Reviewer's report

Title: Mothers' perceptions on their child's enrollment in a randomized clinical trial: poor understanding, vulnerability and contradictory feelings

Version: 1  Date: 28 October 2013

Reviewer: Ruth Freeman

Reviewer's report:

Review comments

This paper makes an important contribution to the literature on mother's experience of taking part in an RCT. No research can be conducted without participants' consent. As such, studies like this can be seen just as critical as the results of RCTs. The case is further strengthened in the context of paediatric dentistry where a decision is made on behalf of the young child by their parents. This study was appropriately designed for the nature of its aim with a semi-structured interview allowing mothers greater freedom to express their views while reserving some structure for essential questions in line with study objectives. The analysis of the interviews revealed some of the complexities of mothers' feelings about taking part in RCTs and on allowing for their children to receive randomly allocated procedures.

I would like the authors to modify the paper in the following ways:

a. Clarity of expressions

It is understood that the paper was prepared by a non-native user of the English language. While any reader would not have great difficulty with understanding the main findings of the study, better clarity may be required.

b. Quantitative details

Although this was a qualitative study, points exist within the paper where some numeric information would have helped the reader with understanding. Examples include: reporting how many were recruited under "Participants" instead of reporting recruitment continued until saturation was reached; or relating which mothers refused to take part in the RCT part when reporting and analysing the transcribed responses; and reporting how many mothers had to sit in the interviews with their children. It could have also been helpful to include the range of delay intervals between consent and interviews (in an appropriate unit) in the Method section.

c. Structural details

Sub-sections of the Method should be made clearer (e.g., italicising the headings). Table 1 does not seem to be referred to anywhere in the text even though it provides important information on the consent process. An additional table with the details of the structural interview and the set of fixed questions
could be helpful.

Overall however, this is an interesting study which adds to the domain of patient experience on research studies. The recommendation is to accept this manuscript subject to satisfactory amendments.

Yours sincerely

Ruth Freeman

Professor Ruth Freeman
Oral Health and Health Research Programme Co-Director DHSRU University of Dundee Dundee
DD1 4HN
Telephone: +44 (0) 1382-381717 or 381710