Author's response to reviews

Title: How do parents experience being asked to enter a child in a randomised controlled trial?

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Dear Sirs,

MS: 1169064572229059 - How do parents experience being asked to enter a child in a randomised controlled trial?

We would like to thank the reviewers for their helpful comments.

In response to the discretionary revision suggested by Dr Rodriguez we have included a discussion of the limited research on factors affecting the recruitment of different socio-economic and ethnic groups to randomised controlled trials of medicines for children. This discussion can be found on pages 13-15 of the manuscript.

We have also made several small changes to the main body of the text beyond the request of the reviewers which we hope will be acceptable to the editorial board. These changes comprise:

1. The deletion of the sentence “and parents sometimes see trials as a source of hope” from the abstract (page 2 line 16).

2. The rewording of the sentence “recommendations for discussing randomised clinical trials” to recommendations for how to discuss randomised clinical trials” (page 3 line 24).

3. The rewording of the sentence “Zelen randomisation was viewed negatively by some because they perceived it as preventing the sense that they were operating in the best interests of their child” to read “However, Zelen randomisation was viewed negatively by some parents because they perceived it as preventing the sense that they were operating in the best interests of their child”. (Page 6 lines 20 and 21).

4. The rewording of the sentence “involved in decisions which in their view concerned serious, ‘life or death’ matters” to read “involved in decisions which they viewed as serious”. (Page 8 line 10).

5. The rewording of the sentence “In such research contexts, the day to day management of the child’s condition, their quality of life and the simple practicalities of trial participation may gain importance” to read “In chronic childhood illness, the day to day management of the condition, the child’s quality of life and the simple practicalities of trial participation may gain importance”. (Page 9 lines 3 and 4).
6. Deletion of the word “too” (Page 11 line 20).

7. Insertion of the words “and group” into the title to read “Individual and group differences” (Page 12 line 3).

8. The rewording of the sentence “the therapeutic misconception does not necessarily reflect a failure of the researcher to adequately explain the research methodology” to read “the therapeutic misconception does not necessarily reflect a straightforward failure of the researcher to adequately explain the research methodology or of the parent to understand it” (Page 17 lines 11-13).

I look forward to hearing from you in the near future.

Yours faithfully,

Val Shilling