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A randomized controlled trial


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The effect of using a mobile application (“WhiteTeeth”) on improving oral hygiene: A randomized controlled trial

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Abstract

Objective: To evaluate the effectiveness of the WhiteTeeth mobile app, a theory-based mobile health (mHealth) program for promoting oral hygiene in adolescent orthodontic patients.

Methods: In this parallel randomized controlled trial, the data of 132 adolescents were collected during three orthodontic check-ups: at baseline (T0), at 6-week follow-up (T1) and at 12-week follow-up (T2). The intervention group was given access to the WhiteTeeth app in addition to usual care (n = 67). The control group received usual care only (n = 65). The oral hygiene outcomes were the presence and the amount of dental plaque (Al-Anezi and Harradine plaque index) and the total number of sites with gingival bleeding (Bleeding on Marginal Probing Index). Oral health behaviour and its psychosocial factors were measured through a digital questionnaire. We performed linear mixed-model analyses to determine the intervention effects.

Results: At 6-week follow-up, the intervention led to a significant decrease in gingival bleeding (B = −3.74; 95% CI −6.84 to −0.65) and an increase in the use of fluoride mouth rinse (B = 1.93; 95% CI 0.36 to 3.50). At 12-week follow-up, dental plaque accumulation (B = −11.32; 95% CI −20.57 to −2.07) and the number of sites covered with plaque (B = −6.77; 95% CI −11.67 to −1.87) had been reduced significantly more in the intervention group than in the control group.

Conclusions: The results show that adolescents with fixed orthodontic appliances can be helped to improve their oral hygiene when usual care is combined with a mobile app that provides oral health education and automatic coaching.

Netherlands Trial Registry Identifier: NTR6206: 20 February 2017.

Keywords
health behaviour, health promotion, mobile applications, oral hygiene index and oral hygiene, telemedicine

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INTRODUCTION

While approximately 60% of young adults in the Netherlands receive orthodontic treatment during adolescence, fixed orthodontic appliances have an unfortunate side effect: they make oral hygiene procedures more difficult.\textsuperscript{1} Failure to practise good oral hygiene results in prolonged accumulation of biofilm (dental plaque), which potentially increases levels of cariogenic bacteria such as \textit{Streptococcus mutans}. These produce acids that cause enamel demineralization.\textsuperscript{2,3} As a result, many patients with fixed appliances have dental caries, specifically white-spot lesions, which can lead to aesthetic problems that potentially cancel out the beneficial effect of the orthodontic treatment.\textsuperscript{4-8}

To prevent the development and the progression of dental caries, orthodontic healthcare providers recommend their patients to adhere to a good oral hygiene regimen involving the use of fluoride-containing mouth rinses, toothpastes and varnishes.\textsuperscript{9} However, adherence to these recommendations is low, and oral hygiene in adolescent orthodontic patients is often inadequate.\textsuperscript{10,11} This indicates a need for interventions to improve oral health behaviour and oral hygiene in this special-risk population.

The high use and various features of mobile phones make them suitable for the delivery of health promotion programmes. As portable devices tend to be switched on and to remain with the owner throughout the day, they provide opportunities to bring behavioural programmes into important real-life contexts involving people’s decisions about their health and the barriers they encounter to behaviour change.\textsuperscript{12} The use of mobile technologies to improve health is known as mobile health (mHealth). A recent systematic review showed that mHealth can be used as an adjunct component in managing gingivitis, acquiring oral health knowledge and improving oral hygiene.\textsuperscript{13} Similarly, Araújo et al\textsuperscript{14} showed that using an intra-oral camera in consultation and sending text messages were effective in improving clinical, behavioural and psychological parameters of oral health in adults.

Many health-promoting interventions that successfully changed health behaviour included methods that targeted different stages of the behaviour change process, that is the process of behaviour initiation and maintenance.\textsuperscript{15,16} Examples of these methods include providing health-risk information, self-monitoring of behaviour and behavioural outcomes, prompting barrier identification, setting action and coping plans, and reviewing behavioural goals.\textsuperscript{15-17} However, a combination of these methods has not been applied in orthodontics.\textsuperscript{11}

In orthodontics, studies have combined mobile health technology with oral health behavioural support—particularly sending text messages to deliver prompts or oral health information.\textsuperscript{18-25} In 2017, there were at least 354 apps on orthodontics across Android and Apple operating systems.\textsuperscript{26} Most of them have very simple functions and do no little more than provide basic dental information. Despite the high number of orthodontic apps now available, only two apps have been evaluated for their effectiveness.\textsuperscript{24,25} Although text messages and these orthodontic apps improved oral hygiene, patients’ oral hygiene was still not optimal (ie dental plaque levels were still high) after the intervention period. Neither much detail was provided on the programme content—\textit{a problem for future researchers, who thus have a few options to replicating effective programmes or for attempting to design programmes that are more effective.}

In our study, we chose a combination of changing health behaviour and using mobile health technology. We took a systematic approach to designing the WhiteTeeth app, a mobile-delivered oral health promotion program for adolescents with fixed orthodontic appliances.\textsuperscript{27} Combining multiple behaviour change methods with the advantages of mobile technology, the app provided oral health education and an automatic coaching programme intended to help these users maintain good oral health behaviour and oral hygiene.

To determine the app’s effectiveness, we examined its effect on objectively measured dental plaque and marginal bleeding (primary outcomes), and self-reported oral health behaviours and their psychosocial factors (secondary outcomes). We hypothesized that dental plaque and marginal gingival bleeding would be reduced more in participants who combined use of the app with usual care than in controls.

STUDY POPULATION AND METHODOLOGY

This two-armed, parallel-group, single-blinded randomized controlled trial (RCT) tested the effect of the WhiteTeeth app against a usual care group in 12- to 16-year-olds with fixed orthodontic appliances. Our study design has been published in detail elsewhere.\textsuperscript{28} The study was approved by the Medical Ethics Committee (METC) at VU Medical Centre in Amsterdam (protocol no. 2016.162). The trial was registered with the Dutch Trial Register (www.trialregister.nl NTR6206: 20 February 2017) and was conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.\textsuperscript{29}

2.1 | Participants

The study population consisted of adolescents with fixed orthodontic appliances visiting orthodontic clinics in Alkmaar and Leiden, two cities in the Netherlands. All eligible adolescents were invited to participate by their dental-care provider—who was not further involved in the study—during a regular check-up from October 2016 to October 2017. Baseline assessments were scheduled after adolescents, and their parents had returned the informed consent form. After the completion of the baseline assessments, an independent researcher used a random-sequence generator (http://www.random.org) to randomize the adolescents into either the control or intervention group.

Those assigned to the control group received usual care, which consisted of routine oral health education and oral health instructions during their visits for orthodontic treatment. To protect against observer bias, the outcome assessors and the dental-care providers who provided the orthodontic care—including the usual preventative advice—were blinded.
2.2 The intervention: the WhiteTeeth app

It is increasingly recognized that interventions should be based on theory and should therefore be guided by intervention mapping.\(^\text{20,31}\) Intervention mapping is a protocol for developing theory-based and evidence-based health promotion programmes, whose function is to help health promoters develop the best possible intervention.\(^\text{30}\) Previously, we applied this protocol to the systematic development of the WhiteTeeth application (app) in a way that would improve oral hygiene in adolescents with fixed orthodontic appliances.\(^\text{27}\) A detailed description of the systematic development and of the content and preliminary testing of the WhiteTeeth app has been published elsewhere.\(^\text{27}\)

The app was designed on the basis of the Health Action Process Approach (HAPA) theory, which has been shown to be a useful approach to understanding the oral health behaviours of adolescents with fixed orthodontic appliances.\(^\text{20,32}\) Using behaviour change techniques (BCTs) that target the psychosocial factors outlined by the HAPA theory, the app focused mainly on improving oral health behaviour, and thereby reducing dental plaque levels and gingival bleeding.

Participants randomized to the intervention group were asked to download the app, which was available free of charge in the App Store and Google Play store and was locked with a login code. Each participant received a unique personal login code for the app. An independent researcher gave brief instructions and information on how to use the app and on how to share their user data with the research team. Afterwards, the participants received an email containing these instructions and information.

Upon opening the app, participants were required to answer registration questions and to provide personal details on their oral health behaviour and their motivation for maintaining good oral health. The app used this information to create positive reinforcement and to provide feedback on the participants’ oral health performance. During registration, the app asked participants to use disclosing tablets and to take a selfie of their teeth on which any dental plaque had been disclosed red. Next, the app asked the participants to register the amount of plaque by clicking the disclosed areas on the selfie (BCT: self-monitoring of behavioural outcomes\(^\text{33,34}\)). After interpreting the amount of plaque on the basis of the number of clicks, the app provided tailored feedback on the basis both of this plaque assessment and of the answers to the registration questions on oral health procedures. This feedback was provided as positive reinforcement regarding participants’ behaviour, as oral health education, and/or as instructions in short videos (BCT: providing information on health consequences and demonstrating the desired behaviour\(^\text{25,25}\)).

Next, the app invited the participants to set a particular goal regarding oral health behaviour (BCT: goal setting\(^\text{35}\)) and to formulate when and where they would perform the oral health behaviour (BCT: implementation intentions\(^\text{37}\)). The app provided an option for setting the time at which they wished to receive daily push notifications to remind them of their oral health behaviour tasks and then to monitor them (BCT: behavioural goal reminders\(^\text{18,20}\)).

Every day throughout the 12-week intervention period, push notifications were sent instructing users to enter whether or not they had accomplished their daily oral health behaviour tasks (BCT: self-monitoring of behaviour\(^\text{28,39}\)) and to remind them to use the brushing timer when brushing their teeth. As well as showing where and how to brush teeth as recommended,\(^\text{27}\) the timer showed the time elapsed during brushing (BCT: practical support\(^\text{25}\)). When users had completed brushing, the app provided positive reinforcement.

Each week, the app asked users to evaluate their dental plaque levels by following the same procedure as in the registration phase: using a disclosing tablet, taking a selfie of their teeth and clicking the disclosed areas on the selfie (BCT: self-monitoring of behavioural outcomes\(^\text{39}\)). On the basis of the information registered on the amount of plaque and of the activities reported daily over the previous week, the app concluded whether the user’s goals had been attained. Users were then invited to adjust their goals. If they had failed to attain their goals, they were invited to formulate coping plans, that is, “if-then” plans specifying how they could deal with difficult situations (BCT: coping planning\(^\text{36}\)). For this purpose, the app contained volitional sheets, that is, sheets outlining pre-established difficult situations and solutions.

2.3 Measures

The outcome measures were collected through clinical assessments and self-administered digital questionnaires. At baseline (T0), and at 6 weeks (T1) and 12 weeks (T2) of follow-up, the data were collected before the orthodontic check-up.

The primary study outcomes were the amount of plaque and the total number of gingival bleeding sites in the incisors, canines and first premolars of the maxilla and mandible. Al-Anezi and Harradine plaque index was used to measure the amount of plaque on the buccal surfaces.\(^\text{41}\) The buccal surfaces of the first premolars, canines and incisors were divided into four sites according to the position of the orthodontic bracket: mesial, distal, gingival and incisal to the
behaviour score that ranged from 0 to 122.5. Higher scores indicate a higher frequency of oral health-related activities. Self-dentifrices or products were summed to obtain a total oral health reported tooth-brushing frequency and tooth-brushing duration. Subsequently, the weekly frequencies for the use of each of the oral health-related activities (ranging from 0 to 24.5). Recalculation of these frequencies was used to establish the weekly frequencies of each activity. The remaining variables, a 5-point scale was used, ranging from “totally disagree” (1) to “totally agree” (5). Cronbach’s alpha (α) for all psychosocial factors held acceptable values (0.70–0.95).

The following variables were regarded as potential confounders or effect modifiers and collected at baseline: (a) age (in years); (b) sex (boy/girl); (c) level of education (primary education, pre-vocational education, senior general secondary or pre-university education); (d) cultural background (Dutch or other); (e) smoking status (smoker or non-smoker); and (f) the number of times of exposure to the acids or sugars in foods and/or drinks between main meals (times per day). Orthodontic patient files also provided information on baseline covariates: (g) the type of orthodontic bracket used (e.g., self-ligating or conventional brackets) and (h) the treatment duration (in days).

2.4 | Use of the WhiteTeeth app and its usability

App usage data were collected during the 12-week intervention period. Participants were asked to use the WhiteTeeth app to send their user data weekly from their mobile via to the database. At 6- and 12-week follow-up, all participants in the intervention group were reminded to send their user data via the app. Data files were imported into an Excel file and processed into a format suitable for SPSS. This process was undertaken by an independent researcher who had no involvement in data collection or data analysis.

After the 12-week follow-up period, a digital questionnaire was conducted to determine the usability of the app and the user’s perceptions of several components of the app. For this purpose, we used the System Usability Scale (SUS), measuring subjective assessments of the app’s usability. The SUS ranges from 0 to 10, with responses ranging from “strongly agree” to “strongly disagree.” A SUS score above 68 was considered to be above average. This questionnaire has been published elsewhere.

2.5 | Statistical analysis

Continuous data are presented as means (M) with standard deviations (SD) and categorical data as frequencies and percentages. Descriptive statistics were used to describe the use of components of the app. The independent sample t test and the chi-square test were used to compare the baseline characteristics of dropouts and completers in the total sample. Linear mixed models were used to analyse the effects of the WhiteTeeth app and to take account of the correlated
observations within the participant. To compare the outcome measures between the intervention and control groups, we performed intention-to-treat analyses. To take account of differences in baseline values in all analyses, the outcome of interest was adjusted for the baseline value of that particular outcome. With mixed-model analyses, the intervention effect was evaluated at different follow-up times. This
was done by adding the interaction between the condition and time to the model. The effect-size B is the mean difference in outcome between the two groups. Two models were constructed: (a) crude models and (b) models adjusted for covariates. Since linear mixed-model analysis handles missing observations caused by dropout, no additional action was undertaken to handle missing data. A two-tailed significance level of 5% was considered to be statistically significant in all analyses. The analyses were conducted with the Statistical Package of Social Sciences (SPSS) version 22.0 (IBM Corp).

3 | RESULTS

As Figure 2 shows, 132 of the 230 eligible adolescents with fixed orthodontic appliances agreed to participate (response rate 57%); they provided informed consent, attended baseline and were randomly assigned to one of the two experimental arms. Five patients dropped out of the intervention group, and three patients dropped out of the control group. One patient in each group dropped out because their appliances had to be removed prematurely due to poor oral hygiene. Due to technical complications involving the tablet on which the T0 questionnaire was filled in, the total number of participants who completed all three questionnaires was 121 (92%).

Between T0 and T1, the mean number of weeks (SD) between each appointment was 6.2 weeks (1.4) for the intervention group and 6.2 weeks (1.1) for the control group (P = .997). Between T1 and T2, it was 6.6 weeks (2.1) for the intervention group and 6.7 weeks (2.3) for the control group (P = .962). Due to technical complications, occasional malfunctions meant that the user data—including selfies—were not always sent during the intervention period. For this reason, less user data were available than expected. But according to the user data we received, 40 participants (65%) sent their user’s data an average of 4.94 times (SD = 5.2) to a secure server owned by the Academic Centre for Dentistry Amsterdam. After 6 weeks, most patients used the app less often. In total, reminders were set by seven participants for brushing, by nine participants for rinsing, by 16 for self-monitoring of behavioural tasks and by 11 for taking a selfie. During the intervention period, 20 participants used the brushing timer an average of 9.61 times (SD = 27.8). In total, 38 participants took at least one selfie with the app; the mean number of selfies taken per person was 6.63 (SD = 4.46). Thirty-six participants entered action plans into the app, and seven used the volitional sheets to set a coping plan. Thirty-four participants watched at least once the video on dental plaque and/or on cleaning their teeth with a manual toothbrush, an electric toothbrush and/or interproximal brushes. Personal appearance and attractiveness (white teeth) were given as the commonest motives for cleaning their teeth. The mean SUS was 75 (range 0-100), which indicated a good score for usability.

Table 1 presents the baseline demographic and clinical characteristics of the study sample. Comparison of the baseline characteristics of patients who completed the study and those who dropped

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Patients’ characteristics at baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Characteristic</strong></td>
<td><strong>Intervention group (n = 67)</strong></td>
</tr>
<tr>
<td>Age (y)²</td>
<td>13.2 (1.01)</td>
</tr>
<tr>
<td>Girl (yes)b</td>
<td>41 (61.2%)</td>
</tr>
<tr>
<td>Education levelb (using the standard Dutch abbreviations)</td>
<td></td>
</tr>
<tr>
<td>Primary education</td>
<td>7 (10.4%)</td>
</tr>
<tr>
<td>Prevocational education—Practical Pathway (PP VMBO)</td>
<td>7 (10.4%)</td>
</tr>
<tr>
<td>Prevocational education—Theoretical Pathway (TP VMBO)</td>
<td>16 (23.9%)</td>
</tr>
<tr>
<td>Senior general secondary education (HAVO)</td>
<td>17 (25.4%)</td>
</tr>
<tr>
<td>Pre-university education (VWO)</td>
<td>20 (29.9%)</td>
</tr>
<tr>
<td>Cultural backgroundb</td>
<td></td>
</tr>
<tr>
<td>Dutch</td>
<td>63 (94.0%)</td>
</tr>
<tr>
<td>Moroccan</td>
<td>4 (6.0%)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Smoking (no)b</td>
<td>67 (100%)</td>
</tr>
<tr>
<td>Conventional brackets (yes)b</td>
<td>16 (24.6%)</td>
</tr>
<tr>
<td>Exposure to the acids and/or sugars in foods and/or drinks between main meals (times per day)a</td>
<td>3.6 (1.80)</td>
</tr>
<tr>
<td>Duration at baseline of treatment with fixed orthodontic appliances (d)a</td>
<td>401.0 (212.1)</td>
</tr>
<tr>
<td>Oral health behaviour score (0-122.5)a</td>
<td>20.9 (9.3)</td>
</tr>
<tr>
<td>Plaque index (S&amp;L; 0-192)a</td>
<td>70.8 (29.6)</td>
</tr>
<tr>
<td>Number of gingival bleeding sites (0-48)a</td>
<td>27.8 (8.9)</td>
</tr>
</tbody>
</table>

²Mean (SD), b n (%); no significant differences between the two groups were found.
out before the last assessment shows that completers scored significantly higher on the oral health behaviour score (mean [SD] total sample = 20.67 [8.97]; dropout = 17.88 [2.67]; \( P = 0.04 \)).

3.1 \textbf{The intervention effects on oral hygiene}

Table 2 shows descriptive information on the oral hygiene outcomes for the two groups at baseline, at 6-week follow-up and at 12-week follow-up. It also shows the crude and adjusted intervention effects on oral hygiene at both 6-week and 12-week follow-up. At 6-week follow-up, the intervention effect on the total amount of dental plaque (\( B = -6.86 \); 95% CI: -16.05 to 2.34) and the total sites covered with plaque (\( B = -4.83 \); 95% CI: -9.69 to 0.04) was not significant. Nonetheless, at 12-week follow-up, the reductions in dental plaque accumulation (\( B = -11.32 \); 95% CI: 20.57 to -2.07) and the presence of dental plaque (\( B = -6.77 \); 95% CI: -11.67 to -1.87) were significantly greater in patients in the intervention group than in the controls: while, on average, plaque was present on 62% of teeth in the intervention group, it was present on 73% of teeth in the control group. Explorative analysis showed that the intervention had significantly affected the dental plaque on the mesial, distal and gingival sites to the orthodontic bracket, but not on the site that was incisal to the bracket.

Regarding the intervention effects on gingival bleeding, bleeding scores had improved more in participants in the intervention group than in controls at 6 weeks of follow-up (\( B = -3.74 \); 95% CI: -6.84 to -0.65). At 12 weeks of follow-up, however, the intervention effect was no longer significant (\( B = -1.89 \); 95% CI: -5.00 to 1.22).

3.2 \textbf{The intervention effects on oral health behaviour and its psychosocial factors}

Table 3 shows the descriptive information and the results of the mixed-model analyses for the oral health behaviours. The only significant intervention effect was for fluoride use at the 6-week follow-up: it favoured the intervention group (\( B = 1.93 \); 95% CI: 0.36 to 3.50). No significant intervention effects were found for the oral health behaviour score, tooth-brushing (frequency and duration) and interproximal brush usage.

With regard to the psychosocial factors, significant adjusted effects were found for coping planning regarding tooth-brushing (T1: \( B = 0.27 \); 95% CI: 0.03 to 0.51; T2: \( B = 0.27 \); 95% CI: 0.03 to 0.51; \( P = .028 \)) and intention towards fluoride mouth rinse use (T1 \( B = 0.56 \); 95% CI: 0.15 to 0.96; T2 \( B = 0.42 \); 95% CI: 0.01 to 0.83) at both 6-week and 12-week follow-up. Although not significant, the scores on most psychosocial factors at 12-week follow-up were better in the intervention group than in the control group (data not shown).

4 \textbf{DISCUSSION}

This randomized controlled trial aimed to test the effect of the WhiteTeeth app on oral health behaviour and oral hygiene in adolescents with fixed orthodontic appliances. The app incorporated many behaviour change methods, targeting not only oral health behaviour but also the psychosocial factors that are associated with this behaviour and had been identified through the HAPA theory.\(^{27}\) The behaviour change techniques it incorporated included coaching to set goals, action plans and reminders; self-monitoring of oral health behaviour and dental plaque; providing feedback and practical support; reviewing behavioural goals; and creating coping plans.

Relative to the usual care group, the WhiteTeeth app was associated with significant reductions in gingival bleeding at 6 weeks of follow-up and in dental plaque at 12 weeks of follow-up. Although the app was not effective in changing tooth-brushing frequency and duration, the decrease in dental plaque reflects a change in brushing pattern, as the number of sites covered with plaque decreased significantly. For example, a person may initially have focused on the incisal sites to the exclusion of the distal sites. At both follow-ups, the app was also effective in changing coping planning regarding tooth-brushing.

Previously, only two studies evaluated the effectiveness of a mobile app for oral health promotion in orthodontic patients.\(^{24,25}\) In the first study, Zotti et al\(^{24}\) evaluated a WhatsApp-based program that combined instructions on maintaining oral hygiene during orthodontic treatment with the use of a chat room named the "Brush Game," in which patients could share information, pictures and movies on oral hygiene and orthodontic treatment. At 9 and 12 months, the WhatsApp-based program had been effective in improving both the oral hygiene and oral health of adolescents with fixed appliances: at 12 months, patients participating in the chat room had significantly lower values on the plaque index (\( P < .0001 \)) and gingival index (\( P < .05 \)), and also a lower incidence of new white-spot lesions or caries than those in the control group (control group: 40% vs app group: 15.5%; \( P < .0001 \)).

In the second study, a mobile app had been designed by Alkadhi et al\(^{25}\): it consisted of videos of oral hygiene instructions and text messages encouraging patients to practise oral hygiene tasks. Controls and patients allocated to the app all received traditional oral health promotion in an orthodontic clinic. The study, in adolescents in Saudi Arabia, showed that the app had reduced the dental plaque and gingival indices more effectively (\( P < .05 \)) after 4 weeks of follow-up than verbal oral hygiene instructions had.\(^{25}\)

While our study corroborates these findings, it also goes beyond previous studies by using behavioural theory for the program design, and thus by targeting the underlying factors of oral health behaviour and by evaluating the effects on these factors. By doing so, this study contributes to research involving the understanding of oral health behaviour. In addition, while the researchers in the other studies provided little detail on the content of their app, we previously published a comprehensive description of the intervention content and its incorporated behaviour change methods.\(^{27}\) By adding to the limited evidence base on the effectiveness of theory-based interventions targeting oral hygiene in adolescent orthodontic patients, this will aid researchers to design programmes that are even more effective.\(^{11}\)
### TABLE 2  Descriptive information and the effects of the intervention on dental plaque and gingival bleeding of the first premolars, canines and incisors around the brackets (n = 124)

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>Mean (Standard deviation)</th>
<th>Effects</th>
<th>T1</th>
<th>95% CI</th>
<th>P</th>
<th>T2</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total amount of dental plaque accumulation according to the Al-Anezi and Harradine plaque score (0-192)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>70.79 (29.56)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>75.34 (34.27)</td>
<td></td>
<td>-7.95</td>
<td>-16.81; 0.90</td>
<td>.078</td>
<td>-13.49</td>
<td>-22.37; -4.62</td>
<td>.003</td>
</tr>
<tr>
<td>Control</td>
<td>70.42 (30.72)</td>
<td></td>
<td>-6.86</td>
<td>-16.05; 2.34</td>
<td>.143</td>
<td>-11.32</td>
<td>-20.57; -2.07</td>
<td>.017</td>
</tr>
<tr>
<td>Total sites covered with plaque (0-64)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>45.04 (12.43)</td>
<td></td>
<td>-4.94</td>
<td>-9.44; -0.44</td>
<td>.032</td>
<td>-6.91</td>
<td>-11.42; -2.40</td>
<td>.003</td>
</tr>
<tr>
<td>Control</td>
<td>45.40 (14.35)</td>
<td></td>
<td>-4.83</td>
<td>-9.69; 0.04</td>
<td>.052</td>
<td>-6.77</td>
<td>-11.67; -1.87</td>
<td>.007</td>
</tr>
<tr>
<td>The number of mesial sites covered with plaque (0-16)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>12.77 (3.55)</td>
<td></td>
<td>-1.33</td>
<td>-2.57; -0.09</td>
<td>.036</td>
<td>-1.88</td>
<td>-3.13; -0.64</td>
<td>.003</td>
</tr>
<tr>
<td>Control</td>
<td>12.98 (3.78)</td>
<td></td>
<td>-1.36</td>
<td>-2.71; -0.01</td>
<td>.048</td>
<td>-1.85</td>
<td>-3.22; -0.49</td>
<td>.008</td>
</tr>
<tr>
<td>The number of incisal sites covered with plaque (0-16)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>6.55 (4.34)</td>
<td></td>
<td>-0.86</td>
<td>-2.29; 0.57</td>
<td>.237</td>
<td>-1.20</td>
<td>-2.63; 0.23</td>
<td>.101</td>
</tr>
<tr>
<td>Control</td>
<td>7.26 (4.70)</td>
<td></td>
<td>-0.87</td>
<td>-2.44; 0.69</td>
<td>.271</td>
<td>-1.25</td>
<td>-2.82; 0.32</td>
<td>.118</td>
</tr>
<tr>
<td>The number of distal sites covered with plaque (0-16)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>13.45 (2.94)</td>
<td></td>
<td>-1.35</td>
<td>-2.63; -0.07</td>
<td>.039</td>
<td>-1.82</td>
<td>-3.11; -0.54</td>
<td>.006</td>
</tr>
<tr>
<td>Control</td>
<td>13.18 (3.67)</td>
<td></td>
<td>-1.11</td>
<td>-2.53; 0.32</td>
<td>.127</td>
<td>-1.53</td>
<td>-2.96; -0.091</td>
<td>.037</td>
</tr>
<tr>
<td>The number of gingival sites covered with plaque (0-16)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>12.27 (3.69)</td>
<td></td>
<td>-1.46</td>
<td>-2.79; -0.14</td>
<td>.031</td>
<td>-2.06</td>
<td>-3.39; -0.73</td>
<td>.003</td>
</tr>
<tr>
<td>Control</td>
<td>11.97 (3.95)</td>
<td></td>
<td>-1.51</td>
<td>-2.93; -0.09</td>
<td>.038</td>
<td>-2.15</td>
<td>-3.58; -0.71</td>
<td>.004</td>
</tr>
<tr>
<td>Bleeding on Marginal Probing (0-48)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>27.81 (8.94)</td>
<td></td>
<td>-2.32</td>
<td>-5.31; 0.67</td>
<td>.128</td>
<td>-2.44</td>
<td>-5.45; 0.56</td>
<td>.110</td>
</tr>
<tr>
<td>Control</td>
<td>28.11 (8.25)</td>
<td></td>
<td>-3.74</td>
<td>-6.84; -0.65</td>
<td>.018</td>
<td>-1.89</td>
<td>-5.00; 1.22</td>
<td>.232</td>
</tr>
</tbody>
</table>

Abbreviations: B, mean difference in outcome between the two groups; CI, confidence interval.

*The crude effects are adjusted for baseline values of the outcome of interest;

*The adjusted effects are adjusted for baseline values of the outcome of interest and for sex, age, education level, type of toothbrush, oral health behaviour, cultural background and the duration of orthodontic treatment.
The evaluation of orthodontic oral health promotion programmes has focused mainly on preventing demineralization by improving oral hygiene procedures during fixed-appliance orthodontic treatment. Interestingly, however, no studies have investigated the effect of oral health promotion targeting the use of fluoride mouth rinses. Our study showed that, after 6 weeks of follow-up, the app was effective in improving not only the intention to use fluoride mouth rinse, but also its actual use. However, at 12-week follow-up, only the effect on the intention was still significant. The attenuated effect on the mouth rinse use may have been due to the fact that, after 6 weeks, most patients used the app less often.

In order for an oral health promotion app to be effective, it must be engaging for users, thus allowing them to be exposed to its incorporated behaviour change techniques. It was demonstrated that a large proportion of users of mHealth interventions do not maintain engagement. High degree of attrition undermines the potential of apps to be effective. Strategies most likely to engage users with an app were ease of use, design, tailoring of design and information and unique smartphone features.

Usability has been identified as one of the factorsthat may determine engagement with a mobile app. Therefore tested the usability of the WhiteTeeth app with the SUS. The usability was perceived as good (SUS = 75).

Unfortunately, due to technical problems that occurred during the intervention period, data on the use of the various components were not reliable, as we did not receive all users’ data. For example, data on creating coping plans regarding fluoride mouth rinse were not registered for any of the patients, and some patients were unable to send their data via the app because they did not install the email function on their phone. These malfunctions prevented us from detecting the extent of compliance with the intervention components and from identifying which component or behaviour change technique was responsible for producing changes in the outcomes, or whether there was a synergistic effect of all behaviour change techniques working together.

Since the launch of the WhiteTeeth app in 2016, the consumer market for oral health apps has expanded, bringing many new features, such as connections to a toothbrush via Bluetooth or sound detection, sensors that detect and record the brushing position, and options for sharing oral-care activity with a dental-care provider. These tools offer opportunities for evaluating and self-monitoring oral hygiene more accurately, which may promote the development of self-regulation skills and successful maintenance of oral health. However, the evidence base for the current range of effective interventions is still very limited, and more research is needed to determine the best ways to leverage consumer-based mobile health technologies and combine them successfully with proven behaviour change methods. Similarly, particular attention should be paid to strategies for involving parents effectively, as previous research has shown promising results regarding the effectiveness of parents’ involvement in changing adolescents’ health-related behaviour. Future studies might thus examine the effectiveness of using the app to share and evaluate adolescents’ goals and oral hygiene with parents and/or the dental-care provider.
5 | CLINICAL RELEVANCE

5.1 | Rationale for the study

In the absence of good oral hygiene, patients with fixed orthodontic appliances can develop white-spot lesions that remain visible for the rest of their lives. It is therefore necessary to establish the extent to which innovative oral health promotion programmes can further improve patients’ oral hygiene. However, little is known about the effectiveness of continuous behavioural support via mobile phones (mHealth).

5.2 | General findings

The WhiteTeeth app was effective in reducing dental plaque in adolescents with fixed orthodontic appliances.

5.3 | Practical implications

The use of a mobile app as an adjunct to usual care may be a viable method of improving oral health promotion. There is need for more research that can further develop mHealth’s great potential for improving dental care.

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CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

AUTHOR CONTRIBUTIONS

JS (principal researcher) wrote the first draft of the protocol and was responsible for obtaining ethical approval for the trial. All authors contribute to the development of the protocol through various amendments. JS, GK and TB coordinated the data collection. JS and TB collected, managed and restructured the data. JS performed the analyses. PE, AP and JT were consulted for statistical guidance and checked the analyses. All authors reviewed and approved its final version.

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