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]

Authors:

Judith M Lumley (J.Lumley@latrobe.edu.au)
Rhonda E Small (R.Small@latrobe.edu.au)
Stephanie J Brown (Stephanie.Brown@latrobe.edu.au)
Lyndsey F Watson (L.Watson@latrobe.edu.au)
Creina A Mitchell (C.Mitchell@latrobe.edu.au)
Jane Gunn (j.gunn@unimelb.edu.au)

Version: 4 Date: 19 December 2005

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)

The marked paper which follows does not include the tables, except for Table 4 which was not in the original paper.
Abstract

Objective: To reduce maternal depression and improve mothers’ physical health in the six months after birth with a multi-faceted intervention in primary care together with community-based supportive strategies

Design: A community-randomised cluster trial.

Setting: Sixteen local government authorities, eight metropolitan and eight rural, in the State of Victoria, Australia.

Participants: 18,555 women who gave birth in the 16 communities from 7/02/00 to 5/08/01, surveyed six months after birth.

Main outcome measures: Primary outcome: probable depression (Edinburgh Postnatal Depression Scale score ≥13) and the Physical and Mental Health Component Scores of the Short Form 36.

Results: 6,248/10,144 women (61.6%) in the intervention (I) arm and 5,057/8,411 (60.1%) in the comparison (C) arm completed the survey at six months and there was no imbalance in major covariates. The proportions of women with an EPDS score ≥13, 15.7% (I) and 14.9% (C) were not significantly different, odds ratio_{adj} 1.06 (95% confidence interval 0.91 - 1.24). Their mean EPDS scores were 6.9 in the intervention arm and 6.8 in the comparison arm with the same standard error in both (SE_{adj} 0.11). Their mean mental health scores were 47.6 (SE_{adj} 0.115) (I) and 47.9 (SE_{adj} 0.19) (C) and mean physical health scores 50.2 (SE_{adj} 0.10) (I) and 50.3 (SE_{adj} 0.10) (C).

Conclusions: Given the study size, the comparability of the two groups in their social and obstetric characteristics, the evidence of implementation of the strategies, and the marked similarities in the primary outcomes, it is unlikely that this complex intervention improves maternal emotional or physical health.
Background

Maternal depression is common in the months after birth. We found the point prevalence of probable depression, assessed with the Edinburgh Postnatal Depression Scale (EPDS score ≥13) to be between 14 and 17% in three Australian population-based surveys [1-3]. Follow-up of the first survey found that 30% of women who had been depressed at eight to nine months were depressed when their infants were two. Only a third of women who had been depressed had sought help from a health professional. When they did seek help it was from a general practitioner (GP) or a maternal and child health nurse (MCHN) [4]. Only 15% of women with depression had sought help from, or been referred to, a mental health professional [4].

Specific physical health problems such as back or perineal pain, mastitis, haemorrhoids, and urinary incontinence were identified in the second survey as being common as were sexual problems, relationship difficulties and severe fatigue. There were complex associations between physical health problems and depression [5]. Earlier studies in the UK [6-7] found that despite the persistence of symptoms for at least a year only half the affected women sought treatment, with even lower consultation rates for perineal pain (21%), urinary incontinence (27%) [8] or faecal incontinence (14%) [9].

Reluctance to seek help was not because of limited contact with services. MCHNs make a home visit soon after hospital discharge to 94% of mothers, and participation by mothers in visits to MCH centres at two, four and eight weeks, and four to eight months is 87-96%. New mothers’ groups run by the MCHN are attended by 60% of first-time mothers [10]. There are lower levels of satisfaction with the service in relation to maternal issues [11]. The mean number of visits to GPs by a mother/baby dyad in the six months following birth is 7-7 [12]. A large survey found that 92% of GPs provided postnatal care, but neither the common physical health problems described above, nor depression, were issues which GPs considered part of the routine six-week check, and both were areas where the GPs rated themselves as not very confident [13]. A more detailed discussion of the evidence is included in the study protocol [14].
In the intervention arm of the PRISM trial we aimed to re-focus the existing postnatal health care contacts on maternal physical and mental health (enhanced, evidence-based, primary care), to implement community strategies to increase the availability and accessibility of ‘time-out’, provide better information about common health problems and local services, with encouragement and incentives to use them (more family and community support for mothers), and to measure the impact of these strategies on maternal health. Theories around social networks and social support were influential in trial development as were the principles of cooperative problem solving, forming coalitions and building capacity for effective local action [15-16]. At the time the trial was developed there were no published trials taking this approach though Regier and colleagues at the National Institute for Mental Health had already argued for the importance of community-based interventions in mental health on very similar grounds: that only a minority seek professional help for mental health problems, when they do they turn to the primary care sector and that even then mental health problems are under-recognised [17].

A detailed discussion of the background and development of PRISM is given on the PRISM website [18-22]. The website is an important resource for viewing the design and implementation of PRISM in context, as it includes examples of the materials developed in the course of the project by the research team and in communities, as well as information on staff training and on monitoring processes.

Methods
The unit of randomisation was local government authorities (LGA) [23]: because of their responsibility for the Maternal and Child Health Program, their provision of other family/community services, and their responsibility for data on new mothers based on statutory birth notifications from hospitals. LGAs gave informed consent to community participation. The eligible LGAs were all those in Victoria, Australia with 300 to 1,500 births a year, except one metropolitan LGA in the centre of the capital city (Melbourne) and one rural one with shared services and population flow across the State boundary with New South Wales. The 33 eligible LGAs were sent an information package [24] and offered a formal briefing. Twenty-six agreed, 25 followed through and 21 signed a Memorandum of Understanding [25] about randomisation and participation.
After stratification into rural and metropolitan areas all possible pair matches in each stratum were identified, taking into account the size of each area, a rating of current and recent community activity, the annual number of births, non-contiguous boundaries, with one set of eight pairs randomly selected [26]. We could not seek informed consent from individual women prior to the intervention since the interventions were implemented at the community level and there was no way of identifying women in advance of the birth. The Ethics Committees of Monash University (1994) and La Trobe University (1995) approved the project.

*The PRISM intervention program*

*PRISM* drew on social ecological theory, with program development around existing high impact ‘leverage points’ (e.g. MCHNs, GPs and community organisations), encouraging both person-centred and environment-centred change [27].

The objectives in primary care were:

- to increase the recognition of depression in mothers of young children at all contacts;
- to facilitate an active response to the recognition of depression;
- to provide explicit offers of time to talk by both MCHNs and GPs;
- to increase the recognition and treatment of physical and mental health problems which are common after birth;
- to encourage practitioners to think of ‘community’ solutions to isolation and lack of support.

The strategy was to develop multi-faceted education and training programs for GPs and MCHNs. This involved 10 hours of workshops, simulated patients, two clinical practice audits and evidence-based guidelines (*Guidelines for Assessing Postnatal Problems*) for GPs [28]. A similar education program was provided for MCHNs with 12 hours of training in year one and three hours in year two [29].

The objectives at the community level were:
• to increase the availability and accessibility of support and 'time-out' for recent mothers;
• to provide better information about local services to mothers and families, with encouragement and incentives to use them;
• to increase the ‘mother-and baby-friendliness’ of local environments (e.g. shopping centre car spaces for parents with prams, improved baby-change facilities);
• to increase inter-organisational collaboration and advocacy for parents and young children.

The key minimum strategies were:

• assessment of the availability and accessibility of facilities and services such as occasional child care, recreational, library, and counselling services, neighbourhood houses, local parks), with a focus on the extent to which they were mother-and baby-friendly;
• an information kit for mothers, distributed to women by MCHNs soon after hospital discharge [30], including:
  o a listing of local services for mothers and babies;
  o two booklets outlining common physical and emotional health issues for mothers and strategies other women have found helpful developed by the co-ordinators and piloted with women;
  o a booklet for fathers, developed and piloted by a father with fathers;
  o a package of free or discounted service vouchers for mothers.
• a range of mother-to mother support strategies based on the principle of non-professional befriending [31].

Local co-ordination was achieved by the establishment of local steering committees with broad membership and a full-time community development officer (CDO) appointed with local selection processes in each intervention community for two years from November 1998. Their duties and responsibilities were to: liaise with local government and non-government agencies and primary care providers; identify local community services, compile information on services for mothers, seek voucher
contributions from businesses and local agencies, contribute to the mothers’ information kits; facilitate supportive social networks, and provide support to the steering committee in intervention development and implementation, and its subsequent integration into local services and programs. This included working with GP Divisions and with GP liaison officers.

Steering committees and CDOs were able to develop other supportive interventions locally and to decide how to implement them. Extensive communication between the CDOs, discussion on Steering Committees, and articles in the PRISM project newsletters facilitated creative responses to common difficulties and sharing of local strategies [32].

Health outcomes
Health outcomes were measured by postal questionnaire mailed six months after births to women giving birth from 7/02/00 to 5/08/01. Mothers of infants who had died were excluded. Questionnaires were packaged with a covering letter, and a prepaid reply envelope, grouped and mailed to LGAs where a name and address label was added from their MCH program data system. Reminder cards were sent two and four weeks later. Questionnaires were returned direct to the research team to ensure anonymity and confidentiality. The primary outcome measures used to assess women’s health and well-being at six months were the EPDS (a 10-item scale developed for use in the postnatal period, in which a score $\geq 13$ identifies probable depression [33], and the physical and mental component scores (PCS and MCS) of the Short Form 36 (SF-36), a widely used general health status measure [34]. The PCS and MCS were calculated using norms from the 1995 Australian National Health Survey [35] using appropriate female age-group subscale means.

Other questions included women’s views of the practical and emotional support they had received, social contacts, making new friends, ‘time out’, mother and baby friendliness of local settings, receipt and use of the mothers’ information kit and vouchers. We asked about the extent to which their own GP and MCHN were supportive and understanding, and about their use of other health services.

Sample size and power
The sample size to detect a relative risk reduction in probable depression (EPDS ≥ 13) of just under 20%, (an absolute difference of 3%), given the depression prevalence of 15 to 17% and individual randomisation, with $\alpha=0.05$ (2-sided), $\beta=0.20$, would be 2337 in each arm. To allow for the pair-matched cluster randomisation design it was estimated that with eight pairs, and an average cluster size of 800, a matching correlation of at least 0.3 would be required; an inflation factor of approximately 2.5 [35]. This sample size would be able to detect two point differences of clinical importance in the summary mental and physical scores of the SF-36. Adjustment for a likely adjusted response fraction of 67%, based on earlier surveys of recent mothers [1-3], increased the required sample size to 9,600 per arm. As routine monitoring of responses during the trial showed a lower response fraction than predicted, data collection was extended to 18 months of births with the support of all 16 participating LGAs [14].

Analysis
The analysis of the data used logistic regression to estimate the effect of the intervention on probable depression, adjusting for cluster effect and approximating the logistic-normal model [36]. Pair-matches were broken in the model to provide more power [37]. Linear regression was used for the analysis of other health outcomes. The analysis was carried out with Stata, version 8.

Results
Figure 1 shows the participant flow diagram [38]. No clusters were lost from the study. The adjusted response fractions were 6,248/10,144 (61.6%, range 50.4% to 68.7%) from intervention (I) communities and 5,057/8,411 (60.1%, range 57.0% to 66.1%) from comparison (C) communities. Two women were inadvertently included who gave birth outside the birth-date range but within a week. Characteristics of the clusters are shown in additional Table A1.

Table 1 summarises the social and reproductive characteristics of the survey participants by group showing similar proportions in social and perinatal characteristics. There were also no differences in infant sex with 51.7% male, multiple births 1.5% (90 twin, 4 triplet (I), 72 twin, 1 triplet, 1 quadruplet (C)), identification as Indigenous (23
Data on all women giving birth in the 16 communities during the study period, obtained from the Victorian Perinatal Data Collection Unit (VPDCU) are also shown in Table 1. Survey respondents included fewer women who were under 20 or 20–29, Indigenous, without a partner, of non-English-speaking background, or without private health insurance.

Figure 2 displays response fractions by LGA, for intervention and comparison communities in the top panel. The other panels show the primary outcomes by LGA: proportion of women with EPDS scores ≥13, mean EPDS scores, mean mental health component scores (MCS) and mean physical health component scores (PCS) of the SF-36. There is no evidence of differences between intervention and comparison communities on any outcome.

Table 2 summarises the differences in the major outcome variables across intervention and comparison communities, adjusted for clustering using survey analysis procedures. The proportions of women with probable depression (EPDS ≥13) were 15.7% (I) and 14.9% (C), adjusted odds ratio 1.06 (0.91–1.24), and the mean EPDS scores were 6.9 (SE_{adj} 0.11) and 6.8 (SE_{adj} 0.11). The mean PCS scores were 50.24 (SE_{adj} 0.10) and 50.26 (SE_{adj} 0.16), and the mean MCS scores were 47.58 (SE_{adj} 0.15) and 47.91 (SE_{adj} 0.19). Sub-scale scores of the SF-36 are also displayed. Statistical comparisons are shown from univariate analyses as there was no imbalance in key covariates. Interaction effects are summarised in additional Table A2.

**Implementation**

The Mothers’ Information Kit was received by 88.2% of women in intervention areas, with only 2.7% of those in comparison areas reporting having received it and 9.3% being unsure. In five LGAs distribution of the kits to mothers was sustained at 90% or more for 18 months. In the other three it fell to 60 to 70% in the last six months. Over 90% of women who received the kit had some positive response to the vouchers, 35% who received the kit had used the vouchers, and 62% rated the local community guide as very or fairly helpful.
The proportions of women reporting receipt of written information were significantly higher in intervention than comparison communities for: information for fathers (60% vs 27%), information on local services for mothers (90% vs 64%), and vouchers or special offers for mothers with a new baby (88% vs 64%) (Table 3). There were no differences between intervention and comparison communities in the proportions of women reporting encouragement to talk about their own health at every visit to the MCHN (36% in both), in those feeling able to talk to their MCHN and finding her very supportive and reassuring (40% and 39%), or in those feeling able to talk to their GP and finding her/him very supportive and reassuring (46% and 43%). Restricting the comparisons to women having more frequent or regular contacts, with MCHNs or GPs, gave the same results. There were no differences in the proportion of women who had made new friends since the birth (53% and 54%), had more social contacts (54% in both), or in women who had time-out, at least once a week, when someone else was caring for the baby (39% and 40%). There was no difference in the proportions describing their local community as very or fairly mother-and-baby friendly (56% and 54%). Despite the marked difference in the proportion of fathers in intervention and comparison communities reported as receiving printed information on ‘ways to support you and be involved with the baby’ (60% vs 27%), there was no difference between intervention and comparison communities in mothers’ rating of partners’ practical and emotional support. The mean scores were 6.9 (SE_{adj} 0.03) (I) and 6.9 (SE_{adj} 0.07) (C) derived from a set of six questions.

Discussion
The imbalance of births in intervention and comparison communities in PRISM was explained by fewer births in most rural LGAs and rapid population growth in a few metropolitan intervention areas (Victorian Perinatal Data Collection Unit, unpublished data.) The adjusted response fraction was slightly lower in PRISM than in our earlier postnatal population surveys [1-3], possibly because we could not afford to send a second copy of the questionnaire, but the differences in social characteristics between all eligible women and survey participants were very similar to prior surveys and the prevalence of probable depression was the same as in earlier surveys [3]. As individual consent for participation had not been sought the adjusted response fraction does not demonstrate serious loss to follow-up but rather a relatively high response to receiving a mailed questionnaire ‘out of the blue’.
Although the power calculation showed that a particular sample size would be required to identify a statistically and clinically important difference in the primary outcomes between the intervention and comparison groups the finding of no effect of the intervention is strongly based in the similarity of the proportions responding to the outcome questionnaire in the two arms of the trial, and the almost identical primary and secondary outcomes. Thus it is clear that the interventions in this trial did not have an impact on women’s mental and physical health six months after childbirth.

With the exception of Gunn’s trial [39], which was a little earlier, the universal postnatal intervention trials – those recruiting women across the whole postnatal population — were all designed at the same time [40-46]. All used the same mental health outcome measure (see Table 4) and all but one also measured overall health status (mental and physical) with the Short Form 36. The interventions in the six trials were very diverse, although PRISM and the trial of MacArthur and colleagues had some components in common. The similar timing of the six trials meant that they were not influenced by the others’ findings. The lack of effectiveness of all the interventions implemented in these trials, except that of MacArthur and colleagues, is in contrast to the marked effectiveness of a wide range of postnatal counselling interventions, provided by a variety of practitioners, to women who had been diagnosed as being depressed or probably depressed. The pooled estimate of effect for those interventions is a large reduction in depression: with a relative risk of 0.52 (95% CI 0.40, 0.65) and no significant heterogeneity across the trials [47].

Our hypothesis from the beginning was that the inclusion of physical health as well as mental health and the community-based interventions would make a real contribution beyond the trials focused on individual women. That hypothesis was subsequently borne out by the outcomes of the trial of MacArthur and colleagues which was effective in reducing depression [44-45]. Distinguishing features of that trial were its use of existing staff and services to provide redesigned community postnatal care, the integration of their community midwives into primary services and their focus on women’s individual physical and psychological health needs. Although there was substantial common ground between MacArthur’s trial and PRISM,
including the finding of no effect on physical health in either trial, there were some differences which may have been important. The lack of integration of MCHNs with other primary care services (general practitioners) in Australia is one and the negative impact of a fee for service system on ready access to a GP in Australia is another. However, the success of MacArthur’s trial raises the possibility that PRISM could have been more effective, and we consider below a number of possible explanations for why it was not.

The impact of education and training on primary caregivers in PRISM, assessed in terms of women’s ratings of their care, was much less than we had hoped for. There was a real but small impact on GPs taking part in the education program [28] but these were a small proportion of all GPs in participating communities, and academic detailing was limited. We saw the role of MCHNs in PRISM as pivotal but recognised that the education and training in PRISM involved a role shift from a focus on action around the health and well-being of babies, child health surveillance, immunisation and child protection, to a much more open-ended role involving ‘active listening’ to mothers, enhanced communication skills and much less certainty about what should be done [48].

The CDOs had a five-day residential training program at the start of employment, eight all day meetings as a group with the research team, and three all day meetings with a range of participating community representatives in Melbourne, as well as having frequent email and telephone contact with each other and with the PRISM co-ordinators [22]. However, their employment was for only two years which may not have been long enough, especially given the changes to local government (described below) which militated against community building.

The negligible impact of the whole intervention on women’s partners was disappointing, and could have been a limiting factor in the effectiveness of the intervention in improving women’s health outcomes.

One explanation for the lack of effect of the intervention might have been that the elements of PRISM or other major alternative maternal health programs were implemented in comparison communities. Local government changes made that
unlikely but we assessed the evidence in 2001-2 through ‘unobtrusive monitoring’ [49] of policies, programs and funding at local, state, and commonwealth government levels [50], and an audit of GP Divisional projects, strategic plans and business plans. We also analysed systematic samples of local newspaper coverage of mothers and maternal health [51] and surveyed the MCH team leaders in each comparison community to ask about specific local initiatives, finding almost none.

In the five years this trial was being planned (1993-1997) there were marked changes to local government implemented by the State government, including the dismissal of elected local councillors, appointment of commissioners, and the amalgamation of local councils from 210 to 78 [52]. Service-contracting became a prominent feature of councils’ operation for the first time, with a requirement that at least half of all municipal services be put out to compulsory competitive tendering - including, in most municipalities, the MCH Program [53]. ‘In-house’ business units, comprising staff previously employed to provide the service directly, won some of the contracts for health and family support services. Some were won by community-based agencies, e.g. community health centres, some by hospitals, and some by private companies. Although the straitened funding co-incident with the reforms made the 50% chance of being provided with resource kits for mothers, professional development for MCHNs and a CDO for two years very attractive, the enforced competition was not the ideal context for a community intervention [54].

Conclusions
Given the study size, the comparability of the two arms, the evidence of implementation, and the almost identical health outcomes on all measures, it is most unlikely that this complex multi-faceted intervention improves maternal physical or psychological health.
<table>
<thead>
<tr>
<th>Author and year</th>
<th>Outcome measure</th>
<th>Timing of outcome assessment</th>
<th>Prevalence of probable depression (%)</th>
<th>RR [95% CI] of depression</th>
<th>OR [95% CI] of depression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gunn 1998 [39]</td>
<td>EPDS ≥13</td>
<td>3 months</td>
<td>16.8 vs 13.6 11.6 vs 12.8</td>
<td>RR 1.24 [0.81 to 1.90]</td>
<td>RR 0.91 [0.56 to 1.48] 7.38 vs 7.48 5.87 vs 6.08</td>
</tr>
<tr>
<td></td>
<td>EPDS mean score</td>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Morell 2000 [40, 41]</td>
<td>EPDS ≥12</td>
<td>6 weeks</td>
<td>17.8 vs 18.0 18.9 vs 21.6</td>
<td>RR 0.98 [0.69 to 1.41]</td>
<td>RR 0.89 [0.62 to 1.27] 7.4 vs 6.7 6.6 vs 6.7</td>
</tr>
<tr>
<td></td>
<td>EPDS mean score</td>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MacArthur 2002 [44, 45]</td>
<td>EPDS ≥13, multi-level modelling EPDS mean of cluster means</td>
<td>4 months</td>
<td>14.4 vs 21.3</td>
<td>OR&lt;sub&gt;adj&lt;/sub&gt; 0.57 [0.43 to 0.76] 6.40 vs 8.06</td>
<td></td>
</tr>
<tr>
<td>Reid 2002 [42, 43]</td>
<td>EPDS ≥12</td>
<td>3 months</td>
<td>14.6 vs 11.7 14.8 vs 9.6</td>
<td>RR&lt;sub&gt;w&lt;/sub&gt; 1.21 [0.79 to 1.85] ¶</td>
<td>RR&lt;sub&gt;w&lt;/sub&gt; 1.55 [0.95 to 2.52] ¶</td>
</tr>
<tr>
<td></td>
<td>EPDS mean score</td>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Priest 2003 [46]</td>
<td>Depression by DSM-IV criteria</td>
<td>Depression diagnosis during 1&lt;sup&gt;st&lt;/sup&gt; postnatal year</td>
<td>17.8 vs 18.2</td>
<td>RR 0.98 [0.80 to 1.02]</td>
<td></td>
</tr>
<tr>
<td>PRISM 2005</td>
<td>EPDS ≥13</td>
<td>6 months</td>
<td>15.7 vs 14.9</td>
<td>OR&lt;sub&gt;adj&lt;/sub&gt; 1.06 [0.91 to 1.24] 6.8 vs 6.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EPDS mean score</td>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* offered to all women, i.e. neither indicated nor selected

¶ Probable depression outcomes for the intervention subgroups (information pack ((P), invitation to group (G) or both (PG)) were pooled and compared with standard care (no pack, no group); RR<sub>w</sub> Mantel-Haenszel weighted relative risk
References


