Author’s response to reviews

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

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Author’s response to reviews:

Dear Editor,

Thank you and the reviewers for taking the time to review our manuscript and for the valuable comments and suggestions. Please see our responses to the reviewers’ comments below and a description of the changes included in the revised manuscript. The changes made are highlighted with red font in the manuscript.

Editor comments:

1. Please ensure that the trial registration date, registry name and the trial registration number are appended to the Trial Registration section at the end of the Abstract in the online submission field, and in the manuscript.

The full details of the trial registration have now been included in the abstract (also in the online submission field) and in the manuscript (see Abstract, page 2-3 and Declarations, page 25).
2. According to the ICMJE guidelines, to qualify as an author one should have:

• made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; AND

• been involved in drafting the manuscript or revising it critically for important intellectual content; AND

• given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; AND

• agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

According to these criteria we believe that MLH and EP do not qualify as authors. Please kindly clarify whether MLH and EP contributed to other relevant aspects of the study and manuscript preparation.

If these individuals do not qualify for authorship we would ask that they are included in the Acknowledgements only.

MHL and EP have substantially contributed to the development of the Shine! intervention, the conception and design of the study, and the training; and they are involved in data collection and interpretation. They have critically revised the manuscript that MdJL and DD had drafted and they agreed to the final version. Reading the ICMJE criteria, we believe that MHL and EP qualify as authors. We clarified the authors’ contribution section in the manuscript accordingly (see Declarations, page 26).

3. Please ensure that you append, if appropriate, that ‘All authors read and approved the final manuscript’ to the Authors’ contribution section of the declarations.

We have added this sentence to the Authors’ contributions sections (see Declarations, page 26).

Reviewer 1 (Peter Milgrom):

This is a protocol for evaluating the efficacy of an intervention to boost parent skills in promoting tooth brushing for preschool children.
We thank the reviewer for taking the time to review our manuscript and for the valuable comments and suggestions for improvement.

1. The abstract and paper are confusing. For example, registration of the trial retrospectively implies the trial has already been conducted. However, the paper presents the trial as prospective. Sometimes the text switches verb tenses.

We understand the confusion with the word ‘retrospectively’ and the alternating use of present and past tense. This manuscript indeed presents a prospective study. However, at the time of manuscript submission and registration of our trial, we had already recruited a number of dental practices for the study. The BMC guidelines write that ‘if the trial is registered after the enrollment of the first participant, the words “retrospectively registered” should be included’.

However, given the confusion this raises, and the fact that this study is still in its early recruitment phase, we have decided to write the full manuscript in future tense, and to delete the word ‘retrospectively registered’. This has now been adjusted throughout the manuscript.

2. The paper should more closely follow the CONSORT statement or similar guideline where the title includes the design.

We have changed the title to: The Shine! intervention: promoting parenting strategies to improve children’s tooth brushing behaviour. Design of a clustered controlled trial.

3. This is a quasi-experimental design with two arms. Repeatedly there is confusion about the purpose. The study does not actually measure parenting skills. Rather the primary outcome measure is caries increment. In various places the paper fails to differentiate between primary and secondary outcomes. All of this would be clarified if the evaluation questions were stated up front.

Based on the comment of the reviewer, we have made adjustments in the manuscript to clarify the aim, intervention components and outcomes of the ‘Shine!’ intervention. We also added a
figure in which the intervention components and outcomes are schematically presented (see Figure 1). See below for our clarification:

• The aim of the ‘Shine’ intervention is twofold: 1) to improve the practice of twice daily tooth brushing in children, and subsequently 2) to prevent childhood dental caries on the long term.

• To achieve this, the components of the intervention are: 1) to identify barriers that parents may experience with brushing their children’s teeth, and 2) to promote parenting strategies (related to tooth brushing) to tackle the identified barriers, using principles from learning theory.

• The hypothesis of the intervention is that that the promotion of specific parenting strategies will facilitate oral hygiene behaviour change in parents, resulting in the improved practice of twice daily tooth brushing in children and - on the long term - lower development of dental caries in children.

• Therefore, the behavioural outcome of the study is twice daily tooth brushing in children; operationalised using 3 proxy measures:

1. Children’s tooth brushing behaviour,

2. Parent’s confidence in brushing their children’s teeth when experiencing barriers (self-efficacy),

3. Children’s dental plaque scores.

• The clinical outcome of the study is children’s dental caries experience after 24 months.

This has now been clarified throughout the paper (see Introduction, The ‘Shine!’ intervention, page 6; Methods, The ‘Shine’ interview method and Outcome measures, page 11, 15-16). The data collection and analysis sections of the manuscript are now structured accordingly (see page 14, 15 and 17).

The feasibility and perceived usefulness of the ‘Shine!’ intervention are our secondary outcomes.
We changed the term ‘parenting skills’ to ‘parenting strategies’, because the intervention focuses more on discussing parenting approaches and strategies to address barriers to tooth brushing rather than on skills.

We decided not to include parenting strategies as an outcome measure of the study for a number of reasons. The main reason is tooth brushing and caries in children are our main outcomes we want to change with the intervention. The second reason is that parenting strategies are very difficult to measure. Validated questionnaires of general parenting are not suitable, because the ‘Shine!’ intervention does not address parenting in general. Measures of parenting strategies related to tooth brushing do not yet exist, and need first to be developed. However, for each parent, different parenting strategies will need to be measured, depending on their experienced barriers.

However, we will obtain qualitative data on whether parents perceive that they’ve changed parenting strategies as a result of the intervention through qualitative interviews with the parents. We now state this more clearly (see Methods, Feasibility and usefulness of the Shine!’ intervention, page 19).

4. The authors state that the intervention practices are a group of volunteers. The comparison practices are also volunteers matched by practice population and SES of the region. The method of matching and a justification are required. The authors should address selection bias.

The methods and justification of the matching procedure are now described in the manuscript (see Methods, Study sample, page 9).

Control practices are matched by similar size of the patient population, with a maximum deviation in size of 500 registered patients, and by same SES of the region, as classified by the Dutch Central Bureau of Statistics on a scale from 1 (lowest SES) to 7 (highest SES), see reference 24. We decided to match for these two factors, because the size of the patient population gives an indication of the characteristics of a dental practice (e.g. solo or large group practice). The SES of the region is indicative of the population’s (oral) health, with higher caries levels being reported in low SES regions.

The risk of selection bias has now been more clearly addressed in the discussion section (see Discussion, paragraph 7, page 23).
5. Children and parents in the intervention practices are to be chosen randomly. The methods are not described. Will more than one child from a family be eligible.

Children will be recruited using simple random sampling. Details of the procedure are now described in the manuscript. In cases of twins, only one child of the family will be selected (see Methods, Study sample, Children and their parents, page 9).

6. Documentation of the number and characteristics of those accepting and refusing is missing. One assumes there is a similar evaluation of the non intervention practice patients?

We ask the coordinating dental therapists in both the intervention and control group to document the number of subjects that agreed to participate out of the number of eligible subjects that were approached, as well as reasons for non-participation. Non-participating parents will be asked two questions on their highest completed level of education and country of birth, to be able to assess potential response bias. This is described in the methods section, under the new heading ‘Measures of fidelity’ (see Methods, Measures of fidelity, page 19).

7. The authors should address contamination bias.

We expect the risk of contamination bias to be very low, given the clustered design of the trial, and the fact that control practices will not be informed about the practices that are in the intervention group and vice versa. Both groups will be contacted separately to inform them about the study procedures and provision of ‘care as usual’. Furthermore, control practices will not be able to provide the ‘Shine!’ intervention without having received the supporting tools and training in methods and underlying theory. Information on the risk of contamination bias has now been added to the discussion section (see Discussion, paragraph 7, page 23).

8. The sample size section makes it clear that the primary outcome is dfms. This is a rather imperfect proxy for parenting skills and makes unstated assumptions about the interpretation of dmfs. The study may be underpowered assuming a 2 dfms difference between groups. The justification is unclear.
We would like to refer to our response to comment 3 regarding the outcomes of our study (behavioural and clinical).

A power calculation indicated that we need 330 children to detect a minimum difference of 2 dmfs (clinical outcome) between the intervention and control group. A difference of 2 dmfs was considered clinically relevant, given that 6-year-olds in The Netherlands have a mean dmfs of 5.

Since our behavioural outcome is twice daily tooth brushing, we now also conducted a power analysis for tooth brushing outcomes. The analysis showed that a sample of 330 children will be amply sufficient to detect at least a 20% difference in the proportion of children who brush their teeth twice a day. For this reason, we decided to still base our power analysis on the clinical outcome - dmfs. This has now been clarified the manuscript (see Methods, Power calculation, page 10-11).

9. There are no measures of fidelity described. There is no provision for a change of personnel in any given practice.

Fidelity aspects were initially incorporated in the qualitative section on the feasibility of the ‘Shine!’ intervention, but are now more clearly described under a separate heading ‘Measures of fidelity’. Measures of fidelity include: 1) documentation of selected barriers and action points of participants, 2) qualitative focus group interviews with dental therapists, which includes questions on the implementation of the intervention, 3) qualitative telephone interviews with participating parents, which includes a description of the research visit, and 4) documentation of the number and characteristics of non-participants (see Methods, Measures of fidelity, page 19).

10. The training of the interventionists is specified. It is unclear if the training includes the standard practices of the Ivory Cross guideline and if the practices have to agree to change existing procedures. This has implications for the comparison with the non-intervention practices.

Details about training / information on the study procedures for both the intervention and control group is now added to the manuscript (see Methods, Training of oral healthcare professionals, page 15).
Dental practices in both the intervention and control group will separately be informed about the study procedures, including the recruitment of participants and methods of data collection, as well as the provision of care as usual and dental health education according to the national guidelines. It is expected that this is standard procedure for practices, but the importance of adherence to the guidelines for this study will be emphasised.

11. Note, the authors report pilot work that asserts that parents already have tooth brushing knowledge. However, they do not cite other work in the literature that documents that parents are often confused by the information they receive (for example, the amount of toothpaste to be applied to the brush).

We agree with the reviewer that literature shows that there is confusion among parents about certain oral hygiene messages, such as the amount of toothpaste to use, or the time interval between eating/drinking and brushing. Yet, with this intervention, we only want to concentrate on the key message of twice daily tooth brushing with fluoride toothpaste. However, in addition to the intervention, dental therapists will provide dental health education according to the Ivory Cross guideline, which includes more detailed recommendations on for example, the amount of toothpaste.

12. The authors should explain what they will do if parents miss appointments.

Details of our procedure when appointments are missed are now added to the manuscript (see Methods, Study outline, page 14). The interval between T0.0 and T1 is allowed to deviate by 2 months, and the interval between T1 and T2 may vary with 3 months. If parents miss their appointment at T1 and T2, or at T2 only, they will be treated as dropouts. If they only miss the appointment at T1, missing data for T1 will be imputed. Missed telephone recalls will be documented to account for this in the analysis.

In relation to this comment, we would like to note that we made an adjustment in the schedule of contact moments, based on reflection from practice staff who are currently testing the ‘Shine!’ method in practice. Practice staff communicated that it was logistically challenging to schedule a telephone recall with parents after already one week. Therefore, we now only include one telephone recall one month after T0.1 (instead of two recall intervals, each after one week) (see Methods, Study outline, page 13, 14).
13. The dentists in the practices are evaluating their own patients. One assumes this is also true for the non-intervention group dentists. One also assumes there is only one dentist per practice. They receive training on ICDAS but there are no criteria for certification and no measure of reliability.

From each intervention and control practice, one dentist will be trained to perform the clinical examination according to WHO and ICDAS criteria for the study participants – also in the case of multiple dentists per practice. Training will be provided by a certified ICDAS trainer, and during the training session the inter-examiner reliability between dentists will be assessed. This information is now added to the manuscript (see Methods, Clinical outcome: children’s dental caries experience, page 17-18).

14. The source of questionnaires and their reliability and validity in Dutch is not given. Exactly how the questionnaires will be administered should be described.

The questionnaire concerns a self-administered questionnaire, to be completed by the parent. The questions are selected from a validated questionnaire from Pine et al., and have been forth and back-translated and tested in the Dutch context. This information has now been provided (see Methods, Behavioural outcome: twice daily tooth brushing in children and Other variables, page 16, 18).

15. The analytic section should be structured to reflect analysis of the primary and secondary outcomes in an ordered way. The analysis should account for missing data.

Based on the suggestion of the reviewer, we have re-structured the analysis section, by first presenting the statistical approach for the behavioural outcomes, and then for the clinical outcome, followed by the qualitative data analysis (see Methods, Statistical analysis, page 19-20). Depending on the patterning of missing data, a method of data imputation will be applied.

16. The references appear to be accurately cited except that #3 appears incomplete.

We thank the reviewer for noticing this. The reference has been completed (see reference #3).
Reviewer 2 (Deborah Polk)

The manuscript presents a study protocol to evaluate the process and effectiveness of the 'Shine!' intervention in preventing dental caries in children that attend a dental clinical practice. The authors hypothesize that the parents who receive the 'Shine!' intervention will gain better parenting skills and a higher self-efficacy to brush their children's teeth twice a day, resulting in better oral hygiene and less dental caries development over a period of 24 months, compared to the control group.

The outcome measures of this trial are:

1) Children's oral hygiene
2) Parents' self-efficacy in relation to tooth brushing
3) Children's dental caries experience over a period of 24 months

The second objective is to evaluate OHP's perception regarding the feasibility and acceptability of the 'Shine!' intervention.

In general the paper is well written and easy to understand. This topic is appropriate for this journal. Although the aim of this protocol is to prevent childhood dental caries, this intervention has many limitations, which the authors are aware of and express in the manuscript.

We thank the reviewer for taking the time to review our manuscript and for the valuable comments and suggestions for improvement.

1. Authors need to clearly include the percentage of 3-year-old children attending oral healthcare professionals in the introduction or discussion section; in order to estimate the percentage of children that would benefit from this practice.

In the Netherlands, 35% of two-year olds are visiting the dentist, which increases to 95% when children reach the age of four. This information is now provided in the methods section (see Methods, Study sample, Children and their parents, page 10). See also our response to the next comment.
The consequences of this in terms of potential selection bias and limited generalisability of the study are now discussed in the discussion section (see Discussion, paragraph 7, page 23). “Also, children who do not visit the dentist at the age of three and four will not be included in the study, which could potentially bias the sample towards more motivated parents and children.”

2. Authors need to explain why they selected only 3-year-old children.

In response to this comment, we first would like to note that we decided to widen the inclusion to three to four-year-old children (36 to 59 months old), based on reflection from practice staff who are currently testing the ‘Shine!’ method in practice. They noted that a proportion of children only visit the dentist from the age of four, and this is confirmed by Dutch national statistics (see also our response to the previous comment where the reviewer raises this issue).

Information on why we only select three to four-year-old children is now added to the manuscript (see Methods, Study sample, Children and their parents, page 10).

“The ‘Shine!’ intervention is developed to target parents of two to ten-year-old children. Yet, three to four-year-olds are selected for this study for two reasons. First, the restriction of the age group reduces variation in dental caries levels, allowing better comparison of the intervention’s effect. Second, children are preferably targeted from a young age when oral health behaviours are still shaped and more amendable to change. Yet, only 35% of two-year-olds are visiting the dentist, which increases to 95% when children reach the age of four [26]. Therefore, the choice was made to include three to four-year-old children, increasing the number of young children that can be reached.”

3. A baseline oral examination must be included. Dental Caries status should be measured at baseline.

We will extract the dental caries status of children at baseline from personal dental health records from the dental practice. Data on fillings, extracted teeth due to caries and tooth decay are systematically registered during every dental visit to ensure that the patient records are up-to-date and complete. This data will be used to analyse whether there are differences in dental caries experience between intervention and control children at baseline, and if so, to adjust for this in the analysis. This is now described in the manuscript (see Methods, Clinical outcome: children’s dental caries experience, page 19, and Statistical analysis, page 19-20).
The performance of a baseline clinical oral examination by calibrated dentist is unfortunately logistically not feasible for this study.

4. In The 'Shine!' interview method section, the third paragraph (lines 48-49) is confusing.

To improve the readability, we have adjusted the text by deleting the second part of the confusing sentence. The sentence now reads: “Then, the OHP shows a set of nine cards, with on the front side barriers to twice daily tooth brushing (in text and in illustrations)”. Further in the paragraph is described what’s on the back-side of the card, which was originally the second part of this sentence (see Methods, The ‘Shine!’ interview method, page 12).

5. In the statistical analysis section, it is mentioned that statistical differences in plaque scores, parental self-efficacy scores and dental caries between children in the intervention and control group at T1 and T2 will be analyzed. However, dental caries status will only be measured at T2.

We thank the reviewer for spotting this error. This has now been corrected.

We have fully re-structured the analysis section, by first presenting the statistical approach for the behavioural outcomes (tooth brushing variables), and then for the clinical outcome (dental caries), (see Methods, Statistical analysis, page 19-20).

6. Authors should specify which are the dental treatments (preventive and restorative care), that the children often receive in the control and intervention group.

The preventive and restorative dental treatments that young children often receive are now described in the manuscript: (see Methods, The intervention, page 11). “Care as usual consists of regular dental check-ups, dental health education following the Ivory Cross national guideline, and if indicated, preventive treatment (fluoride application and / or fissure sealants) and / or caries treatment (fillings, non-restorative caries treatment or extractions).”
Reviewer 3 (Marja-Liisa Laitala, PhD, DDS)

The present protocol describes a trial evaluating the effect of a caries preventive intervention project called ‘Shine!’ The intervention aims to improve children's oral hygiene and dental health as well as parents' self-efficacy in relation to tooth brushing.

In my opinion, the topic is important and the upcoming trial very interesting. The study protocol is meticulously designed and the manuscript clear and explicit; I have only some minor comments and questions:

We thank the reviewer for taking the time to review our manuscript and for the valuable comments and suggestions for improvement.

1. Key words: should 'self-efficacy' be included in key words?

We agree with the suggestion of the reviewer and have added ‘self-efficacy’ to the key words.

2. Background: The scientific basis including underlying theory is quite thoroughly written, but I still miss some literature concerning e.g. Motivational interviewing (Miller & Rollnick) and possible previous studies concerning (children's) oral health.

We have now included literature on motivational interviewing in the manuscript (see Discussion, Paragraph 5, page 22).

The ‘Shine!’ intervention uses conversation techniques and counselling principles that are also applied in motivational interviewing (MI), including creation of a positive interpersonal atmosphere, expression of empathy and acknowledgement of people’s own autonomy and strengths. This is now described in the methods section (see Methods, The ‘Shine!’ intervention, page 12).
3. General dental practices: Matching of the general dental practices was based only on similar size of the patient population and socioeconomic status of the region (lines 53-54). Could it be possible, that previous working experience and/or previous education of the therapists/hygienists are different in the intervention and control groups? Any calibrating of the therapists before the onset of the study?

We agree with the reviewer that there may be differences in age and working experience of dental therapists between the intervention and control group. We do not match for these factors when recruiting control practices, since data on characteristics of dental staff is often not prior available in order to identify, select and approach potential control practices. However, based on the suggestion of the reviewer, we plan to collect data on the dental therapists’ characteristics, so that we can assess and report whether these characteristics differed between intervention and control practices (see Appendix 2).

To standardise therapists for this study, dental practices in both the intervention and control group will receive information about the study procedures, including the recruitment of participants and methods of data collection, as well as the provision of care as usual and dental health education according to the national guidelines (see Methods, Training of oral healthcare professionals, page 15).

4. Children and their parents: It is said that a random sample is to be recruited. This remains a little indefinite; how is the randomization performed in practice? The first 10 children-parent pairs who are willing to participate?

Children will be recruited using simple random sampling. Eligible children will be listed from the patient registry and given a random number by the coordinating dental therapist, using the website http://random.org. Subjects will be approached in numerical order, until at least 10 children are included in the study. These details of the procedure are now described in the manuscript (see Methods, Study sample, Children and their parents, page 9).

5. On the whole, the exclusion criteria of the participants are clearly stated. Power calculation: (line 56), an error in typing (dmfs))
We thank the reviewer for noticing this typing error, which has now been corrected (see Methods, Power calculation, page 10).

6. The intervention: (line 22) 'care as usual' is said to consist of regular dental check-ups. To a foreign reader this is unclear. Are these check-ups performed on an individual base / annual to every child / something else?

   Regular dental check-ups for young children are generally scheduled every six months, or at shorter intervals when children are identified as having an increased caries risk. This is now added to the manuscript (see Methods, The intervention, page 11).

7. Study outline and timeline: especially Figure 1. is essential and informative.

   Data collection: A questionnaire on children’s oral hygiene; is this questionnaire validated and piloted / used in other surveys? e.g. how is the frequency of skipping tooth brushing asked/categorized? Could this questionnaire be attached in the manuscript?

   The questions are selected from a validated questionnaire developed by Pine et al. The questions have previously been forth and back-translated and tested in the Dutch context. This information is now included in the manuscript, together with the relevant references (see Methods, Behavioural outcome: twice daily tooth brushing in children and Other variables, page 16, 18).

   Based on the suggestion of the reviewer, we have included the questionnaire as an Appendix, so that the questions and response options are available to readers (see Appendix 1).

8. Data collection: Is the intra-examiner reliability assessed?

   Yes, during the training the inter-examiner reliability between dentists in scoring ICDAS and dmfs will be assessed. This information is now added to the manuscript (see Methods, Clinical outcome: children’s dental caries experience, page 17-18).
9. Discussion: I agree with the authors that one strength of this study is that it is conducted in 'real world' settings. This, of course, brings some risks for the study. It is possible that not only the study participants but also some of the hygienists/therapist will drop out. I suggest that these things are more discussed.

We agree with the reviewer that there’s a risk that participants, as well as dental therapist may drop out of the study.

We have now provided information of our procedure when participants drop out, or when they have missing data (see Methods, Study outline, page 14). “If parents miss their appointment at T1 and T2, or at T2 only, they will be treated as dropouts. If they only miss the appointment at T1, missing data for T1 will be imputed. Missed telephone recalls will be documented to account for this in the analysis.”

When a dental therapist will drop out of the study, a colleague from the same dental practice will be requested and trained to collect follow-up data from the already included participants. This information is now added to the discussion section (see Discussion, paragraph 7, page 23).