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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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.

1) Please indicate in the title that this is "pilot" or "feasibility" trial.
   • In the title we now explicitly refer to the research as a feasibility trial.
2) Please provide the registration information for the pilot trial in the abstract.

- We explored ClinicalTrials.gov, but unfortunately found that our study did not meet the eligibility criteria, as this particular database appears to be U.S. focussed. However, we are exploring other options. Nevertheless, as with our HABIT study (Eskyte, I., Gray-Burrows, K., Owen, J., Sykes-Muskett, B., Zoltie, T., Gill, S., . . . Day, P. (2018). HABIT—an early phase study to explore an oral health intervention delivered by health visitors to parents with young children aged 9–12 months: study protocol. Pilot and Feasibility Studies, 4(1), 68.), it may be challenging to find an acceptable option for the current study.

3) Please clearly label the feasibility objectives or aims of the pilot trial as primary, and then make objectives secondary.

- The primary and secondary feasibility aims and objectives have now been clearly labelled and expanded upon to better reflect the aims and objectives of a feasibility trial (pages 9-10, lines 210-232).

4) Please provide justification of the sample size based on the primary feasibility objectives.

- Further information on the sample size and how it will help inform and modify the sample size calculation for any subsequent full trial has now been included (pages 14-15, lines 336-343).

5) Please specify the criteria for success of feasibility.

- A table has been added to the manuscript that outlines our progression criteria to move to a definitive clinical trial.

6) The analysis plan should also include analysis of feasibility outcomes.

- A statement on the analysis of recruitment and retention rates has been added to the analysis plan (page 14, lines 327 – 330).

7) Please see the following editorial (Pilot and Feasibility Studies 2019;5:37), for further guidance on the reporting of protocols of pilot and feasibility trials.

- Thank you for recommending this editorial. We have read it and feel it has deepened our understanding on the reporting of pilot and feasibility trials, and thus has been useful when preparing this manuscript.