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 the revision of our article - Disappointment and adherence among parents to newborns allocated to the control group: A qualitative study of a randomized clinical trial. Once again we are very flattered that you have taken the time to make so elaborate and thoughtful comments.

We have been through your comments, have responded to every comment in full and are now submitting a revised version for you to consider. We have been through the manuscript thoroughly several times in order to get the chronology optimized and make the entire manuscript more coherent. We acknowledge that English is not our native language and have and have had an external revision for language mistakes on our final manuscript. Due to all the changes made to the document, we have uploaded a clean version. The “track changes”-version was simply unreadable. Below we have given a detailed description of our response to every comment from you.

We are looking very much forward to hearing from you.

With best wishes,

Sandra Meinich Petersen, sandrameinich@gmail.com
Reviewer's report:

Comments to authors

I still feel that the sentence “Altruism was reported as a parental motive for entering RCT’s for children suffering from pneumonia [10], congenital heart failure [11] and asthma [12]” is at odds with your central focus. I would be inclined to drop this or move it to the discussion to say of course personal gain is not the only reason that people take part in trials .........., but in our study ...... Alternatively you could keep this sentence where it is but reduce the way it undermines the thrust of the paper e.g.

Their motives for letting the child participate are complex. While altruism has been reported as a parental motive for entering RCT’s for children suffering from pneumonia [10], congenital heart failure [11] and asthma [12, the hope of getting a new and better treatment has also been shown to be important in a number of studies [2,9].

The reference has been moved to the discussion where we want researchers to build on altruistic motives for participation.

Methods

The methods section was a problematic part of the paper in the original submission and in reading through the current version it still unclear. P 6-9 therefore still requires some clarification, partly in relation to the terms used, partly in relation to the structure used in the text.

Although the term “focus group interview” is sometimes used in the literature, they are commonly referred to as simply focus groups. You sometimes refer to your focus group as “the interview” and this can be confused with the telephone interviews. It is important to keep them distinct and this can be achieved by referring to the focus group and the telephone interviews.

The paragraphs which deal with the two methods are still a bit muddled. Please remove the heading “Interviews” on P6 as in this section you are talking about your rationale and change of plan not the interviews. I recommend ending this section of text after “group of mothers” which would mean your intro to the methods section would be the opening sentence plus the sentence starting “Originally we planned ...” up to “group of mothers.” This would give you an overview of the methods from which you could go on to describe the methods in detail.

Then you should move to a paragraph on the focus group, and then move on to deal with the interviews separately. Your approach had a chronology to it – focus group, learning from the focus group and developing your interview schedule,
then interviews, and your text should clearly follow this chronology. At the moment it is mixed up, for instance at the start of the methods section you mention themes identified in the focus group before you have described the focus group, and recruitment strategy for the interviews comes before the focus group difficulties which shaped your approach to recruitment for the interviews.

“Focus group interview” and “interviews” changed to “focus group”. Header “Interviews” removed. We have now described the process in a more chronological manner to address the issues mentioned above.

In my original feedback letter I pointed out that the paragraphs on focus group, interviews and analysis contain no methodological references. References are still needed here to indicate the value of your choice of method.

We have put in a reference to Krueger about focus group interviews.

Analysis of data
P9 There is the same problem with chronology here as in the methods section, as you describe thematic analysis before you mention coding your data. As you describe your approach later in the paragraph I suggest dropping the first sentence – “Thematic analysis was ...” and working in reference 21 later in the paragraph.

The term “asked directly into the main topics” does not translate well and it is not entirely clear what is meant. Do you mean that they were similar?

Changed to meet the comments of the reviewer, both regarding chronology and unclear sentences. See p. 9, p2

The figures 2 and 3 have switched order, so that number 3 is now number 2 and vice versa.

Results
There are two difficult sentences on P12 starting “Especially parents ..” Can I suggest a rearrangement:

Some of the parents were themselves affected by atopic diseases and were aware of the burden of the disease to which their children would be predisposed. These parents were disappointed at allocation to the control group.

Changed according to the reviewer’s suggestion. Next sentence was also problematic and has been changed to give it a better flow.

Discussion
On P17 you argue that your findings on disappointment raise four issues. For the first point I think that it stands alone as a valid query without needing to refer to recall bias. That suggests that the issue would go away if the participants remembered things differently but presumably your point transcends this. For point 2 you argue that trust may be undermined if “interventions perceived as beneficial are tested in placebo controlled trials”.

Is the issue not the perception of the intervention (sounds as if you are saying trials should nt explore intervention which are perceived as beneficial) but that trials are testing an
intervention without it being made clear that there are some potential concerns about its use? If interventions might be perceived as beneficial, greater efforts need to be made to make clear what queries exist around that intervention to make a trial necessary. That is really an extension of point 1. The issue of trust flows (potentially) from the quality of information and I am not sure that it is a separate point. For point 4 the sentence “This is obviously .... is beneficial” is confusing and I suggest dropping it.
I also wonder about including your Greisen reference here. I don’t know the paper (my Danish is non-existent!) but suspect it refers to the play the winner approach to randomisation. If this paper does not provide empirical evidence that trial participants prefer play the winner approaches in situations where they may have a preference, it does not seem to be an appropriate reference. If it does, I think the text needs to be clarified as no everyone will know what it refers to.
The text from “Yet policy makers ..... clinical care” is difficult to make sense of and does not flow well. The final point is not clear.

The entire paragraph has been rewritten. See p. 17.

Minor comments
P3 Para 1 – Please change “randomised trial (RCT)” to “randomised controlled trial (RCT)”
Done
P4 Para 1 The numeric reference [7] should be moved to the end of the following sentence i.e “... understand the study design. [7]”
Done
P4 Para 2 – Please change “parents has” to “parents have” and the sentence would be easier to read if “as would be relevant if” were replaced with “as if they were”
Done
P4 Para 2 – Please change “benefit of” to “benefit to”
Done
P4 Para 2 – The sentence “Parents are very satisfied with being asked for consent .... “ could be rephrased. In English the reference to satisfaction suggests that they are happy with the process, whereas what I think you are saying is that they feel that it is an appropriate role and would not wish to have this role taken on by someone else. There are a number of papers which show that parents want to be the decision maker. What about “Research has shown that parents see the decision about trial participation as an important responsibility and see asking for their consent as appropriate, even if .... “
Done
P4 Para 3 – Please change “parents to children” to “parents of children.”
Done.
P4 Para 3 – Please add a full stop after “doing nothing”.
Done

P14 Para 2 – Please change “interest for” to “interest in”
Done

P15 Para 4 – Please change “child vaccinated three” to “child vaccinated at three”
Done

P16 Para 1 – It would be more neutral if “was a risk” was replaced by “was a possibility”
Done

P17 Para 2 – Please change “parents describe that” to “parents described how”
Done

P17 Para 2 – Please change “achieve to get” to “are able to access”
Done

P17 Para 2 – Please change “it questions if” to “it raises the question of whether”
Done

P18 Para 3 – Please change “parents in risk” to “parents at risk”
Done

P17 Para 3 – The clause “and thus feel as having been led astray in the initial consent process” does not fit easily into the sentence. If you cut this clause the sentence is easier and still makes sense.
Done

P20 Para 1 – Suggest changing “didn’t pick up the phone or didn’t have time to participate” for “did not participate.”
Done

P20 Para 2 – Please change “determine if” for “determine whether”
Done

P17 Para 2 – Please change “of a healthy population” to “parents of a healthy population of children rather than parents of a sick population.”
Done

P17 Para 2 – Please remove the sentence starting “Finally the experience” – the whole point of the study is to look at a blinded study – it is not a limitation.
Done