Reviewer’s report

Title: Lessons Learned on Recruitment and Retention in Hard-to-Reach Families in a Phase III Randomised Controlled Trial of Preparatory Information for Children Undergoing General Anaesthesia

Version: 0 Date: 10 May 2017

Reviewer: Luciane Costa

Reviewer's report:

This is one-of-a-kind study that should be encouraged in the field of paediatric dentistry research. I congratulate the authors for their efforts in aiming to share clinical trial design issues and solutions. Much appreciated. I could not find similar studies focusing on longitudinal paediatric dentistry trials, but I did find analogous papers using this kind of design in other fields (e.g. Aventin Á, Lohan M, Maguire L, Clarke M. Recruiting faith- and non-faith-based schools, adolescents and parents to a cluster randomised sexual-health trial: experiences, challenges and lessons from the mixed-methods Jack Feasibility Trial. Trials. 2016;17:365).

However, I have some questions/comments that could help in the clarification of this report:

1. As this is a "research article" type, it should follow the BMC Oral Health Author Guidelines:
   1.1. Abstract: The abstract must include the following separate sections: background, methods, results, conclusions, trial registration.
   1.2. Introduction should be named "Background".
   1.3. The name "Methods" is not written. In fact, methods' subheadings were presented: The current trial, Sample description.
   1.4. Methods should include the design of the present study. It is not clear for me if it has a qualitative or quantitative approach. Do the authors see it as a descriptive study? This definition will also guide the analysis of the data produced in the study.
   1.4. Results section. I understood that the authors chose to blend results and discussion. It has benefits but also limitations, because the description of the results were lost in some parts, as detailed below. The authors should justify their choice for this format and amend the text as needed.
2. I have some questions about the contents themselves:

2.1. Please provide a detailed description of the pilot study in the Methods' section, because it was cited many times in the following parts of the manuscript.

2.2. Please add the method for the analysis of the "data" from this study. It is not clear how did the authors systematically collected data to support their results on "lessons learned". For example:

- Page 6, lines 16-18: "We found that time spent (...) family engagement." What kind of data does support this statement? Did you have cases where you did not spend time with child assent?

- Page 6, lines 31-35: "We found that asking (...) participate".

2.3. What did the authors learn from the pilot study that led to changes in the clinical trial processes, regarding recruitment and retention of participants? Maybe, the authors could clarify what they did make different after the pilot study. This would be a concrete analysis, in my opinion, that would support the discussion provided. In fact, we can observe some results from the pilot study in the current version of the manuscript, namely "Flexibility with recruitment timings" and "Lessons learned concerned retention of participants", but it should be improved.

2.4. Page 9, lines 26-33: Descriptive data for those statements?

2.5. What are the limitations of this study?

2.6. Can conclusions be rewritten to not repeat results, but to consolidate them?

3. Typo mistakes:

- Page 5, line 4: "are typically are"

- Page 6, line 29: "[ref here]"

- Page 11, line 10: "[ref]"; "a the personal"

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.
Yes

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Yes

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

**Quality of written English**
Please indicate the quality of language in the manuscript:

Acceptable

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