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 thank the reviewers for their painstaking review of this manuscript. Their helpful comments have aided us in improving this paper.

Please find below, the original comments by the reviewers followed by our responses in italics.

We hope that you find the revision suitable for publication.

Yours sincerely,

Gagandeep Kang

Comments from Reviewer 1 (Holly Taylor):

This is an interesting article but fails on a number of important points. First, no literature that supports the team's hypothesis that a group counseling session may be better than a one-on-one conversation regarding subject/patient understanding is provided. I could argue that the group process may be worse as individuals may be embarrassed to ask questions in front of others, etc. It is also not clear that the trial was controlled in any way to not come to the exact result that they found. That is, 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 the 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 (and the latter would also be unethical so I understand why they wouldn't do this but it would certainly get in the way of getting a reliable answer to their research question OR they could have assessed their understanding before the discussion and after, etc.. What the results of this study seem to show is that neither approach is very good at providing information that the subject will be asked to retain for 48-72 hours. We know for example, that understanding is best assessed right after the information about which the individual will be quizzed. It is not a surprise that few retained the information, nor that particular aspects of the information shared was less likely to be retained (i.e. this is not a contribution to the literature) There is also a concern with the statistical analysis conducted. I am not an expert in statistical analysis but I imagine there are statistical ways in which the fact that some learned in groups and others on their own has an effect on how they should be 'counted' in the analysis, that is, is a
group counted as 1 or as 8 if there were eight participants. If the latter then there is no presentation of any adjustment made for the role of the group process.

We appreciate the concerns raised by the reviewer on different aspects of the paper. Prior to conducting this study, we did a literature search using PUBMED. To the best of our knowledge, there were no reports on the efficacy of group counseling in administration of the informed consent. We have already mentioned this in the ‘Background’ section (page 4, lines 20-22) of our manuscript. Subsequently, a study on factors influencing recruitment and preference for informed consent process among low-income women found that a majority of participants preferred a ‘group’ consent process (Kneipp et al., Public Health Nursing, 26: 362-369). We have now added this citation to our manuscript as a proof of our hypothesis (page 4, lines 25-26):

“In a community-based survey involving low-income women, the participants preferred a ‘group consent’ process [16].”

Regarding the discussion between the person administering the informed consent (study nurses) and the participants in both, the group and the individual counseling arms, the consent administrators were provided with a checklist covering all relevant points in the informed consent document (outlined in page 6, lines 20-21). Following administration of the informed consent, the participants were encouraged to foster discussion among themselves by the study nurses, who also acted as facilitators, answering any specific queries raised by the group or the individual. This procedure was followed to avoid any bias in the administration of the informed consent as well to make the informed consent process as close to a real-life scenario as possible.

The survey to assess the comprehension of the informed consent was conducted 48-72 hours after administration of the informed consent to facilitate independent reviewers to assess comprehension, and hence reduce information bias. As already mentioned in the manuscript, the assessors were blinded to the allocation group of the respondents (page 7, lines 12-13). Similarly, we did not opt for a before-after design as we would not have been able to blind the assessors, thereby leading to a potential bias in the outcome assessment.

Although the unit of randomization was a balwadi to prevent contamination, the statistical analysis was conducted using individuals as units. We understand that cluster randomized trials could have a ‘design effect’ which needs to be adjusted for during the analysis. Hence, we had calculated the intracluster correlation coefficient (ICC) to understand the effect of ‘clustering’ in this study, the results of which have been added to our manuscript. Our analysis suggested that the design effect was low; therefore, we did not adjust for this in our analysis. We have now made it more explicit in our manuscript, by adding the following sentences (page 8, lines 3-6) to the statistical analysis section:

“The intracluster correlation coefficient (ICC) calculated for the present study was found to be 0.02. Consequently, the design effect was calculated as 1.1 (1.0 -1.2), with a median (range) cluster size of 7 (3 -12). This was considered to be low [18], hence, standard methods of analysis were used.”
Comments from Reviewer 2 (Zelee Hill):

The paper is clear and well written and is a useful addition to the limited data on methods of improving informed consent in developing country settings. I am not a statistician but I am concerned about the small sample size and feel that the authors need to justify and discuss it.

We thank the reviewer for her comments. Taking into account her reservations on the sample size for the study, we have now added a sample size calculation to the methods section of the manuscript. We hope that this will address the concern raised by the reviewer. The paragraph on sample size (page 7, lines 18-24) now reads:

“Sample size was calculated considering knowledge of the study intervention as the primary outcome variable. Accounting for a 10% loss to follow-up the sample size was calculated to be 120. With an alpha error of 5%, this would have a power of 80% to detect a difference of 25% in the primary outcome variable between the intervention (group counseling) and the control (individual counseling) arms. We did not adjust for clustering as we expected a very low design effect, given the homogeneity in the socio-demographic and educational profile of our potential participants.”

Minor Essential Revisions:

# The end of paragraph 2 page 4 reports that recall is affected by delivery method. The statement somewhat contradicts paragraph 1, which reports that retention of information is poor regardless of delivery method. Perhaps it would be better to say that although delivery method can make some difference, retention levels remain low in most settings.

We have now modified the two paragraphs taking into account the suggestion by the reviewer. The paragraphs read as follows (page 4, lines 2-17):

“The doctrine of informed consent is a cornerstone of ethical medicine, both in clinical and in research settings. However, research has shown that often participants do not understand all of the information required to make an educated choice [1-3]. Studies have shown that the participants’ ability to recall facts differ with different methods of providing information [4-6], although retention of information is usually poor in most settings. There are profound difficulties concerning the understanding of risks, which is crucial information that patients need to comprehend to make appropriate decisions and act in what they believe to be their best interests [7]. The comprehension of informed consent is also often influenced by the socioeconomic background and the environment of the study participants [8].

Studies, particularly from developing countries, are often carried out in settings with individuals from different cultural backgrounds and education levels, thereby posing challenges in administering the informed consent [9]. The moral importance of appropriate and complete communication of information cannot be overemphasised in this context.”

# Page 5 paragraph 3, please insert the number of balwadis and the total number of children surveyed to find the 128 respondents.

We have now added the total number of malnourished children identified and the total number of balwadis. The sentence reads as follows (page 6, lines 3-5):
“Out of a total of 141 malnourished children identified from the balwadis, 128 (90.8%) children were enrolled following written informed consent given by their parents [17]."

# When describing the study site on page 5 please indicate whether this is a predominantly rural or urban area. In the same paragraph please state what the blood samples were for.

The study was conducted in 16 rural balwadis in the Kaniyambadi block of Vellore district. The blood samples were collected for estimation of serum albumin, plasma zinc, plasma vitamin B-12, hemoglobin and red cell indices. We have now mentioned these and the paragraph now reads (page 5, lines 21-26 & page 6, lines 1-5):

“A survey was conducted in 16 rural pre-schools (balwadis), run by CHAD in the study area, to identify children with malnutrition. Children attending these balwadis come from families with similar educational background and SES status (CHAD, unpublished data). The parents of these children were then approached to allow their child to participate in a study wherein they were randomized to receive either a nutritional supplementation and health education or health education alone for a period of three months. Blood samples were collected at baseline and towards the end of the study for the estimation of serum albumin, plasma zinc, plasma vitamin B-12, hemoglobin and red cell indices. Monthly anthropometric measurements were also obtained. Out of a total of 141 malnourished children identified from the balwadis, 128 (90.8%) children were enrolled following written informed consent given by their parents [17]."

# Page 6 paragraph 1, please explain whether randomization to supplement or control group was also by balwadi, and confirm that a similar number of supplement and control balwadis were in the group and the individual counseling arms.

The study on malnutrition supplementation used a separate randomization scheme and was run independent of the study on informed consent. In that study, which has been submitted for publication elsewhere, the children individually were randomized to receive either the nutritional supplement (RUTF) and health education or health education alone. We have referenced that study (Singh et al., Ref. No. 17) in our manuscript, but did not provide the details as we think that this could confuse the reader.

# Paragraph 2 page 6, confirm the number of study nurses administering the consent? In the acknowledgments there appear to be two nurses but in the text only one is referred to. If there were two nurses describe how the group and individual arms were divided between them. If one nurse administered all of the group consent and another all of the individual consent include this as a limitation.

There were two study nurses who administered the informed consent. The balwadis were distributed in such a way that both nurses had an opportunity to administer the group as well as the individual informed consent. This was done to reduce potential bias that could have arisen from one nurse administering all individual consents and another administering all group consents. This fact has now been made more explicit in the paper. Page 6, lines 18-20 now reads:

“The informed consent was administered by two study nurses, well versed with the study protocol. Each nurse was assigned equal number of balwadis in the group and individual informed consent category.”
# In paragraph 3 page 6, confirm that the fieldworker and the study nurse are different people.

We have now modified the paragraph, making it more explicit that the persons administering the informed consent (study nurse) and the outcome assessors (field workers) were different people. The paragraph (page 7, lines 4-16) now reads:

“Approximately 48-72 hours following administration of the informed consent, each participating family representative was approached by a field worker, not involved with the informed consent process, and interviewed with the help of a structured questionnaire. The questions were primarily focused on assessing the respondent’s recall of key elements of the informed consent, which were understanding the fact that his/her child was participating in a research study, recognizing the nature and purpose of the study, the risks and benefits of participation, random allocation to either intervention or control arm, the voluntary nature of participation and the freedom to withdraw at any point. Socio-demographic data were also collected at baseline. The interviewers (field workers) were blinded to the allocation group of the respondents. Verbal consent was obtained from all participants prior to administration of the questionnaire. Both the study on informed consent and the study on nutritional supplementation were independently evaluated and approved by the CMC Institutional Review Board.”

# Page 7 paragraph 1, replace the word ‘comprehension’ with “recall’.

As suggested by the reviewer, we have replaced the word ‘comprehension’ with ‘recall’. The sentence (page 7, lines 7-12) now reads:

“The questions were primarily focused on assessing the respondent’s recall of key elements of the informed consent, which were understanding the fact that his/her child was participating in a research study, recognizing the nature and purpose of the study, the risks and benefits of participation, random allocation to either intervention or control arm, the voluntary nature of participation and the freedom to withdraw at any point.”

# In the paragraph on statistical analysis please explain whether the data were corrected for clustering or if they needed to be weighted – it is unclear whether the 128 children represented all of the children in the balwadis with malnutrition or a sample.

The intracluster correlation coefficient for this study was found to be 0.02. Given the small cluster size (median=7, range = 3-12), the design effect was low (1.1, 1.0-1.2). Hence, we did not correct for clustering in the analysis of data and used the standard methods of analysis. However, adjustment for clustering would not have affected the overall findings of this study as the results would be more conservative following the adjustment. We have now added a sentence in the statistical analysis section of the manuscript addressing this issue. The sentence (page 8, lines 3-6) reads as follows:

“The intracluster correlation coefficient (ICC) calculated for the present study was found to be 0.02. Consequently, the design effect was calculated as 1.1 (1.0 -1.2), with a median (range) cluster size of 7 (3 -12). This was considered to be low [18], hence, standard methods of analysis were used.”
Baseline assessment of malnutrition in the 16 balwadis identified a total of 141 children with malnutrition, out of which 128 (90.8%) families provided written informed consent and participated in the study.

# Unless it is the journal policy reduce the number of decimal places. Using 2 decimal places gives a false idea of the accuracy of the results.

Based on the recommendation of the reviewer we have now reduced the number of decimal places to 1 decimal place throughout the manuscript as well as in the tables.

# Table 2 is not referred to in the text.

We have now added a sentence in the text referring to Table 2 at the end of the results section. The sentence (page 10, lines 10-12) reads:

“Table 2 summarizes the result of the comparison of the respondents’ understanding of the key elements of the informed consent between the intervention and control arm.”

# Paragraph 4 page 10 – Clarify whether the authors’ hypothesis is that SES is too low for any method of gaining consent to work and discuss the strategies and option for improving consent in more detail.

We believe that it is not just SES but also education that influences understanding. We have now added a discussion on different strategies and options for improving the informed consent in this paragraph (page 11, lines 14-26). It now reads:

“This apparent lack of difference between the intervention and control group could be due to many factors including the fact that a large proportion of our study population comprised mainly of people from the low SES and with lower literacy levels. Previous studies have shown that illiteracy and SES adversely affect a participant’s comprehension of the informed consent [26-28], although, in a multicentric trial of a lipid lowering agent, researchers noted that the comprehension of the study participants did not differ by education or SES provided the consent form is explained in a simple language [29]. 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 to have also been shown to improve the participants’ comprehension [30-32]. Devoting more time for explanations, use of the local language and obtaining consent at home have also been suggested as potential means to improve the informed consent process [33].”

# Paragraph 1 page 11 – this is a little confusing as it is not clear whether the two issues discussed in this paragraph are linked. I would like the first sentence to be expanded; the authors could explain that participants in different types of studies may respond differently to the informed consent delivery mechanisms – a hypothesis for why this may be the case should be given. The authors should then clarify that ‘A second limitation is that all recruitment in a particular…’

We have now modified the paragraph as suggested by the reviewer. It (page 12, lines 2-14) now reads:
"A major methodological limitation of this study was that it was not conducted across different studies. It has been shown that parents of children with acute life-threatening conditions find it more difficult to comprehend information than parents of children with less acute conditions [34]. Also, researchers have found that inability to concentrate at the time of signing the consent form could also adversely affect comprehension of the study procedures and outcomes [35]. Under such circumstances, the group consent process might be more effective as the participants are more likely to share information amongst them. A second limitation of this study was that all recruitment in a particular balwadi (for the study on nutritional supplementation) was done on the same day, thus the effect of intervention may have been diluted to some extent as the control group could possibly have discussed the research study. Studies conducted across a more diverse population group and in a more controlled environment might provide better results."

# I have serious concerns about the sample size of the study – especially given that it was cluster randomized. Can the authors please present a retrospective power calculation so we can judge whether the lack of difference was due to small sample size.

We had calculated the sample size based on the assumption that knowledge about the study intervention (primary outcome) would differ by 25% between the intervention (group counseling) and control (individual counseling) arms. Based on the above hypothesis, and taking into account a 10% loss to follow-up, the total sample size was determined to be 120. No adjustment was made to account for clustering because we expected a very low design effect, given the homogeneity in the socio-demographic and educational profile of our potential participants, which is reflected in the intracluster correlation coefficient for this study (page 8, lines 3-4). This would have had a power of 80% to detect the above-mentioned difference. We have now added the sample-size calculation to our manuscript (page 7, lines 18-24). The paragraph on sample size calculation thus reads:

"Sample size was calculated considering knowledge of the study intervention as the primary outcome variable. Accounting for a 10% loss to follow-up the sample size was calculated to be 120. With an alpha error of 5%, this would have a power of 80% to detect a difference of 25% in the primary outcome variable between the intervention (group counseling) and the control (individual counseling) arms. We did not adjust for clustering as we expected a very low design effect, given the homogeneity in the socio-demographic and educational profile of our potential participants."

# The final sentence in the conclusion does not relate to data presented in the results or discussed in the discussion. Remove or include the data that illustrate this in the discussion. This should also be removed from the abstract.

As per the suggestion of the reviewer, we have now removed the sentence from the conclusion as well as the abstract.

# In the tables please include % in brackets for the categorical variables. In table 2 consider presenting the difference between the intervention and the control and a confidence interval.

We have now modified the tables, incorporating the suggestion of the reviewer.
Comments from our Associate Editor:

There are a number of concerns identified by the reviewers, some of which are fairly significant. The authors will need to respond to the concerns raised by both reviewers in order for the manuscript to be accepted. Both reviewers have identified particular concerns related to statistical analysis, and the authors might want to consider seeking advice or input from an expert on this point.

*We have now modified the manuscript extensively, keeping in consideration the suggestions of the reviewers. We have added the rationale for the sample size consideration and the analytical approach adapted in this paper. We hope that the reviewers and the editor find our explanation and modifications satisfactory and favourably consider our manuscript for publication.*