Author's response to reviews

Title: Disappointment and adherence among parents to newborns allocated to the control group: A qualitative study of a randomized clinical trial

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Author's response to reviews: see over
Cover letter

Dear Claire Snowdon, Associate Editor of Trials

Thank you for considering our article - *Disappointment and adherence among parents to newborns allocated to the control group: A qualitative study of a randomized clinical trial* and for your very elaborate and thoughtful comments. We are very delighted to hear that you feel that our findings are interesting and useful.

We have been through the comments from both reviewers and from you and have responded to every comment in full and are now submitting a revised version for you to consider. We have used “track changes” in the manuscript to make it easier to follow the changes made. Below we have given a detailed description of our response to every comment from both reviewers and from you.

We are looking very much forward to hearing from you.

With best wishes,

Sandra Meinich Petersen, sandrameinich@gmail.com
Comments on - Disappointment and adherence among parents to newborns allocated to the control group: A qualitative study of a randomized clinical trial (Petersen et al)

P3 para 1 – please change “the need of randomization” to “the need for randomization”
Done

P4 para 1 – please drop “only” in “only few studies have addressed this issue”
Done

P4 I think that the following paragraph is somewhat problematic.

When the patient is a child the informed consent has to be given by the parents. Their motives for letting the child participate are complex, but the hope of getting a new and better treatment is important [2,9]. Altruism was reported as a parental motive for entering RCT’s for children suffering from pneumonia [10], congenital heart failure [11] and asthma [12].

The third sentence does not follow on logically from the second in fact it feels as if it counters it. The second sentence sets up desire for a better treatment as a primary motive with two references. The third which is referring to a very different motivation, altruism, has three references. This feels as if it is out of line with your focus. Your introduction is positing the possibility of disappointment on allocation to control precisely because you are focusing on the evidence that the primary motivation is access to benefit. The evidence that you put forwards for this is however more heavily weighted towards altruism. If altruism is an important motivator and benefits to others is the driving force, presumably allocation to control might not be an issue, in fact it may even be desirable. My view is that you need to balance things up a little here to introduce the reader to some of the issues which have been raised in the literature about parental reactions to the offer of trial participation. You might find the following two references from the same team give a useful overview in this regard:


Shilling VW, Williamson PR; Hickey, H; Sowden, E; Smyth RY, Young B. Processes in recruitment to randomised controlled trials of medicines for children (RECRUIT): a qualitative study: Health Technology Assessment, 2011.

See changes on p. 4 in the “Background” section. Both suggested articles has been incorporated to the manuscript and we have elaborated more on the description of parent’s motive for enrolling their child in a trial.

P4 reports the views of parents involved in the UK ECMO Trial. This is my research so I can clarify some things here. There are three papers about the parents in this trial. One looks at parents’ accounts of their decision to take part, and their thoughts on the design and process of allocation. That is paper 2 in your references and this showed parents to be disappointed on allocation to the control group, essentially because the experimental arm was viewed as highly desirable in the context of critical illness, and the comparison, continuing with standard intensive care as before, was viewed in comparison as doing nothing. In this study the parents were not aware of the outcome of the trial.

In a later study with a different group of parents from the same trial, we looked at reactions to the study once parents had been told the outcome of the trial: parents were told that ECMO had been
shown to be effective and had saved lives. These parents had to incorporate their new understanding and interpretation of their child’s allocation into their own previous model of the trial: as only parents of babies who survived were interviewed, allocation to control was viewed in the context of survival regardless of the outcome of the trial. This tells us about situated reactions to allocation to control i.e. in hindsight and in relation to survival. I thought that you were referring to this paper when you said:

Almost all of the parents understood the ECMO treatment as superior to standard care and especially the parents of the intervention group objected to the concept of randomization since they thought that the intervention had saved their child. The parents of the “standard care” group had experienced that their child had survived without intervention and were less critical of the concept of randomization.

In paper 2 which this refers to in your text, they cannot be said to have understood the treatment to be superior, only to have perceived it to be so, as at the time of the interviews this was unknown. I think that it would help your text if you either kept the citation as is but changed “understood” to “perceived” or separated these two elements out and referred to the two papers separately. They both deal with parental reactions to allocation to control so this would be appropriate. The reference to the results paper is: Snowdon C, Garcia J, Elbourne D. Reactions of participants to the results of a randomised controlled trial: an exploratory study. BMJ. 2001 Jan 6;322(7277):49-50.

Both articles are used as reference and the text has been changed to avoid misunderstandings as to what is referred to (p. 4-5 of the background section).

P5 – For the paragraph starting “Written information about the study was sent to the parents ...” I think it would help to have a preceding sentence which makes it clear that recruitment for Calmette took place during pregnancy, with randomisation delayed until post delivery. At the moment this is not clear to anyone unfamiliar with the reference to the third trimester, and they have to read further into the paragraph until it becomes obvious that the trial involved an antenatal recruitment strategy.

Done. P6 In line with Alan Tait’s comments it might be appropriate to state in the methods section that parents of children who were allocated to the intervention group were not interviewed. Also please change “parents to children” to “parents of children.”

Done.

P7 Para 1, please change “didn’t” to “did not” and “mothers to children” to “mothers of children”

Done

P8 Para 2, please change “educations” to “education”

Done

P9 You do not say how you organised your data. If you used a qualitative analysis package such as NVIVO or Atlas-ti please give details. If you used word or excel or another approach please add this.

Done. (Word was used)
P10 Para 1, please change “didn’t” to “did not” - occurs twice in this paragraph, and again in Para 4.
Done

P12 You use the phrase “would not be stung” to refer to the vaccination. I wonder if this is a literal translation as it is not a phrase that would be used in English. There is not an easy equivalent for formal writing although in casual speech we would refer to a vaccination as a “jab.” I think here you might have to say – would not be hurt by a needle, or would not have to have the vaccination.
Done

Para 4 Please change “couldn’t” to “could not”
Done

P14 Para 1 Please change “parents to children” to “parents of children”
Done

P16 Your two paragraphs on strengths and limitations of the study (paras 2 and 3) feel out of place and break the flow of the discussion. I think the discussion would read well if you moved these paragraphs to the end with a heading “Strengths and limitations of this study” and so allow the discussion itself to concentrate on drawing out the value of the data. Alan Tait made some useful comments on the lack of interviews with parents in the experimental arm as a comparison and you might consider incorporating a sentence on that in this section.

“Strengths and limitations”-section has been moved to the end of the discussion.

Regarding Alan Tait’s comment, such a sentence has been incorporated in this section:

We did not interview parents of children allocated to the intervention arm of the Calmette study, and therefore we are not able to determine if the reactions of parents in the control group differ from the reactions of parents in the intervention group.

P18 I feel that the most important part of your paper comes at the bottom of P18 where you state that research staff could emphasize the important role the child plays in the control group. This is the contribution to the literature that your paper makes and perhaps it could be given some further emphasis or prominence. You could for instance add a sentence on the implications for parents of feeling that their input has been of little value, or their time has been wasted. You could reflect on the importance of researchers indicating to their participants that they value their input. You may wish to reflect on the importance of educating the public about research. Whether or not you change this is up to you but I think that your very interesting finding is a bit underplayed here.

We have elaborated on this in the discussion. See page 20.

P19 Could you add a statement which outlines your plans for using your figure to support understanding of allocation to intervention or control arms. Will it be the subject of future study? Will you be using it in research practice? Is it already in use?
We have elaborated on this in the discussion. See page 20.
Reviewer 1:

Reviewer’s report
Title: Disappointment and adherence among parents to newborns allocated to the control group: A qualitative study of a randomized clinical trial
Version: 1 Date: 28 November 2013
Reviewer: Helen Sammons

Reviewer’s report:
Thank you for asking me to review this nice article. It focused on the views and feelings of parents when they are randomised to the control group. I found it well written and clear. It focused on the parents recruited to the control group using a focus group and interview methodology will saturation of themes. A good description of the trial was given and the recruitment process. The results were clearly described and well discussed.
The paper contains important information as to how important it is to give good information and ongoing support to the control group for their engagement and continued follow up.

Minor essential revisions
- It sound to threaten not threat.
- The fissures do not follow in order in the text.
- The figures do follow in order in the text. Figure 2 is mentioned for the first time in the “methods” section under “analysis of data” and figure 3 is mentioned for the first time in the “results” section.
- Figure 2 needs some further thoughts and discussion and how this might be used with parents and the outcomes of what a research team should do depending on the results.

We have elaborated on this in the discussion. See page 20.

Reviewer 2:

Reviewer’s report
Title: Disappointment and adherence among parents to newborns allocated to the control group: A qualitative study of a randomized clinical trial
Version: 1 Date: 31 October 2013
Reviewer: Alan R Tait

Reviewer’s report:
This study examined parents’ responses to having their child randomized to the control arm of an RCT of early BCG vaccination. While I think this is an interesting study, the findings are not entirely surprising.
1. This is a study wherein both the safety and efficacy of the experimental arm (BCG) are well-established and furthermore there is the potential for additional benefits with respect to reducing other infectious diseases in the first years of life.
The risks appear minimal. As such, I am not surprised that some parents were disappointed at being allocated to the control group. Although the authors allude to this in the limitations, it would have perhaps been more compelling to have done this study following an RCT that offered greater equipoise.
We agree that it is also be interesting to look at parent’s experiences in other kinds of trials, but we think that we have some important findings even if risks of participation appear to be minimal.

2. I also wonder why the authors did not interview subjects who received the experimental treatment. I imagine that they would be uniformly satisfied but it is also possible that some had regret. Interviewing the experimental arm group would have given you a better feel for any differences in the ways in which these 2 groups viewed their participation.

Agree, it would have been interesting to know if parents of infants in the intervention group were satisfied with their participation.

3. Feelings of satisfaction and disappointment are often a function of expectations. As such, it would be interesting to know exactly what subjects were told regarding the randomization process and the risks and benefits of each arm of the study. Perhaps the authors could include a copy of the consent document that dealt with these issues as an appendix.

English version of the information is attached as an appendix.

4. Did the fact that the focus group and telephone interview questions differ affect the identification of themes?

This has been commented in the text (p. 9)

5. For readers that are unfamiliar with qualitative research, it may be helpful to describe how thematic saturation was achieved.

This has been commented in the text (p. 8)

6. Results: It would be helpful to provide numbers. Terms such as “most” and “few” tell the reader very little.

For a qualitative study as this, we believe that numbers might mislead the reader to think that quantitative conclusions can be drawn which is why we have decided not to use too many exact numbers in the text.

7. The use of a tool to examine subjects’ attitudes towards research participation in an RCT is intriguing. Suggest further development and testing.

We have elaborated on this in the discussion. See page 20.