Author’s response to reviews

Title: “Strong Teeth” – a study protocol for an early-phase feasibility trial of a complex oral health intervention delivered by dental teams to parents of young children

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Version: 1 Date: 24 Apr 2019

Author’s response to reviews:

Comments to address:

We would like to thank the reviewers for their comments and are delighted to be invited to re-submit our paper. We appreciate the feedback and have amended the paper accordingly as outlined below.
Reviewer #1: I congratulate the authors for choosing such a relevant research topic, which deserves research with adequate methodological design.

- We thank Reviewer 1 for their positive comments.

I respectfully understand that the article has potential, but still needs adjustments to meet the basic requirements of a scientific report. Especially, two points need to be better described:

- Material and methods - as written, does not allow reproducibility.

- Conflict of Interest - What is the rationale for using electric brush? In many regions of the world, people who have cavities can not afford to buy electric toothbrushes.

- A rationale for the provision of an electric toothbrush as part of the intervention is now included in the Introduction and is reiterated in the aims/objectives, including recognition of the need to assess the acceptability of electric toothbrushes to families, which includes assessing cost.

- To provide reassurance to our reviewer, our earlier qualitative work with parents of young children living in deprived areas, such as Bradford, has found that some parents are willing to purchase electric toothbrushes for their children. These findings have been borne out when interviewing older children (aged 7-11 years old) who report using an electric toothbrush. We have chosen not to include this information, however, as it is as yet unpublished.

- Articles not yet approved for publication - these should not be included in reference lists, as they have not yet been peer-reviewed, may undergo major modifications and are not accessible.

- These articles have been removed.

The comments and suggestions are detailed below.

1) Background:

- Perhaps the HABIT paper published in this journal should be commented in the rationale of this study.

- The concept of complex intervention should be better described.
A definition of complex interventions has been provided, along with a rationale why oral health behaviours are complex and thus need such a methodology applied to them.

Specific challenges identified by the cited references have now been added to clarify the nature of the challenges faced by dental professionals (for example, on page 7, lines 148–151).

Page 7, line 161, "Strong Teeth": Please cite the URL where we can find the foundation of the intervention.

URL to “Strong Teeth” website, which includes access to all the intervention resources and implementation guide, which outlines the background to the intervention has now been included (for example, on page 9, line 200).

2) Objectives: "PSB" - Do parents brush the children's teeth? I looked for the meaning of "supervision" and understood that it is related to direct, observe the toothbrushing. I wonder if children in this age range (3-5 years old) can effectively brush their teeth having and adult observing them.

National PHE guidance uses the term “supervised”. We agree the term “supervised” is vague and indeed have sought to clearly clarify what this term means in our intervention, thus thank you for bringing this to our attention. We have now clearly defined the term in the objectives.

3) Methods:

Page 9, line 194: Does the sample size allow the "generalisability of the findings"?

Thank you for bringing this to our attention. This should be about the representativeness of the sample to the local population. This has now been rectified.

Page 9, line 205: Please give more the details on the oral hygiene and toothbrush behaviour questions.

The full baseline questionnaire has now been included as Appendix 1.

Page 9, line 211: How is parent-child interaction going to be "measured" or "described"?

The parent-child interaction will be coded using an established index, which is now included as Appendix 2.

Page 10, first paragraph: The "Strong Teeth" recommendations should be summarised.
A summary of the “Strong Teeth” intervention has now been provided with additional details also provided on how to access the full implementation guide that outlines the background to the intervention, the intervention components and the behaviour change techniques underlying the intervention (for example, on page 12, lines 270 – 283).

Page 13, "We will formulate a preliminary measurement model and calculate factor loadings. Factor loadings will be available from the measurement model.": I admit I did not understand the process. In your HABIT paper you used diagrams. Is it possible to do more clarification without self-plagiarism?

The process is the same as in our HABIT paper, as such we have requested permission from the authors to include the diagrams with appropriate citation for inclusion in the present paper. This is included as Figure 1.

4) Conclusions: I would take this section out. It seems strange to think of conclusion for a protocol of an "early-phase" study.

The conclusion has now been removed upon your suggestion.

5) Author contributions: Only 3 out of 14 included authors are mentioned here. What about the others mentioned in the beginning of the manuscript? Do they fulfil the criteria recommended in this journal Editorial Policies? If yes, they should appear here. If not, they should have been removed from the Authors section and maybe cited in an Acknowledgement section.

Thank you for your comment. We have now changed this to reflect the contributions all the authors made to the manuscript.

6) Competing interests: Please revise the Competing interests in the Editorial Policies and amend this section.

We have reviewed the competing interest section in the editorial policies, but are uncertain how we need to amend this section as we feel we are compliant with it. Please could the reviewer or editor provide further advice?

7) References:

- References 20, 21 and 22: They should be deleted until the paper is accepted.

These references have been removed as at present they are still under review for publication.

- Reference 36 is the same of reference 11.

Thank you for bringing our attention to this. We have now rectified this mistake.
- Have you done a literature update before submission? After a quick and dirty search in the PubMed, I selected the following papers that could add some insight to your rationale or discussion:

- Thank you for bringing these articles to our attention. We have read the articles and have included the most relevant one (Martin et al. 2019) in our paper.

Reviewer #2: The study protocol describes a mixed methods research project which aims to explore the acceptability and feasibility of an oral health intervention ("Strong Teeth") for parents of children aged between 0-5 years old and dental team members. This proposed research would provide valuable insights into stakeholders’ experiences of using evidence-based oral health interventions in NHS dental services. However, the study protocol could be improved and should provide more detailed information about the proposed study design and analysis as outlined below:

- We thank Reviewer 2 for their positive comments.

Page 5: What is considered 'regular dental attendance' for children (every 6 months or every 12 months)?

- Thank you for drawing our attention to this omission. We have now clarified that the dental recall interval can vary between 3-12 months for children based on an oral health risk assessment.

Page 6: What would preventative advice following the "Delivering Better Oral Health" Guidance likely involve and how does this differ from the "Strong Teeth" intervention?

- The nature and content of both the “Delivering Better Oral Health” guidance and the “Strong Teeth” intervention has now been provided (for example, on pages 6 – 8, lines 143 – 182).

- Delivering Better Oral Health” is the national guidance provided by Public Health England (PHE). We have worked with PHE to ensure the guidance provided in our “Strong Teeth” intervention aligns with PHE guidance.

Page 6: The authors state that complex interventions should be underpinned by psychological theory, however, it is not clear whether their intervention was guided by a behaviour change model/framework/theory. Also how was the “Strong Teeth” intervention ‘co-developed’ and how did the research team synthesise the findings from the rapid reviews with the qualitative data generated from the interviews with stakeholders?

- Reference is now included highlighting the psychological theory/framework underpinning the “Strong Teeth intervention. In addition, details are provided on how to access the full implementation guide that outlines the background to the intervention, the
intervention components and the behaviour change techniques underlying the intervention (for example, on pages 7 – 8, lines 154 - 182).

- Regarding the co-development of the “Strong Teeth” intervention, we believe this is beyond the scope of the current paper and justifies being a separate paper in its own right. Indeed, we are currently preparing a manuscript that will provide full, explicit detail of the interventions development and have made reference as such in the present paper.

Page 6: What are the key oral health behaviours that should be promoted? This may seem obvious to the authors but I think this is worth making explicit within the paper. Which oral health behaviours are ‘targeted’ by the "Strong Teeth" intervention?

- Thank you for your comment. We have now provided examples of key oral health behaviours and have included a link to the “Strong Teeth” implementation guide, which outlines in full the oral health behaviours targeted by the intervention (for example, on page 12, lines 270 – 283).

Pages 6 & 10: There is a lack of information provided about what the "Strong Teeth" intervention actually consists of and what evidence-based strategies or techniques are incorporated within the intervention.

- We feel a full description of the “Strong Teeth” intervention and its development is beyond the scope of the current paper, and we are indeed in the process of putting together a separate paper that will outline this information. Nevertheless, we have added more detail about the nature and content of the “Strong Teeth” intervention and provided a link to the implementation guide that outlines the intervention, the accompanying resources, and the underlying theory and evidence for example, on pages 7 – 8, lines 154 – 182; and page 12, lines 270 – 283).

Page 7: What did the 'rapid reviews' entail? More detail about how these reviews were undertaken should be provided to promote transparency.

- Papers providing a comprehensive account of each rapid review are currently in preparation, and this is now referenced in the present paper (page 9, lines 203 – 204).

Page 7: The second workstream involved interviewing parents and children aged between 7-10 years old to investigate their experience of receiving oral health advice however the current project is targeting children (and parents of children) aged between 0-5 years. How might this younger group of children have different experiences?

- Explanation has now been added as to why we explored the 7-10 age range and why the final intervention is only currently targeted to 0-5-year olds (pages 8 – 9, lines 190 – 197).

Page 7: How many participants were involved in the 12 focus groups?
The number of participants in the focus group and the split between parents and dental professionals has now been included (page 9, line 202).

Page 7: Aim 2 - it is not clear how the objective and self-report measures of oral health behaviours will be compared and the rationale for why this is being examined is not presented in the introduction (this is discussed briefly in the discussion section of the paper).

- A rationale of the importance of utilising both objective and self-report measures of toothbrushing has been included in the Background and Methods (for example, on pages 7 – 8, lines 170 – 176; and page 11, lines 265 – 265).

Page 8: Aim 3 - Again this aim/objective appears without any rationale - is using an electric toothbrush as key part of the "Strong Teeth" intervention?

- A rationale for the provision of an electric toothbrush as part of the intervention is now included in the Background and is reiterated in the aims/objectives (for example, on pages 7 – 8, lines 170 – 176; and page 10, lines 233 – 235).

Page 8: It is not clear how the different objectives will be met within the proposed study. For example, how will the 'mechanisms for action' be examined? How will the impact of the electric toothbrush be assessed within the study?

- A full list of the mixed methods used to evaluate the intervention is now included. For example details of how the “mechanism of action” will be examined are provided (for example, page 10, lines 220 – 222; page 16, lines 361 – 365; and page 17, lines 391 – 392).

Page 9: How will parents be approached? Will patients' details be taken from NHS waiting lists? Who will approach families to invite them to take part in the study? How do the research team hope to gain access to families who are not engaging with dental care? What criteria will be used to purposively sample members of the dental care teams?

- Figure 2 has been included to show the recruitment process.

Page 9: At what stage will the research team film the tooth brushing behaviours of the parent and their child? Has this method been used before? Is there evidence to suggest this observational method is a valid tool for assessing parent-child tooth brushing behaviour?

- More detail has been provided on this measure (for example, on page 11, lines 256 – 260) and the full measure has been included as Appendix 2. Furthermore, a diagram of the research process has been included as Figure 2 to aid with clarity of the evaluation design and timeline.

Page 9: More detail about the measures which will be used in the proposed study (e.g. to assess oral health (e.g. tooth brushing) and dietary behaviours) should be provided. This should include
the validity/reliability estimates of the measures and example questions included in the questionnaires etc.

- The full questionnaire is included as Appendix 1 and the validated measures it is based on are referenced.

Page 13: Specifically how will the Theoretical Domains Framework guide the interviews and/or analysis? How will the researchers use the TDF to understand the 'active ingredients' of the intervention and how these variables are exerting change?

- Greater explanation of the use of the Theoretical Domains Framework to guide questionnaire and interview topic guide development to elucidate the active ingredients of the intervention, and how we have used this in our previous work is now included (for example, on page 7, lines 158 – 167; and page 16, lines 361 - 365).

Page 13: 'We will formulate a preliminary measurement model and calculate factor loadings'. This is a little confusing - what measurement model are the authors referring to here? Specifically what analysis do they plan to undertake and what software will they use to undertake this analysis?

- The process is the same as in our HABIT paper, as such we have requested permission from the authors to include the diagrams with appropriate citation for inclusion in the present paper (for example, on page 16, lines 372 – 381). This is included as Figure 1.

Page 16: 364-366 how does this specific component of the data collection approach aim to support parents?

- We have made it clearer that if the parents have questions or want advice about oral health they can seek this at the point of intervention with their dental practice or at the end of the whole study with our research team (for example, on page 19, lines 435 – 441).

A Figure/flow chart could be used to clearly illustrate the different stages of the study. This would help the reader understand the specific variables/outcomes that the research team plans to assess at baseline, the 2 week and 2-3 month follow-ups and could outline the time points at which the interviews with the different groups would take place etc.

- Figure 2 has been included to show the data collection process.