Reviewer’s report

Title: Promoting parenting strategies to improve tooth brushing in children. Design of a non randomised cluster-controlled trial

Version: 1 Date: 07 Jan 2019

Reviewer: Peter Milgrom

Reviewer's report:

This revised manuscript is greatly improved but still requires a major revision.

Overall, it requires editing by a native English speaker. For example, there is an incomplete sentence that begins on line 9 of the abstract. This design is not really a "cluster randomized trial" as the clusters are not randomized. Rather this appears to be a prospective cohort design. Another example, line 31, page 8, is the use of the word "convenient". The correct word is "convenience" but it is not used appropriately in any case as the unit of analysis is the child. This may be moot if the design is not a cluster randomized. If the study is determined to be cluster randomized, the authors should review and complete the appropriate CONSORT checklist for cluster trials.

Very often in the manuscript there is a confusion between parent and child behavior. At times the focus is on the parent brushing the child's teeth where other times the focus seems to be on child brushing. The manuscript needs to be consistent.

The review of the relevant theory is in several different places in the manuscript and is repetitive.

Line 22, page 9. Clarify who is making the list of patients and randomizing. If this is being done by a researcher, this may be a violation of patient privacy. Also, the authors should clarify how the actual exclusions are to be defined. They seem to be excluding potential participants who might benefit from the intervention and limiting the generalizability of the results.

The flow diagram in figure 2 should conform to the CONSORT guidelines for cluster trials.

The online references should be archived at webcite or a similar place so that they remain available in the future. Could the authors provide a more complete reference for #3 (web reference points to a general UK government website) and #49?

All of the supplementary material is in English while the language of the study is Dutch. The authors should provide the supplementary material in the language of the study. The general principle is that another investigator should be able to repeat the study based on the information provided.

The information given to the practices should be provided as a supplement, in Dutch.
Key concerns that remain:

1. The primary outcome(s) of a trial need to be specified a priori. This is fairly clear for the caries measure but still lacks precision. How will the ICDAS information be used to derive an outcome measure? A lot of the caries lesions are likely to be in the enamel where measurement is notoriously unreliable. Will they use the active vs inactive lesion measure? When this is cleared up the abstract will need to be modified along with the body of the paper.

The authors’ presentation is unclear as to how they expect the intervention to work. There is no real model. This leaves open the question of how they will interpret the results and concern about post hoc analyses. There are three variables that apparently will be used to assess the behavioral outcome but no detail on how these variables will be combined or how this "outcome" will be calculated. What point in time is primary (see line 51, page 10)?

There is no hypothesis suggesting that they expect to plateau and then diminish although they build in booster interactions.

Similarly, there are variables such as the plaque index that require some explanation. How does this fit into the model? What if the plaque index shows a lot of plaque, the parent self-report indicates regular twice a day toothbrushing, and there is no caries increment? How will this be interpreted?

2. The hypothesis testing in the analysis section needs to be clearer. This is a clinical trial. As is customary, the hypotheses should be tested without adjustment for co-variates. Then, differences between the groups should be systematically investigated. If there are to be subgroup analyses they need to be prespecified to be sure they are adequately powered.

3. The authors need to specify that the analysis follows the intent to treat principle. There are various points where parents may drop out, miss appointments or be excluded. This creates the potential for bias, which is not addressed.

4. A major confound appears to be potential differences in how the children were cared for during this period. There does not appear to be any collection of information about differences in the practices. It is hard to believe that children who are at higher risk might not have received treatments that modify the results. The practice matching does not address this problem and the ICDAS exam might not capture this.

Note also that in many countries children of this age group are in preschools or kindergartens where toothbrushing is a supervised required activity.

5. If it is determined that this is indeed a cluster randomized design, additional attention is required in the sample size section. The authors should clarify that the number of clusters and cluster size were determined concurrently. Further, they should report the plots of power or precision against cluster size to enable identification of points beyond which further increases in cluster size make no material contribution to the study. They should also report the sample size
required under individual randomization. The authors might also justify their decision to have the same number of test and control practices.

If this is actually a prospective cohort design, this section will require modification in any case.

6. The authors need to specify the required level of inter and intra-rate reliability required for certification of examiners. Also, the authors should specify when the clinical training will occur. One assumes it will be just before the exams?

7. There needs to be a section added on blinding.

8. The authors need to specify the criteria for certifying the interventionists.

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?
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