Author's response to reviews

Title: Midwife-led debriefing after operative birth: four to six year follow-up of a randomised trial [ISRCTN24648614]

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Version: 4 Date: 23 January 2006

Author's response to reviews: see over
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Version: 2
Date: 23 January 2006

Authors’ response to reviews: see over
Thank you for the opportunity to respond to reviewer comments and to revise our manuscript.

Revisions have been made in the manuscript in response to the reviewer comments, and are detailed below, in blue and embedded in the two reviewer reports below:

**Reviewer 1:**

**Reviewer’s report**
Midwife-led debriefing after operative birth: four to six year follow-up of a randomised trial
Title: [ISRCTN24648614]

**Version:** 2 Date: 12 December 2005

**Reviewer:** Ellen Hodnett

**Reviewer’s report:**

General

1. Is the question posed by the authors new and well defined?
   Yes. It is an important, well-defined question.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?

   In general, yes, but I would recommend more detail on the methods used to trace and follow-up the trial participants.

   Also, did the investigators consider collecting data by telephone from those who failed to return questionnaires but were contacted by phone?

   **Resources did not permit further contact for data collection by telephone**

3. Are the data sound and well controlled?

   Yes

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

   In general, yes, but I would like the authors to include a table comparing responders to non-responders in terms of demographic characteristics, delivery outcomes, and EPDS scores at 6 months post delivery. A simple statement that there were no statistically significant differences is not particularly reassuring. There could be differences that are potentially important but did not quite meet the conventional criteria for statistical significance.

5. Are the discussion and conclusions well balanced and adequately supported by the data?

   Yes

6. Do the title and abstract accurately convey what has been found?

   Yes
7. Is the writing acceptable?

Yes. The manuscript is very well-written and succinct.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. A little more detail regarding methods of follow-up

More details have been provided about the tracing and follow-up of trial participants with the addition of the following on page 4:

“The initial mail out of the postal questionnaire and two reminder postcards to the contact addresses obtained at recruitment resulted in 322 completed questionnaires returned, (31.6%). Extensive telephone follow-up of women who had not responded was then undertaken, again utilising information obtained at recruitment. Upon contact and agreement to participate, the offer of sending a second questionnaire was made. A significant minority were in fact contactable at the same phone number, though at a new address, and so had not received the first questionnaire. Tracing via the current electoral roll and telephone directories of all women whose questionnaires were returned to sender, or were not contactable at the listed phone number was also undertaken and new questionnaires sent to those women able to be traced to a new address. With specific ethics approval we also initiated a new telephone contact procedure for identifying study participants from women with the same name, but several possible new addresses. After this extensive tracing and follow-up, 534 women (51.4%) responded. Not all women able to be contacted by telephone agreed to participate, and some who did, did not subsequently return questionnaires. We did not re-contact these women to collect data from them via telephone, mostly due to a lack of resources.”

2. A table (as noted above) describing responders and non-responders.

A new Table 1 demonstrating the comparability of recruitment characteristics of the responders in the two arms of the trial has been included, providing evidence for the claim made in the text of the manuscript that the trial groups were comparable (page 4).

“Responders in the two trial arms remained comparable in terms of women’s status at recruitment, with no differences in mode of birth, parity, maternal age, marital status, education, income or hospital admission status (Table 1).”

The second sentence of the Abstract has also been corrected to reflect this claim as it should have done originally (rather than claim that responders and non-responders did not differ, a mistake in the submitted Abstract):

“Responders from the two trial groups remained comparable at 4-6 years postpartum.”

The new Table 1 also provides the recruitment characteristics of the non-responders at 4-6 years and a sentence has been added on page 4 to note the differences between responders and non-responders, as per the data in Table 1:

“The differences reported between responders and non-responders at the six month follow-up\(^5\) were also apparent at the longer-term follow-up, with responders at 4-6 years more likely to have been married, older, better educated and to have higher family incomes at recruitment than non-responders. Additionally they were also somewhat more likely to have been having their first baby at trial recruitment than the non-responders.”

In response to the request to provide more information about the proportions of women responding and their EPDS scores at six months, the following information has been included on page 5:
“Of women responding at four to six years, there was no significant difference between the trial arms in the proportions who had scored as depressed at six months postpartum: 35/81, (43.2%) responded from the debriefing arm and 34/65 (52.3%) from the standard care arm; OR=0.69; 95% CI: 0.34-1.41).”

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

None

Discretionary Revisions (which the author can choose to ignore)

Consider including a sentence or two to explain why you did not try to collect data by telephone from those who failed to return questionnaires.

We note in an additional sentence on page 4, that after the extensive follow-up already undertaken to achieve a satisfactory response, resources did not permit additional contact via telephone to collect data from non-responders:

“We did not re-contact these women to collect data from them via telephone, mostly due to a lack of resources.”

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:
I declare that I have no competing interests.

Reviewer 2

Title: Midwife-led debriefing after operative birth: four to six year follow-up of a randomised trial [ISRCTN24648614]

Version: 2  Date: 14 December 2005

Reviewer: Debra Creedy

Reviewer's report:

General
This paper presents results of an important longitudinal (4 to 6 years) follow-up study to an earlier RCT. The response rate of 51% is good for a mailed survey and there were no significant differences in the proportion of women allocated to the original trial arms in terms of demographic
and birthing variables as well as depression at 6 months. The original trial suggested that participating in a single structured debriefing session in the early postpartum period, prior to discharge from hospital, did not reduce the prevalence of depression or show improvements in health as measured by the EPDS or the SF-36 sub-scales. The authors now conclude there are no longer-term adverse effects of debriefing after an operative birth.

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**Major Compulsory Revisions**

(that the author must respond to before a decision on publication can be reached)

The authors correctly identify the controversy surrounding debriefing following a traumatic event. Critique of debriefing in the childbirth literature concludes that that studies [6] & [9] reported unusually high levels of depression in the control arms and attribute this to possible adverse effects of assignment. In the case of the Gamble et al study, women were screened for trauma symptoms as an inclusion criteria. As there is a high level of co-morbidity between anxiety and depression and no significant differences were reported between cohorts in the trial, this statement should be amended as the rates of depression refelct the cohort not assignment.

Acknowledgement has been made (page 3) of the selection of women on the basis of trauma symptoms in the Gamble et al trial as a possible explanation for the high rate of depression in the control arm at three months (32%, vs 4% in the intervention arm; there were no differences in depression at 4-6 weeks postpartum, both arms around 33%).

However, this does not rule out a possible adverse effect of assignment to the control arm. Selecting for women who experienced trauma may indeed increase such a possibility. In this trial women were asked on four occasions about trauma and mental health issues: first in the third trimester of pregnancy, then within 72 hours of birth, again at 4-6 weeks postpartum and finally at three months postpartum, with no response to reporting of problems offered to women in the control arm.

The trialled intervention did not reduce the prevalence of Post Traumatic Stress Disorder at 4-6 weeks or at 3 months, though a small difference in mean number of trauma symptoms (2.54 vs 3.83) was found at 3 months favouring the intervention group. However the confidence intervals around these estimates overlapped. Given the lack of effect of the intervention in relation to PTSD and the fact that no differences in depression had been detected at 4-6 weeks postpartum, the continued high level of depression in the control arm at 3 months with a significant reduction in the intervention group, seems difficult to explain in terms of the intervention alone.

The conclusions drawn are possibly misleading. The statement in regards to a “hint” of adverse effects for women of debriefing at the initial follow-up at 6 months postpartum needs to be revised. The earlier trial concluded that debriefing was ineffective not harmful. It is also not feasible to conclude that short debriefing interventions do not improve mental health outcomes for women when the initial trial did not screen for trauma symptoms as an inclusion criteria nor did it measure anxiety or trauma symptoms as an outcome variable.

A reading of our BMJ paper will show that our conclusions about the findings at the initial six-month follow-up referred specifically both to the ineffectiveness of debriefing and, to quote: ‘we are not able to rule out the possibility that debriefing contributed to poorer emotional health’ (p1046) – a statement based on the consistent trend of our findings on all measures and one significant finding (for the role emotional sub-scale mean scores on the SF-36) favouring the control group. This was one of the reasons for conducting the longer-term follow-up of the debriefing trial participants, as we state in this manuscript.

We have therefore not amended the statement referring to the hint of adverse effects found at six months postpartum.
Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)

What next?: Accept after minor essential revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No