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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Version: 4 Date: 25 Jul 2019

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OHEA-D-18-00435R3

The Shine! intervention: promoting parenting strategies to improve children’s tooth brushing behaviour. Design of a non-randomised cluster-controlled trial

BMC Oral Health

Dear editor,

We thank you and the reviewers for reviewing a revision of our manuscript. Please find our response to the remaining comment of Reviewer 1 below, and a description of the changes we made to our manuscript.

Reviewer 1: Peter Milgrom

The response of the authors in this revision is not fully responsive. The paper needs to say that the primary outcome is caries experience at 24 months. This is the measure that the power is calculated on. The other measures are secondary measures unless the authors can add a statistical justification for a behavioral outcome. What seems not to be understood by the authors is that the outcome of the trial needs to be specified a priori. If they list 4 such possible outcomes, what will they declare as a significant outcome of the study. Will they just pick and choose among the
results? Is one positive finding of the four a successful outcome, two?, three? one and four? This approach violates primary tenet of conducting prospective trials and to me this is unacceptable.

We would again like to thank the reviewer for critically reviewing our manuscript.

We have now clarified in the manuscript that dental caries experience after 24 months is the primary outcome, and that tooth brushing-related outcomes are secondary outcomes (see Abstract, page 2; Methods, Power calculation, page 10; Methods, Outcome measures, page 15; and Figure 1).

We now also specified in the manuscript what we consider a significant outcome of the study.

We consider the intervention successful when a 25% reduction in dental caries experience is observed in the intervention group in comparison to the control group. This corresponds to approximately 2 dmfs in Dutch five to six-year olds, on which we based our power calculation. Since the intervention aims to prevent dental caries in children through the improvement of parents’ tooth brushing practices in children, we included secondary outcomes on tooth brushing behaviour. These outcomes are assessed to provide additional information on the intervention’s effect and on the pathways by which the intervention might affect children’s caries experience. If one of more tooth brushing-related outcomes are significantly more favourable in the intervention group compared to the control group, but dental caries experience is not reduced by at least 25%, the intervention is not considered successful.

This information is now included in the Methods section (see Methods, Outcome measures, page 15).

All outcomes (dental caries and three tooth brushing-related outcomes) will be reported in a results paper, disregarding of whether results are positive or not, to avoid selective outcome reporting.

General comment:

This paper reports on the Uitblinkers intervention, which we translated as the ‘Shine!’ intervention. However, after giving it many thought, we decided to adhere to the Dutch name, and not provide an English alternative name. Therefore, we deleted the word ‘Shine!’ throughout the manuscript, and now just refer to ‘the intervention’.