Author’s response to reviews

Title: Women’s experiences of participating in a randomised trial comparing alternative policies for timing of cord clamping at very preterm birth: a questionnaire study

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Author’s response to reviews:

Dear Editor-in-Chief,

RE: Re submission ‘Women’s experiences of participating in a randomised trial comparing alternative policies for timing of cord clamping at very preterm birth: a questionnaire study” (TRLS-D-18-00818)

Following the helpful reviewer comments on our paper, we have prepared a detailed response and revised the manuscript. Therefore we would like to resubmit our paper for consideration by Trials.

Please let me know if you require anything further.

Yours faithfully,
Lucy Bradshaw
Reviewer reports:

Reviewer #1:

- Thank you for asking me to review this paper.
I think it is well-written and important to publish

Thank you for your positive comment.

- Major comment is that it is crucial to have more information about how and when women were initially approached so the reader can understand the context. It is not enough just to refer to protocol and trial results - the paper should stand on its own. Also applies to places where say "described in detail elsewhere" without saying where, and [submitted for publication”. Need to explain what two stage consent pathway involves?

Response:

We have added a paragraph on the recruitment and consent process, including details of the two stage consent process, into the methods section of the manuscript (page 5).

The paper describing the responses to other questions on the questionnaires about symptoms of anxiety and depression, satisfaction with care at birth, and breastfeeding/expressing was recently published and so is now referenced in full in the manuscript.

- There were different response rates by trial arm. Did the women know the results of the pilot trial at the time of completing either questionnaire?

Response:

Women were not aware of the any of the results of the pilot trial at the time of completing either questionnaire (completed between June 2013 and September 2016). Women were sent the results
of the analysis of the outcomes to discharge from hospital after all follow-up for the women and their children (up to 2 years) had been completed in October 2017.

- There is mention of seven babies who died and did not complete or were not sent one or more questionnaires. It is not clear whether these were the total deaths and what checks were in place before sending questionnaires. Was there any adaptation to the approach or questionnaire if a baby had died? Although the responses were not quantitatively different between bereaved and non-bereaved parents, were there any qualitative differences?

Response:

We have revised the methods section to give more details of how we checked the status of the baby prior to contacting the family for the questionnaire follow-up, and how we adapted the approach if the baby died (page 5 and 6).

Twenty two babies died before discharge and for seven the site advised us not to contact the parents for the first questionnaire.

There were five parents whose baby died who completed the first questionnaire and four completed the second at one year. This small number does not allow qualitative differences between bereaved and non-bereaved parents to be fully explored. We have added a paragraph in the results section to clarify this (page 10).

- Page 4 line 78: ?add "and improving the experience of participants"

Response:

We have added this text as suggested.

- Page 13 lines 293-4: could be disappointed even if had fully understood. Reword?
Response:

We have rephrased this sentence.

Reviewer #2:

Interesting paper as it addresses a topic of clinical importance at a time when participants may be under considerable stress and therefore unwilling to contemplate participation in research so well done for managing to get many to respond.

Response:

Thank you.

- I like the presentation of the results and the introduction of the quotes in the table rather than the text. I would like to know why the authors used excel and not N6 which is a specialist software for handling qualitative data. Can you please comment on the analytic framework for the analysis? It would seem to me to be content analysis?

Response:

Thank you for your positive comment about the presentation of the results. Excel is one tool that can be used to organise qualitative data, and has been described as a useful tool for grouping open-ended responses into categories that can be summarised qualitatively and quantitatively, as we did in the current study (e.g. Meyer & Avery 2009, reference added to manuscript). We used inductive content analysis as the framework for analysis and have included this information in the manuscript (Page 7, paragraph 1).

- The clarity could be enhanced by a summary presentation of the trial and its findings.
Response:

We have added more detail to the methods section on the recruitment and consent process for the trial on page 5.

As described above in response to reviewer one, women were not aware of the trial results at the time of completing the questionnaires. We have not therefore added a summary of the trial findings to the manuscript as we do not feel this will contribute to understanding the women’s experiences of participating in the trial.

- Also I would like to see more discussion/presentation of the potential ethical issues around contacting participants in distress. Some statements are made throughout but worth considering all of those issues under 1 heading.

Response:

We worked with parent representatives from the National Childbirth Trust and Bliss (UK based charity for babies born prematurely or sick) to plan and conduct the trial (added on page 5), including contacting participants in distress. For example our work with Bliss prior to the trial with mothers whose babies died following preterm birth indicated that these mothers wanted the opportunity to continue to be involved and contribute to the findings.

- As some women appeared to have difficulty in understanding the randomisation process, how was that considered in the trial overall?

Response:

As we discuss, this is a common finding in similar studies and merits further research. As recruitment closed before we completed this analysis, we were not able to apply our finding to this pilot trial.
Other

Please note that we have corrected an error in the author contributions section.