throughout including in the abstract.

2. Please define low income. Authors should also explain rationale for excluding women with low income as this seems potentially problematic.

3. A significant proportion of women will be excluded due to suffering domestic violence, being single parents etc. This will impact on recruitment rates and don’t appear to have been factored into the calculations of expected recruitment rates as only the number of pregnancies booked in per month are provided. How many are likely to be excluded at each stage and what impact will this be expected to have on recruitment? Currently the manuscript states that 5% will be high psychosocial risk which seems low bearing in mind the number of women likely to be single, or low income, or experiencing partner violence etc unless I have misunderstood the protocol.

4. Will the research nurse be trained in how to address domestic violence? Disclosure of domestic violence leads to exclusion from the CBT intervention and could be potentially harmful if the perpetrator realises that a disclosure has occurred. Is there a safety protocol for this? Please clarify.

5. Details of the pilot intervention include telephone guidance from a research team. Telephone guidance is not mentioned as a component in the intervention described for this trial - please clarify whether it is included as part of the intervention and, if so, who will deliver this?

6. The primary hypothesis is confusing to read - is the hypothesis that women in
the intervention group will be above the cut off in either of the scales or both? Ie is it "and" or "or"? And is this adjusted for baseline scores?

7. Sentence on allocation concealment is unclear. This seems to suggest the research coordinator will be told of the allocation

8. Please explain how the nurse (or other health professional in the non-trial situation?) will be costed in to the economic analysis

9. Measures need to be described in more detail. The Maternity Experiences Survey is being used to collect some important information and it is not currently clear in this protocol whether it has been validated for domestic violence for example.

10. Will covariates likely to impact on fetal and infant outcomes be collected eg smoking, BMI? They are not currently listed but should be available from maternity notes

11. Primary outcome - at which time point is the data on mental health the primary outcome? In table 5 it appears at 4 follow up points as the primary outcome but elsewhere appears as post-intervention. Please ensure consistency throughout the manuscript

Discretionary revisions
The authors state they do not expect much missing data and therefore do not plan imputation. What if they do end up with a lot of missing data though? Is there a level of missing data that wo

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I am Chair of the NICE guideline (update) on Antenatal and Postnatal Mental Health and receive reimbursement for this role. NICE is likely to examine the results from this trial in the future.