Reviewer's report

Title: Antenatal psychosomatic programming to reduce postpartum depression risk and premature childbirth: a randomized controlled trial in Spain and France

Version: 2 Date: 2 February 2013

Reviewer: Simone Vigod

Reviewer's report:

This is a multi-centre randomized controlled trial evaluating a psychosomatic group educational intervention for prevention of postpartum depressive symptoms in at-risk women. Given the public burden of maternal psychiatric morbidity, and the minimal evidence that exists for preventive interventions, this type of study is extremely important.

Major Compulsory Revisions:

1. The population is not well-described.
2. More information on the scale that was used to select the couples is needed. There was one reference, but has this been used elsewhere? how does it work?
3. It appears that this was an intervention for couples, and that couples filled out the standardized questionnaires. However, the evaluation taking place in this paper seems to be focused on the mothers, but that is not entirely clear. If it is focused on the mothers, then shouldn't the fathers’ data (i.e. their depressive symptom scores, etc...) be part of the analyses?
4. The authors discussed randomization sequences, but did not describe whether allocation to groups was blinded, or the blinding of the outcome raters.
5. The authors also do not report on many potentially prognostic factors for PPD and preterm birth risk in their Table comparing the exposure and comparison groups. Examples of important prognostic factors included: the PPD risk scale scores, social support, previous psychaitric history, substance use history, SES, intimate partner violence, etc... for PPD. There are no prognostic factors presented for preterm birth risk
6. Outcome: It should be noted by the authors that the outcome is self-report for PPD symptoms and the preterm birth outcome is not defined at all (i.e. is it < 37 weeks?), nor is it clear how the "clinical" interview gave the information on preterm birth.
7. Analysis:
   a) The loss to follow-up is extensive and although the authors state that they intended to perform an intention to treat analysis, it is not clear to me how this was done, particularly given that there were subjects who were excluded from the analysis post-randomization
   b) The multi-centre study design is not accounted for in the analysis and should
be included as a covariate in the primary analysis of the primary outcome.

Minor essential revisions:

1. The abstract is unclear. I would recommend that the authors use a more structured abstract format (e.g. JAMA) where the exact objective of the study is clear (i.e. the objective is to evaluate an intervention but in the abstract the authors indicate the goal was also to design an intervention), the methods are clear (i.e. multi-centre, randomized, controlled trial comparing a psychosomatic intervention to standard psychoeducational intervention where the primary outcome was EPDS score > 12 at 4 weeks postpartum and the secondary outcome was preterm birth (as defined by??), etc...

2. The introduction could be made more clear by eliminating the extensive background information about interventions with evidence for prevention. This belongs in the discussion to put the results into context. Also, the extensive background for the psychosomatic intervention belongs in the methods section.

3. I believe that the number of tables should be reduced because having so many takes away clarity from the main results: i.e. Table 1 comparing the intervention and control groups on potential prognostic factors, Table 2 for the primary and secondary outcome results.

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

**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.