Author's response to reviews

Title: Comparison of group counseling with individual counseling in the comprehension of informed consent: a randomized controlled trial

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Author's response to reviews: see over
The Editor,
BMC Medical Ethics,

Dear Editor,

On behalf of the authors, I would like to you and the reviewers for their comments on the revised version of the manuscript.

Please find below, the original comments followed by our responses in italics. We have highlighted all changes made in the revised manuscript as ‘track-changes’.

We hope that you find this revision suitable for publication.

Yours sincerely,

Gagandeep Kang

Comments from Reviewer 2 (Zelee Hill):

I have read the authors responses and the new draft of the manuscript and feel that the authors have addressed my main points.

We thank the reviewer for her favourable comments on our revisions.

I suggest the following minor changes.

1- page 5 line 2 change comprehend to recall

As suggested by the reviewer, we have now changed the word from ‘comprehension’ to ‘recall’. The sentence (page 5, lines 2-3) now reads:

“This study was conducted to assess whether participants subjected to group counseling recall the informed consent better than those subjected to individual counseling.”
2- page 5 line 25 add 'individually' randomized to the description

We have now added the word ‘individually’ randomized to describe the randomization scheme adapted for the study on nutritional supplementation. The sentence (page 5, lines 24-26 & page 6, line 1) now reads:

“The parents of these children were then approached to allow their child to participate in a study wherein they were individually randomized to receive either a nutritional supplementation and health education or health education alone for a period of three months.”

3- correct typo on page 11 line 23

We have corrected the typo on page 11, line 23. The sentence (page 11, lines 21-24) now reads:

“Using a simplified version of the written consent document with pictorial representation and the use of consent educators or professional nurses with prior research experience have also been shown to improve the participants’ comprehension [30-32].”

Comments from the Associate Editor:

There is one additional modification that I think the authors need to make, which is to note the following comment of Dr Taylor as a limitation of their study:

“there is no discussion of what if anything was discussed in the groups that may have fostered understanding, nor any discussion of what was not said in individual sessions. Unless the individual obtaining consent from the individual refused to engage in discussion, there is little of substance to compare across the two groups of subjects”

I think that as long as the authors note that it is a potential limitation of the study that we can’t know for certain what was discussed in the group sessions / not discussed in the individual sessions, and that this might be relevant to their results, that should take care of this concern.

As suggested by the editor, we have now modified our discussion section to incorporate this as a potential limitation of our study. The sentence (page 12, lines 12-18 now reads):

“Further, although the study nurses were provided with a checklist to cover all the relevant points at the time of administration of informed consent, the researchers did not exercise any control over the discussions during the counseling session, either group or individual. Comprehension of potential participants who were counseled individually could have been adversely affected if they felt intimidated to engage in a discussion with the study nurse.”