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: 2 Date: 12 February 2014

Reviewer: Claire Snowdon

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].

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.
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.

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?

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.

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 test 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.

Minor comments

P3 Para 1 – Please change “randomised trial (RCT)” to “randomised controlled trial (RCT)”

P4 Para 1 The numeric reference [7] should be moved to the end of the following sentence i.e “… understand the study design. [7]”

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”

P4 Para 2 – Please change “benefit of” to “benefit to”

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 .... “

P4 Para 3 – Please change “parents to children” to “parents of children.”

P4 Para 3 – Please add a full stop after “doing nothing”.

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

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

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

P17Para 2 – Please change “parents describe that” to “parents described how”

P17Para 2 – Please change “achieve to get” to “are able to access”

P17Para 2 – Please change “it questions if” to “it raises the question of whether”

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

P17Para 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.

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

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

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

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.