**Author’s response to reviews**

**Title:** Study Protocol of a Randomized Controlled Trial to Test the Effect of a Smartphone Application on Oral-health behavior and Oral Hygiene in Adolescents with Fixed Orthodontic Appliances.

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Dear Editor,

Thank you for considering our manuscript for publication in BMC Oral Health. Please find enclosed our revised manuscript entitled: "A Study Protocol of a Randomized Controlled Trial to Test the Effect of a Smartphone Application on Oral-health Behavior and Oral Hygiene in Adolescents with Fixed Orthodontic Appliances.” (Manuscript ID OHEA-D-17-00008R1).

We would like to thank you and the reviewers for the valuable comments. We believe that they have helped us to significantly improve the manuscript. We have answered all comments in this rebuttal letter. We hope that we have addressed all reviewers’ comments in a satisfactory way. We have sent our manuscript to an editing service for the English language, which resulted in textual changes.

Sincerely yours, also on behalf of the co-authors,

Janneke F.M. Scheerman,

REVIEWER #1: Robert Jones

Reviewer’s comment:

The abstract should mention that this study will examine if a behavior intervention based app can improve oral health behaviors during the time period studied. Stating that it will work outside of the study time has limitations.

Authors’ response:

We understand this comment as that the aim of our research is not clearly stated in the abstract. We have now described the aim as follows: “This article describes the protocol of a randomized controlled trial (RCT) to evaluate the effects of the WhiteTeeth app on oral-health behavior and oral-hygiene outcomes (presence of dental plaque and gingival bleeding) compared with those of care as usual, in patients aged 12-16 with fixed orthodontic appliances” (page 3; line 10-14).
We also understand that the reviewer questions whether the effect will continue beyond the study time. From literature it is known that habit formation on average takes about 66 days (Gardner B, Lally P, Wardle J. Making health habitual: the psychology of “habit-formation” and general practice. The British Journal of General Practice. 2012;62(605):664-666. doi:10.3399/bjgp12X659466.). We, therefore, expect sustained effect after the study period.

Reviewer’s comment:
Discussion on the intention of having a dual academic and private practice environment for the study. Will these environments be controlled regarding the number of subjects in each group.

Authors’ response:
Partly the choice of having academic and private environments is to ensure sufficient participants. We will include the same number of participants from both study sites. We have added this specification in the manuscript (page 7; line 13-14). Moreover, we will select practices with the same protocol and same intensity of care as usual.

Reviewer’s comment:
This statement was not clear "In order to prevent contamination, the patients of the control group do not have access to the intervention, since the app is locked by a personal code that only can be used once."

Authors’ response:
We realize that the text was not clear. We altered the text (page 8 line 5-8) as follows: “To prevent treatment contamination, adolescents in the control group will not have access to the intervention, as the app will be locked with a personal code that will only be provided to the adolescents in the experimental group”. We hope to have clarified the procedure.

Reviewer’s comment:
Please elaborate on the sentence "A peer model will demonstrate how to clean teeth with fixed braces". It is unclear what this statement means and if there are health privacy concerns using this type of model system.

Authors’ response:
A peer model is a person who is perceived as being similar to an individual (see: Schunk, D. H., & Hanson, A. R. Peer models: Influence on children's self-efficacy and achievement. Journal of educational psychology, 1985, 77(3), p.313). The term ‘peer model’ is frequently used in health psychology. To make our intention more clear we altered the text (page 10, line 10-14): “If the adolescent has not complied with these recommendations or if dental plaque is present, personal oral-health advice will be given in short videos and a peer model (i.e. an adolescent with fixed orthodontic appliances) will demonstrate how to clean teeth with fixed appliances.” We do not see any privacy concerns in these demonstrations.

Reviewer’s comment:

The authors mention that 3 minutes is a suitable time for brushing duration for the 5 point step, but it is not clear that the app makes this recommendation. Why is the brushing timer optional for the app? Is it related to having a patient interact with the selfie evaluation part to learn on their own the need to brush longer.

Authors’ response:

To make it clear that the brushing timer includes the recommendations, we included the following sentence (page 11, line 1-2): “As well as showing the time elapsed during brushing, the timer supports good tooth brushing by showing where and how to brush according to the 5-step method.”

The brushing timer is optional to use, so the adolescent can decide if it is helpful. To support autonomy (self-determination theory*) we do not want to force adolescents to use the brushing timer. The brushing timer does not interact with the weekly selfie-evaluation part, but provides direct feedback when using it.


Reviewer’s comment:

The app has an AI system/image registration algorithm to evaluate the selfie image and conclude if the brushing is adequate. More information should be provided in this area.

Authors’ response:

We added the following text (page 10, line 3-14): “The participant has to fit the selfie into a fixed window, upon which the app will superimpose a grid. The adolescent will then be asked to register the amount of plaque by clicking the disclosed areas in the grid. The app will interpret
the number of clicks (i.e. absence or presence of plaque). Then, on the basis of this plaque assessment and of the answers to the questions on oral-health procedures during the registration phase, the app will provide feedback. If the adolescent has complied with the oral-health recommendations and if dental plaque is absent, positive reinforcement will be given. If the adolescent has not complied with these recommendations or if dental plaque is present, personal oral-health advice will be given in short videos and a peer model (i.e. an adolescent with fixed orthodontic appliances) will demonstrate how to clean teeth with fixed appliances.”

Reviewer’s comment:

The authors mention four 'care as usual' parts. Two of these parts (use of mouth rinse and nutrition) are not included in the psychological analysis scoring (see page 13 line 2). Please address why these parts were not included in the study.

Authors’ response:

The focus of our intervention is on controlling dental plaque levels and increasing the use of fluoride mouth rinse. With regard to the use of fluoride mouth rinse we will measure the most proximal psychosocial correlates of oral health behavior being ‘intention’ and ‘action self-efficacy’ (Scheerman et al., 2016*). With regard to the modification of nutritional behavior, this is very complex and requires specific interventions that were not included in the app. We, therefore, did not include this behavior and its psychosocial factors in the evaluation. We decided to measure all psychosocial factors identified by the Health Action Process Approach theory of tooth brushing and of proxy-brush use, because we also measure the clinical outcomes this behavior and we think that these behaviors are the most relevant ones. Focusing on these behaviors and its determinants makes the intervention and the study of its effects already complex.


Reviewer’s comment:

Modified Silness and Loë Plaque Index is appropriate and robust for the study.

The app seems to be well designed and interactive for their behavior intervention study.

Intention-to-treat (ITT) principle for data analysis seems appropriate for this study.
Authors’ response:

Thank you.

REVIEWER # 2: Dorota T Kopycka-Kedzierawski

Reviewer’s comment:

(Reviewer 2): The revised paper describes a study protocol for a RCT to test the effect of a mobile application on oral health behavior and oral hygiene practices among adolescents who currently are in treatment with fixed orthodontic appliances.

As written this manuscript is an elongated method section. I do not see the value of publishing it as presented by the authors. The mobile application is not described, not clear if it is widely available, free of charge or need to be purchased. The authors mentioned that the mobile application was piloted-by whom? Was it tested on adolescents? Is it user friendly? Do we know that teenagers will be using it?

As written, what is the value of this manuscript? It describes two arms of the study that was not yet conducted.

Authors’ response:

The study is not yet conducted since it is a study protocol of a study that will be carried out. In response to the question regarding pilot testing of the app, we added the following sentence (page 11, line 22-25): “For two weeks, a prototype of the app was pre-tested by 28 adolescents with fixed orthodontic appliances. The data from this pilot test showed that the adolescents appreciated the app for its high usability and were very satisfied with it – particularly with the videos.”

We included the following sentence in the method section (page 9, line 16-18): “For the experimental group the WhiteTeeth app is available in the App Store for IOS ≥7+ and in the Play Store for Android ≥4.1 as ‘Witgebit’ (free of charge)”.

REVIEWER # 3: Fernando Hugo

Reviewer’s comment:

As this is a reviewed version of the manuscript, I have only a few questions that are presented below. This is a protocol of a trial to test the effectiveness of a Smartphone App on Oral Health
Behaviors and Oral Hygiene of Adolescents The abstract is well written and has all the information needed. My only recommendation is that authors include information about the intervention that will be delivered to participants of the control group.

Authors’ response:

The control group only receives care as usual. We added the following sentence to the abstract: “The RCT has two conditions: an experimental group that will receive the WhiteTeeth app in addition to care as usual, and a control group that will only receive care as usual. Care as usual will include routine oral-health education and instruction at orthodontic check-ups.” (page 3, line 15-19).

Reviewer’s comment:

Page 6, Line 19. Please, describe what constitutes 'care as usual' in an Orthodontics Clinic.

Authors’ response:

In the paragraph ‘care as usual’ on page 8 (line 10 – page 9 line 3), we describe what care as usual constitutes.

Reviewer’s comment:

Page 6, Line 58. Why only 12 weeks of follow-up, if a treatment with fixed orthodontic appliance lasts for a much longer period?

Authors’ response:

Treatment with fixed orthodontic appliances indeed lasts for a much longer period of time than our experimental period. To date, little experience had been gained with the use of e-health applications in orthodontic clinics. For this reason we first want to obtain scientific data about the short-term effects of the intervention. In case of positive results, we will recommend intervention studies with longer follow-up periods. The intervention period of 12 weeks provides possible information on long-term effectiveness of the app since it is known that this period can be long enough for habit formation (Gardner et al. 2012*). We included the following text on page 20 (line 8-11): “To prevent caries entirely, good oral-health behavior should be maintained continuously over a long period of time. As habit-formation takes an average of 66 days [47], we expect that the 84 days of exposure to the intervention will be long enough to guarantee a long-term behavior change.”

Reviewer’s comment:

Page 7, Line 4. The number of participants is different from the abstract.

Authors’ response:

We indeed made a typo in line 3 page 7. We altered the text.

Reviewer’s comment:

Page 12, Last paragraph. Did author intend to perform any psychometric analysis of the proposed psychosocial factors related to oral health scale that includes a number of questions? This is an important issue, since authors will generate a score based on the sum of the items. In addition, what is the score range? And what is its meaning?

Authors’ response:

Yes, we will measure the internal consistency of the proposed psychosocial factors. We used psychometrically tested questionnaires for the development of our questionnaire. The meaning and the score range can be found in the additional file 3: questionnaire II. We added the following two sentences to the method section (page 12, line 18-19): “The additional file specifies which questions were derived from which original questionnaire.”; and (page 13, line 16-17) “The headers in the questionnaire (part II in the additional file 3) show the items that are summed to generate the score for each psychosocial factor.”

Reviewer’s comment:

Page 13, Line 11. Why authors will assess plaque only on index teeth? There is no reason for that, as white spot lesions are not the only oral health outcome of interest in adolescents using orthodontic appliances. What about gingival inflammation? Lower and Upper First premolar, canine and incisors?

How authors will evaluate compliance of the control group to care as usual - recommendations?

Authors’ response:
The reviewer might to have missed that we measure that we do not only assess plaque, but also gingival bleeding. Gingival bleeding and plaque will be assessed at the buccal surfaces of the first premolars, canines and incisors (see page 13 line 19-21). So we feel that this comment was sufficiently addressed in the original manuscript.

All participants (participants of both the intervention and control group) will receive a questionnaire to measure their oral health behavior at baseline and at follow-up (see page 12; line 2). This questionnaire allows us to see if the oral health behaviors are in agreement with the oral health recommendations. It is not appropriate to ask the control group to register their behavior daily as that would be an intervention (self-monitoring) as well.

Reviewer’s comment:

Page 15, Line 34. Why information of importance to adherence will be given only to participants of the intervention group? This may lead to differences that are due not only to the app.

Authors’ response:

The reviewer is right. We made a mistake in the formulation. The information of adherence to the respective interventions was given to both groups (page 16 line 10-12).