Reviewer’s report

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

Version: 1 Date: 28 November 2009

Reviewer: zelee hill

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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.

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.

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

# 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.

# 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.

# 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.

# In paragraph 3 page 6, confirm that the fieldworker and the study nurse are different people.

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

# 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.

# 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.

# Table 2 is not referred to in the text.

# 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.

# 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….’

# 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.

# 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.

# 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.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**
I declare that I have no competing interests