Author's response to reviews

Title: PRISM (Program of Resources Information and Support for Mothers): a community randomised trial to reduce depression and improve women's physical health six months after birth [ISRCTNO3464021]

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Author's response to reviews: see over
Dear Editors,

We appreciated the comments from the three reviewers and have made some major changes to the paper. We have provided

- more information on the rationale for the intervention components;
- more detail on the intervention’s objectives, strategies and implementation;
- encouragement for use of the protocol and the PRISM website by providing full URLs for specific sections of the information available, and encouraging downloading;
- an additional Table (4) summarising the findings of the other ‘universal’ postnatal intervention trials;
- a copy of the revised paper with changes highlighted in pink text, which we would like to be sent to the reviewers.

Our detailed response to reviewers’ comments follows:

**Reviewer: Susan Watt: Major Compulsory Revisions**

1. What was/were the reasons that the researchers thought the intervention would make any difference to these outcomes? Is there any other evidence about the efficacy of this intervention? Particularly, what is the evidence that led to trying a community intervention? I believe that these thoughts, and the supporting literature, need to be spelled out in the Background for those who are not familiar with the other trials.

1.1 The context for the development of PRISM was our prior descriptive epidemiology of women’s depression after birth, the links between depression and physical health problems, women’s reflections on the factors which they saw as relevant to their depression, and on the factors which facilitated recovery. A more detailed discussion is given in the PRISM protocol and on the PRISM website both available on-line and able to be downloaded; see references 14 and 19. Pages 5 and 6 have a new layout which should make the links between the problems, the objectives, and the strategies clearer.

1.2 There was no strong evidence on the efficacy of the strategies – if there had been strong evidence we would not have carried out the trial. There were influential theories about the importance of community-based interventions in mental health (see page 4 para 1 and 2), which fitted with women’s accounts of isolation and lack of support as contributing factors to their depression.

1.3 The other trials of ‘universal’ postnatal interventions are now in the main text as Table 4. None of their outcomes had been reported when PRISM was in the planning stage.

2. In the Discussion a number of issues about changes in the community are proposed as possible explanations for the lack of effectiveness of the community-based intervention. The proposal that the intervention, in and of itself, regardless of setting, is not effective in producing better outcomes needs exploration. As it is currently presented, it looks as if the researchers have only considered the circumstances or contexts of the intervention rather than the intrinsic efficacy of the intervention in evaluating the outcomes. To leave the article at that level would be, in my opinion, a major shortcoming.
2.1 The Discussion has been substantially modified to take account of these comments: see especially p 11 para 3 and 4, p 12 para 1. The inclusion of table 4 in the main text also provides an important context for the discussion, given that only one of the concurrent ‘universal’ trials reduced depression. However, the complexity of the interventions in PRISM made it important for us to comment on the contextual community factors as well.

**Reviewer Cindy-Lee Dennis**

1. *Abstract: include standard deviations for mean scores:* Included, p 2.

2. *How were the eight pairs of LGAs randomly selected?*
   The complexity of community-randomised, cluster-randomised trials with a relatively small number of clusters (16) makes it difficult to summarise adequately within this paper, hence the reference to the Methods paper (Reference 23) instead.

3. *A rationale is required to explain why the authors drew on *social ecological theory and what are the principles and underlying concepts of the theory*
   New paragraph on p 4, (para 1) with additional references 15-17, 27.

4. *Heading should be Intervention rather than objectives*
   Agreed and changed, with more clarification of objectives and strategies below.

5. *How were the diverse components of the intervention selected? What was their rationale?*
   See responses 1.1 and 1.2 above

6. *How were the materials developed, evidence for the specific components*
   Additional material is now included on pp 5 and 6, together with website references given in full for each component. (References 18-21, 24-25, 28-30).

7. *How were they distributed?*
   Information kits were distributed to women by MCHNs soon after hospital discharge (p 6)

8. *What did the mother-to mother support network entail?*
   See references 31-32, for information on the extent and variety across communities.

9. *CDO selection, training, specific activities, effectiveness?*
   See page 6 revised paragraphs 3 and 4 and the website reference on support for local implementation (reference 22). We were aware from the beginning that it would not be possible to separate out the contributions of different aspects of the intervention, particularly those of the CDOs given their interactions with all the activities in their area.

10. *EPDS & SF36 in more detail*
    A little more information is provided on the EPDS but the SF36 is so widely used now that we provided just the data and references.

11. *Smaller than required sample size?*
    There is a new paragraph in the Discussion (p 11 para 2) which responds to this point.
12 Figure 2 not needed
Figure 2 is important for showing the diversity across communities in relation to mental and physical health outcomes and the similarity of patterns across intervention and comparison groups, so we would prefer to retain it.

13 Results in context of earlier research
Research prior to the development of PRISM is discussed in a document on the PRISM website (reference 19). We have included in the revised paper a 4th Table which summarises the outcomes of all the postnatal interventions offered to an unselected population, providing a context for the PRISM outcomes. It contrasts these interventions with findings from a systematic review of ‘counselling/listening’ interventions provided after birth to women who are depressed/probably depressed. The discussion on p11 para 3 discusses the findings of the ‘universal’ postnatal trials, only one of which reduced depression, before reviewing the factors which might have contributed to the lack of effect of PRISM.

14 Role change for MCHNs? Now clarified on p 12, para 1.

Reviewer Christine MacArthur
No response required.

Judith Lumley (for the authors)