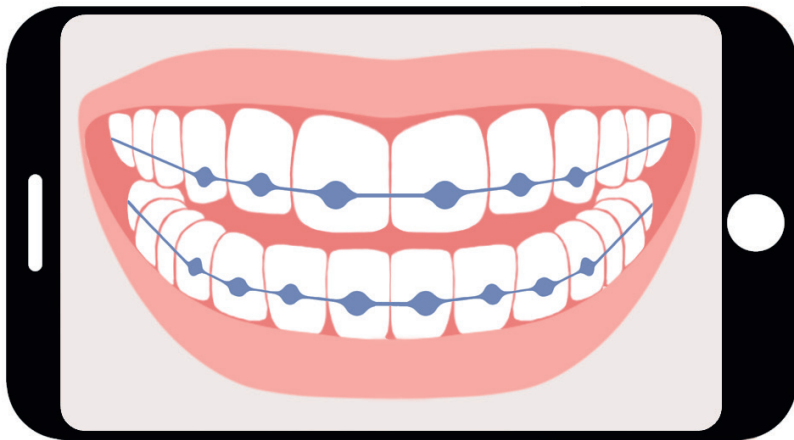


The WhiteTeeth app

The development and evaluation
of a smartphone app for promoting
oral health behavior and oral hygiene
in adolescent orthodontic patients



JANNEKE SCHEERMAN

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COLOFON

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A stylized illustration of a hand holding a smartphone. The hand is rendered in a light pinkish-red color with simple, rounded shapes for the fingers and palm. The smartphone has a dark blue or black frame. The screen is a light gray color and displays a quote in black, sans-serif font. The quote is centered on the screen and reads: "You can work from websites, you can work with Photoshop, I work with my iPhone.. It's ridiculous to fight new media. You can't win, so you just have to incorporate it into your toolbox." Below the quote, the name "LUC TUYMANS" is written in a smaller, bold, sans-serif font. The background is plain white.

**"You can work from websites,
you can work with Photoshop,
I work with my iPhone..
It's ridiculous to fight
new media. You can't
win, so you just have
to incorporate it into
your toolbox."**

LUC TUYMANS

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CHAPTER 1

General introduction



GENERAL INTRODUCTION

1

Fixed orthodontic treatment

Orthodontics is the branch of dentistry concerned with facial growth and the development of the dentition, and with occlusion and the prevention and correction of occlusal anomalies [1]. Approximately 53-57% of Dutch 12-year olds undergo orthodontic treatment—some 100,000 patients each year [2]. Most of these patients are treated using fixed orthodontic appliances (orthodontic brackets), which are used to correct a wide range of dental and skeletal malocclusions and to align teeth. These appliances are fixed to the teeth, forces being applied by the archwires or auxiliaries attached to them [1]. Such is usually performed during adolescence, when the eruption of permanent teeth is complete but craniofacial growth is still progressing. This combines advantages in terms of tooth movement, correction of malocclusion and the maintenance of favorable facial growth [3].

The main objectives of orthodontic treatment are to achieve pleasant smile aesthetics with a stable occlusal relationship and healthy masticatory function [1]. The improvements brought by orthodontics to a patient's facial and dental appearance can also have mental health benefits, as they increased the patient's psychosocial well-being and sense of self-esteem and self-confidence [1,4]. As the ideal alignment of the teeth simplifies oral hygiene, it is also supposed to reduce dental caries and periodontal diseases.

White spot lesions

Individuals with malocclusions typically have many retention sites to which oral bacteria can adhere. The irregularities of the teeth make it easier for dental plaque or a biofilm to form. Bonding attachments such as fixed orthodontic appliances to the teeth also create retention sites on surfaces that are not generally susceptible to caries. As these appliances make it difficult to clean the regions surrounding the bracket, they hamper the maintenance of oral hygiene, explaining why biofilm-related complications such as periodontal inflammation and dental caries formation are common during fixed orthodontic therapy [5-7].



Fig.1. Opaque white spot lesions or decalcification around the brackets and along the gingival margins (picture by courtesy of P.R. Kolodziej).



Fig. 2. Cavities developed during orthodontic treatment with fixed appliances (picture by courtesy of P.R. Kolodziej).

The severity of dental caries can range from decalcification (i.e., white spot lesions; Fig. 1), through the loss of the surface integrity of the enamel, to cavitation (Fig. 2) [8]. White spot lesions can develop rapidly in the four weeks between one orthodontic appointment and the next [9]; nearly 25% patients with fixed orthodontic appliances

have clinically visible enamel demineralization [10]. Demineralized tooth enamel can absorb stains from food and beverages, which eventually discolor the white spot lesions into brown spots [11]. After the removal of orthodontic appliances, these lesions can remain visible for life, their opacity or discoloration seriously compromising aesthetics, potentially canceling out the beneficial aesthetic effect of the orthodontic treatment [11].

Oral health recommendations and adherence in orthodontics

As the prolonged accumulation of dental plaque is an important factor in the development of oral diseases, the maintenance of good oral hygiene is essential to prevent oral conditions such as white spot lesions. The use of fluoride agents is another effective way of preventing the development and progression of decalcification and lesions. Orthodontic healthcare providers therefore recommend their patients to brush their teeth at least twice daily and to use additional dental aids, such as a proxy brush or dental floss, for effective plaque removal, as well as to use fluoridated toothpaste (1450 ppm fluoride) and mouth rinse (0.05% NaF). They also recommend the consumption of an appropriate diet that avoids foods that can debond fixed appliances or increase the risk of dental caries [12].

To prevent white spot lesions during fixed orthodontic treatment, it is essential that patients adhere to such oral health recommendations. Adherence is defined as the extent to which a person's behavior—such as following a diet—is consistent with the recommendations they have agreed with healthcare provider [13]. If orthodontic patients do not adhere to these recommendations, treatment outcomes may be compromised; in some instances, it may be necessary to terminate treatment prematurely. Due to poor oral hygiene, it is estimated that the appliances of 5%-10% of orthodontic patients are removed to prevent further decalcification before orthodontic treatment has been completed [14].

Low adherence to oral health recommendations and poor maintenance of oral hygiene are considerable problems in adolescent orthodontic patients [15, 16]. For example, Geiger et al. showed that fewer than 15% of orthodontic patients rinsed daily with fluoride as requested [17]. Similarly, Aljabaa et al. showed that over 50% of orthodontic patients reported never flossing [18].

Oral health promotion programs in orthodontics

Several programs have been designed to promote oral health among adolescent orthodontic patients. In 2014, Aljabaa et al. conducted a systematic literature review on the effectiveness of these programs. They found the following four randomized controlled trials, each of which used different methods to improve oral hygiene in orthodontic adolescent patients [18]:

(1) Richter et al. (1998) tested the effectiveness of rewards and awards [19]. Participants received either rewards in the form of tangible gifts or awards in the form of a report card that provided feedback on their adherence to various oral health recommendations. For example, some participants were awarded a grade for the amount of plaque they removed.

(2) Wright et al. (2010) tested the effectiveness of providing an information leaflet that had been designed, illustrated and written to be both appealing and comprehensible to adolescents [20]. The leaflet also included photographs showing oral health outcomes of poor oral hygiene and dental neglect.

(3) Arharya et al. (2011) tested the effectiveness of a chairside motivational technique that showed the acidic nature of plaque and used phase-contrast microscopy to visualize the microbial activity of the patient's dental plaque [21].

(4) Feil et al. (2002) evaluated the intentionally induced Hawthorne effect. Specifically, they evaluated whether patients who were deceived into believing they were participating in a clinical trial would have lower plaque scores than those who were unaware that they were in a study [22].

Except for the trial that provided an information leaflet, all the intervention methods were associated with improvements in oral hygiene. However, the quality of these trials was only moderate, and they provided few details of their program content [18].

In 2016, Aljabaa et al. (2016) conducted a three-arm randomized controlled trial in orthodontic adolescent patients to test the effect of three approaches to improve oral hygiene, and patients' knowledge of oral health and oral health behaviors [23]. The three study arms comprised usual care, which consisted of two leaflets as well as verbal instructions; usual care plus mind-mapping; and usual care plus 'if-then' planning. The mind map comprised a single-color diagram detailing aspects of oral care for with fixed orthodontic appliances. Patients were shown the mind map and taken through the information shown on it. Patients in the planning group were asked to identify where and when they would engage in oral hygiene-related behaviors and to formulate an 'if-then' plan (i.e., "if event X occurs, then I will do Y"). Relative to care as usual, neither mind-mapping nor planning were found to produce significant differences regarding oral hygiene, oral health knowledge or behavior.

To date, there has been little empirical evidence that face-to-face programs intended to promote oral health in adolescents with fixed orthodontic appliances are effective. As a result, there is too little evidence for oral healthcare providers to choose and implement the best available oral health promotion programs in their daily practice.

The aim of this dissertation

Due to the use of modern technology—such as mobile devices—the delivery of oral health promotion programs is evolving [24]. The provision of health

promotion programs via mobile devices is known as mobile health (mHealth). As the implementation of such programs may contribute to oral health promotion in patients who receive orthodontic treatment, the WhiteTeeth app was developed. The WhiteTeeth app is an mHealth program intended to promote better oral health behavior and oral hygiene among adolescents with fixed orthodontic appliances. The aim of this dissertation is to describe its development, content and evaluation.

After a general description of mHealth, the following paragraphs describe the effectiveness of current mHealth programs in orthodontic adolescent patients and how they can be optimized.

Mobile health (mHealth)

MHealth has emerged as a sub-segment of electronic health (eHealth), which involves the use of information and communication technology (ICT) for health services and information [25]. MHealth was first introduced and defined in 2003 as mobile-computing, medical-sensor and communications technologies for healthcare [26]. A definition used at the 2010 mHealth Summit of the Foundation for the National Institutes of Health (FNIH) was “the delivery of healthcare services via mobile communication devices” [27]. Today, the term mHealth refers to “the practice of medicine and public health supported by mobile devices”. Most commonly, it refers to the use of mobile communication devices (such as mobile phones or smartphones, tablets and personal digital assistants) and wearable devices (such as smart-watches), for health services, information and/or data collection” [26].

In the past ten years, mobile phones have rapidly evolved into handheld computers—i.e., smartphones. The introduction of smartphones has played a major role in the evolution of mobile health. While the functions of older-generation mobile phone comprised voice communication and text messages (i.e., Short Messages Service (SMS)), the technology available in smartphones has extended functionality.

Text messaging in orthodontics

As text messaging works both on the simplest mobile phones and on the more advanced smartphones, it provides a unique opportunity to send patients cues or information on their phones [28]. A recent systematic review with meta-analysis of randomized controlled trials showed that adolescent orthodontic patients who received text messages reminders had better oral hygiene with less plaque accumulation and gingival bleeding over time than those who did not receive such messages [29]. It also showed that the development of white spot lesions was reduced when a weekly text message explaining the importance of oral hygiene or containing reminders of oral health recommendations was sent to adolescent orthodontic patients or their

parents [29]. Text-message reminders sent to orthodontic patients also helped to reduce patients' self-reported pain and failure to attend appointments [30-32].

Text messaging is a simple intervention to develop and use; not only are its content and schedule customizable, it also provides a push-mode delivery that prompts users to read. On the other hand, it offers limited interaction. As a result, its engagement is merely passive. Neither does it use the latest smartphone features. Using modern smartphone technology may therefore lead to further optimization and greater changes in oral health behavior and outcomes [28].

Smartphones

New generation smartphones have a powerful computing capacity, a very large memory, various hardware devices (such as cameras, GPS, and sensors), links to various networks (such as 4G and Wi-Fi) and open operation systems that encourage software application development. The release of the iPhone in 2007 led the way for developers to create a library of software applications (apps) available to users. Apps are software programs that have been developed to run on a mobile device in order to accomplish a specific purpose. Users can browse a library (such as Google Play or Apple App Store), search for specific apps that serve their needs, and then download them onto their mobile device.

Smartphones have gained popularity as a personal communication device; using them for communication is now part of people's lifestyle. In 2017, there were over 2.3 billion smartphone users worldwide, and forecasts suggest that 2.8 billion of the world's population will use a smartphone by 2020 [33]. The high use and various features of smartphones make them suitable for the delivery of health promotion programs [34]. As portable devices tend to be switched on and to remain with the owner throughout the day, they provide opportunities for bringing behavioral programs into important real-life contexts involving people's decisions about their health and the barriers they encounter to behavior change [34, 35]. Similarly, the connectedness of smartphones facilitates the sharing of behavioral and health data with other people, such as parents, peers and as healthcare providers [34,35]. Due to their ability to provide a wealth of information quickly and efficiently, smartphones are also a valuable information source. And due to their increasing ability to use sensors to infer context such as user location and movement, there is now a prospect of continuous and automated tracking of health-related behaviors and timely, tailored programs for specific contexts [34].

The medical community has embraced smartphone technology, making a great number of health-related apps available for patients and healthcare providers [36,37]. As early as 2012, an estimate put the number of health-related apps at no fewer than 40,000 [28]. Many commercial apps have already been developed to help people manage stress, improve mood, follow a healthy diet, manage weight, increase physical

activity, quit smoking, and self-manage chronic health problems [38,39]. From basic apps composed of text-message reminders to sophisticated apps that coordinate the management of chronic diseases or coach behavioral change, apps have a multitude of functions in health and healthcare [28]. But despite the evidence showing that apps can be a useful adjunct to traditional healthcare, various areas and gaps in our knowledge remain to be explored—including the use of apps as an intervention tool for oral health promotion in orthodontics [39].

Orthodontic apps

In 2017 there were at least 354 apps on orthodontics across Android and Apple operating systems [40]. Most of them have very simple functions and do little more than provide basic information, and provide information on malocclusion, remind patients about elastic wear, track treatment progress, and promote orthodontic products. Very few focus on oral health promotion [40-42].

Despite the high number of orthodontic apps now available, only two apps for oral health promotion have been evaluated for their effectiveness [39,43,44]. Zotti et al. 2015 evaluated a WhatsApp-based program that consisted of instructions to download video tutorials on maintaining oral hygiene during orthodontic treatment, and using a chat room called the “Brush Game” [43]. Patients in this chat room were allowed to share information, pictures and movies on oral hygiene and orthodontic treatment. To show their oral hygiene status in this chat room, they were also asked to share two self-photographs (“selfies”) weekly, before and after using a plaque-disclosing tablet. Every week, a moderator published a ranking of the five best participants. After 6, 9, and 12 months, this app was shown to provide an effective way of improving oral hygiene and oral health in adolescents with fixed appliances.

In another study, Alkadhi et al. designed a mobile app to improve oral hygiene among adolescents with fixed orthodontic appliances [44]. It consisted of videos of oral hygiene instructions and text messages encouraging patients to practice oral hygiene tasks three times a day. Patients allocated to the app and those in the control group received traditional oral health education in an orthodontic clinic. After 4 weeks, the study showed that the app had improved oral hygiene levels effectively.

Although text messages and these orthodontic apps improved oral hygiene effectively in adolescent orthodontic patients, patients’ oral hygiene was still not optimal (i.e., dental plaque levels were still high) after the intervention period, and most of the follow-up periods were short-term. Neither was much detail provided on program content—a problem for future researchers, who thus have few options for replicating effective programs or for attempting to design programs that are more effective. There is therefore a need for optimized oral health promotion programs and high-quality studies evaluating them.

Optimizing oral health promotion programs

The objective of oral health promotion is to induce behavior change and to reinforce and maintain healthy behavior that will contribute to good oral health [45, 46]. Traditionally, on the principle that improving patients' knowledge of their disease may lead them to adopt good oral health behaviors, many oral health promotion programs have focused on the provision of oral health knowledge and instructions [46]. However, research has shown that oral health knowledge and instructions alone are not enough to establish long-term behavior change [47]. Instead, behavior can successfully be changed and maintained by influencing its determinants [48]. Behavioral determinants are causal factors of a particular behavior. As the desired behavior can be induced and maintained by influencing its behavioral determinants, programs should be designed to influence the important determinants related to the particular behavior.

Researchers have developed and tested models or theories of health behavior that identify behavioral determinants and specify the pathways whereby the determinants influence behavior. In other fields of dentistry it has been shown that oral hygiene, oral health behaviors and their determinants are improved more effectively by oral health promotion programs that were designed on the basis of a behavioral theory—and thus targeted behavioral determinants—than by programs that were not based on theory [47,49]. On the basis of reviews of orthodontic programs promoting oral health, whether face-to-face or via a mobile device [23,40,41,43], it can be concluded that most program developers did not use behavioral theories in their program design, but based their programs on common sense. Neither do most programs contain behavior change techniques. Such techniques—also known as behavior change methods—are general techniques or processes that have shown an ability to change one or more determinants of behavior and have their origins in behavioral and social science theory [48]. The application of relevant behavioral theories and evidence can inform the selection of behavior change methods, thereby increasing a program's potential effectiveness [50].

Programs incorporating more behavior change methods tended to have greater effects on behavior than those incorporating fewer methods—possibly a consequence of the fact that different methods target different aspects of the behavior change process [50]. In addition, because studies of orthodontic programs did not describe the determinants targeted by the program or did not evaluate their effect on behavioral determinants, the mechanisms underlying change in oral health behavior in orthodontics are still not understood. For this reason, future studies should not only design theory-based programs targeting the behavioral determinants, but also describe and evaluate their effects on these determinants.

Theories of health behavior change and maintenance

Recent theoretical work on health behavior change, and especially maintaining health behaviors, has focused on self-regulation processes, which can be defined as those “mental and behavioral processes by which people enact their self-conceptions, revise their behavior, or alter the environment so as to bring about outcomes in line with their self-perceptions and personal goals” [51]. Self-regulation involves the setting of goals, cognitive preparations, and the ongoing monitoring and evaluating of goal-directed behavior [52]. Even though different theories emphasize different aspects of self-regulation processes, there is an overlap in the constructs underlying most of these theories. Two phases are commonly distinguished: motivational and volitional. Most earlier theories have focused on the motivational phase of the self-regulation process—a phase that ends with a decision on the goal to be pursued (i.e., intentions) [52]. These theories are known as motivational theories.

Motivational theories assume that the determinant that is most proximal and most important to the performance of a particular behavior is the intention (or motivation) to engage in that behavior. Examples of such motivational theories are the Theory of Reasoned Action (TRA; later extended and changed into the Theory of Planned Behavior) and the Attitude-Social influence-self-Efficacy (ASE) model [53-55]. According to these motivational models, intentions are determined by three factors. The first is attitude, which is based on beliefs or outcome expectancies and is the overall (positive or negative) evaluation of a behavior or behavioral goal. The second factor is social influence, which is based on injunctive or descriptive norms and is defined as what other important people think or do with regard to the behavior or behavioral goal. The third factor is perceived behavioral control or self-efficacy [53], i.e., an individual's perception of his or her ability to perform a specific behavior. A positive intention towards behavior is expected to result from a positive attitude, positive social influences, and a high self-efficacy regarding the performance of the behavior.

Overall, according to these motivational theories, any increase in intention regarding the respective behavior will lead to a concomitant increase in behavioral engagement [56,57]. However, Sheeran et al. (2002) have shown that intentions to adopt new behaviors do not always lead to actual behavior change [58]. In other words, intention alone is not enough to explain behavior—there is a gap between intention and behavior, the so-called “intention-behavior gap” [58]. As motivational theories do not address the question of translating intentions into action, they have been much criticized [59]. Research has increasingly sought to address this question by developing models of the role of cognitive factors in the post-intentional phase, i.e., the volitional phase. One such model is the Health Action Process Approach (HAPA) model [60], which holds that changing health behaviors involves two interacting phases: the motivational (pre-intentional) phase and volitional (post-intentional) phase.

The motivational phase corresponds largely to the theoretical framework of most motivational models. According to HAPA, the motivation (i.e., intention) to adopt health behavior is underlain by the combination of three factors: a growing risk perception, plus outcome expectancies, plus action self-efficacy. Before people start considering the benefits and disbenefits of possible actions (i.e., outcome expectancies) and think about their competence to actually perform them (i.e., action self-efficacy), they should feel personally susceptible to risks, and should understand the risk-behavior relationship (i.e., risk perception). Once intentions have been formed, the volitional phase starts. The behavioral intention has to be transformed into specific planning of when, where, and how to perform the desired action (i.e., action planning), and planning of anticipated barriers and ways to overcome them (i.e., coping planning). Planning is strongly influenced by self-efficacy, as self-efficacious individuals achieve mastery through earlier planning, and visualize successful scenarios that may guide their goal-attainment (i.e., maintenance or coping self-efficacy). People who are confident in their ability to cope with setbacks (i.e., have recovery self-efficacy) will recover quickly if they run into unforeseen difficulties. Once the behavior has been initiated, people may benefit from self-regulatory cognitions that help them to control and maintain the behavior (i.e., action control).

In other fields of medicine, behavior has been changed successfully by programs based on theories involving the pre-intentional/motivational and post-intentional/volitional phases, HAPA being one such theory [60]. In dentistry, however, most of the theories used to explain oral health behavior have addressed only the motivational determinants that lead to behavioral initiation. Theories that include motivational and volitional determinants may thus help to explain and identify important determinants of oral health behavior. If these determinants were targeted, oral health promotion programs could then be optimized, as they would target not only the initiation of behavior, but also its maintenance.

Theories on behavior change techniques or methods

As well as theories that can explain the behavior change process and factors that may influence it, there is a series of health behavior change theories that explain how change can be achieved by using behavior change methods to change the behavior change mechanisms (i.e., determinants). One example is Social Cognitive Theory (SCT) [61]. The determinants of behavior described by SCT include outcome expectancies, self-efficacy, and the perceived behavior of others. According to SCT, perceived behavior of others is not only a determinant of behavior, but also a very effective method for behavior change through modeling. Modeling is the principle of observing another person's behavior, of experiencing reinforcement by observing a person (i.e., a model), and of learning on the basis of this observation how this behavior

is performed. An important feature of behavior change theories is that they explain when such methods are likely to be effective. For instance, modeling is likely to be effective when the model is a role model rather than a mastery model, when it can be identified with, and when the person observing also has the skills necessary to performing the behavior [48].

Considerable gains have been made in identifying theory-based methods that can change and maintain health behaviors effectively (e.g., Michie et al., (2009); Dusseldorp et al. (2014); Webb et al. (2010) [48, 50, 57, 62-64]). Taxonomies have been developed that explain core methods, define relevant constructs, and present the preconditions for the methods to be effective (for examples of taxonomies of health behavior change methods; see Kok et al. (2015) and Michie et al. (2011) [62 63]. The theoretical background for methods in these taxonomies is provided in Bartholomew et al. (2016) [48]). These taxonomies can be used to inform the selection of behavior change methods.

Tailoring content and meeting the needs of the target-group

As shown by studies on a range of health behaviors [65], the efficacy of health promotion messages can be influenced by the tailoring method. Tailoring is defined as “any combination of information or change strategies intended to reach one specific person, based on characteristics that are unique to that person, are related to the outcome of interest, and have been derived from individual assessment” [66]. When tailoring an mHealth program, an application on a mobile device is programmed to generate personalized feedback. As personalized feedback in the form of messages can be provided only on the basis of a particular input from a recipient, individuals answer questions on their health, behavior and (presumed) behavioral determinants. The answers are entered into the mobile device, which is connected through the app to a database [66]. The data are linked to a library that contains health education messages that are suited to a range of possible answers. Software with an if-then algorithm is used to link the answers to the messages. Per individual, the program then generates feedback. Although tailoring can increase the potential effectiveness of oral health programs, none of the available orthodontic apps have used tailored messages.

If a program is to fit the needs of the target group, it is essential not only to understand the needs of the target group, but also to involve the target group in the process of developing the program. To date, only one study has reported that the target group was involved in the design of an orthodontic app [67]. Without the information provided by needs analysis and target group, there is little hope of designing an oral health promotion program that the target group will understand and adopt [48].

How to optimize programs: a brief summary of findings and of studies evaluating these programs

In conclusion, orthodontic programs promoting oral health should not only be based on behavioral theories, but should also incorporate behavior change methods that target various determinants—such as the motivational and volitional factors—that are important in a behavior change process. To optimize oral health promotion programs, program developers should consider incorporating a wide variety of behavior change methods in their program. They should also consider incorporating behavior change methods that have shown to be effective in changing health behavior but have not yet been incorporated in existing orthodontic programs. For example, tailoring can increase the potential effectiveness of oral health programs. To allow replication of the program, researchers need to provide enough details on the content of their programs. To ensure that the program will be accepted and adopted, they should also investigate the needs of the target group. Studies of these programs should describe the behavioral determinants targeted by the intervention, and subsequently evaluate each program's effect on these determinants.

Using intervention mapping

It can still be a challenge to select theories, translate them into behavior change methods, and then translate them into a program design for actually modifying behavior successfully. The selection and translation processes may be helped by intervention mapping (IM), which provides technical assistance with identifying theory-based determinants and matching them with appropriate methods for change [48]. A protocol for the planning and systematic development of health promotion programs, IM has been used successfully in the development and evaluation of various evidence-based health promotion programs [48].

The IM process comprises six steps: (Step 1) Conducting a problem analysis that identifies what needs to be changed and for whom (i.e., identifying target behaviors and behavioral determinants); (Step 2) Specifying program outcomes and objectives; (Step 3) Selecting behavior change methods that match the determinants and objectives, and translating these methods into practical strategies (i.e., program components) that satisfy the criteria for the effectiveness of the methods selected; (Step 4) Producing a fully structured program; (Step 5) Planning for the adoption and implementation of the program; (Step 6) Generating an evaluation plan [48]. Each of these steps comprises several tasks, in each of which theory and evidence are integrated. The completion of the tasks per step creates a product that guides the subsequent step. The completion of all of the steps serves as a blueprint for designing, implementing and evaluating an intervention on the basis of a foundation of theoretical, empirical and practical information. By using intervention mapping to

develop and to plan the evaluation of a smartphone app for preventing white spot lesions through the promotion of oral health behavior and oral hygiene, this dissertation project aimed to contribute to the current lack of evidence in this field of dentistry.

Hypothesis and outline of this dissertation

The hypothesis was that the app would be effective in improving oral hygiene, oral health behavior and the psychosocial factors of oral health behavior. Mapping the development and content of the app is useful because it allows researchers to replicate effective programs, or make attempts to design programs that are even more effective [68].

Understanding oral health behavior makes it possible to identify targets for programs designed to promote good oral health behavior. For this reason, a systematic literature review and cross-sectional study were conducted. Chapter 2 presents the systematic literature review with meta-analysis on the psychosocial correlates of oral hygiene behavior, which aimed to identify the psychosocial factors of oral hygiene behavior among adolescents. Chapter 3 presents the results of a cross-sectional study, which was conducted to test whether the findings of the meta-analysis could be generalized to the specific target group: adolescents with fixed orthodontic appliances. After the identification of important factors influencing the oral health behavior of adolescent orthodontic patients (i.e., the intervention targets), the WhiteTeeth app was developed systematically by following the steps of the intervention mapping protocol. Chapter 4 describes the results of applying the first five steps of intervention mapping. To help define program objectives, part of this systematic process involved semi-structured interviews. To achieve these objectives, the app integrates behavioral strategies that target the underlying factors of behavior identified in the first step of intervention mapping. Chapter 5 presents the study protocol for the effect evaluation of the app—the sixth step of intervention mapping. Chapter 6 consists of a randomized controlled trial in which the app was compared with standard treatment for its effect on outcomes such as oral health behavior, plaque control, gingival bleeding and the psychosocial factors of oral health behavior. Finally, chapter 7 summarizes the main findings of this dissertation.

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CHAPTER 2

Psychosocial correlates of oral hygiene behaviour in people aged 9 to 19 A systematic review with meta-analysis



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ABSTRACT

Objectives: This systematic and meta-analytic review aimed to quantify the association of psychosocial correlates with oral hygiene behaviour among 9- to 19-year olds.

Methods: A systematic search up to August 2015 was carried out using the following databases: PubMed, PsycInfo, Embase, CINAHL and Web of Science. If necessary, authors of studies were contacted to obtain unpublished statistical information. A study was eligible for inclusion when it evaluated the association between the psychosocial correlates and oral hygiene behaviour varying from self-reports to clinical measurements, including plaque and bleeding scores. A modified New Castle Ottawa Scale was applied to examine the quality of the included studies.

Results: Twenty-seven data sets (k) presented in 22 publications, addressing nine psychosocial correlates, were found to be eligible for the meta-analysis. For both tooth brushing and oral hygiene behaviour, random effect models revealed significant weighted average correlation (r_+) for the psychosocial factors: 'intention', 'self-efficacy', 'attitude' (not significant for tooth brushing), 'social influence', 'coping planning' and 'action planning' (r_+ ranging from 0.18 to 0.57). Little or no associations were found for: 'locus of control', 'self-esteem' and 'sense of coherence' (r_+ ranges from 0.01 to 0.08).

Conclusions: The data at present indicates that 'self-efficacy', 'intention', 'social influences', 'coping planning' and 'action planning' are potential psychosocial determinants of oral health behaviour. Future studies should consider a range of psychological factors that have not been studied, but have shown to be important psychosocial determinants of health behaviours, such as 'self-determination', 'anticipated regret', 'action control' and 'self-identity'. Effectiveness of addressing these potential determinants in order to induce behaviour change should be further examined by intervention trials.

Abbreviations: CI, confidence interval; CMA, Comprehensive Meta-Analysis Software; OHB, oral hygiene behaviour; OR, Odd Ratio; HAPA, Health Action Process Approach model; IM, Intervention Mapping; PBC, perceived behavioural control; r , correlation; r_+ , weighted average correlation; TPB, Theory of Planned Behaviour.

INTRODUCTION

Despite great global improvements in oral health during the 21st century, oral diseases remain a major health problem [1, 2]. According to the WHO report, dental caries affects approximately 60-90% of children and the vast majority of adults in developed countries [2]. The performance of adequate oral hygiene is important in the prevention of oral diseases, yet a large proportion of the population fails to sufficiently adopt or maintain adequate oral hygiene behaviour [3,4]. Adolescence in particular can be a time of increased caries activity and periodontal disease due to a decline in the quality of oral hygiene behaviour [5,6]. There is an urgent need for effective programs to improve oral hygiene behaviour in this age group.

A systematic review of interventions in adolescents concluded that behavioural interventions to promote oral health of adolescents had limited success and alternative approaches of oral health promotion should be explored [7]. There is increasing recognition that interventions should be guided by the Intervention Mapping (IM) protocol; however, none of oral health promotion programmes regarding adolescents have used the IM protocol for its development [8]. According to the IM protocol, intervention development starts with the analysis of the health problem including the identification of the determinants related to the problem and the specific health-related behaviour [8]. This is based on the assumption that it is possible to change health behaviour by targeting the determinants of this behaviour (the causal mechanism of behaviour), thus leading to an improvement of the health outcome [9].

Of these determinants, psychosocial factors have been identified as important modifiable determinants of behaviour [10, 11]. In adults, a systematic review demonstrated that interventions targeting psychosocial factors led to changes in oral hygiene behaviour [11]. Until now, behavioural interventions regarding adolescents have, however, rarely targeted psychosocial determinants [7]. This explains why these interventions had limited success. Therefore, insight into psychosocial factors is necessary to design evidence-based oral health interventions. No review has so far attempted to summarise the existing evidence regarding all psychosocial factors related to oral hygiene behaviour.

The purpose of this study is to analyse the associations between psychosocial factors and oral hygiene behaviours by a systematic and meta-analytic review. The research question states: 'what are the associations between psychosocial factors and oral hygiene behaviour among people aged 9 to 19?' We decided to limit our study to this age group, since previous meta-analysis have shown that psychosocial factors in young people are different from those in adults [12]. The cut-off point of the age of 9 was chosen, because children aged 9 years and older are supposed to practice oral hygiene behaviour independently without parental supervision [13].

METHODS

Data sources and search strategy

This systematic and meta-analytic review is reported in consistent with MOOSE guidelines [14]. The following databases were searched from inception up to 24 August 2015: PubMed, Embase, Ebsco/PsycInfo, Ebsco/CINAHL and ISI/Web of Science. All languages were accepted. The comprehensive search strategy was designed in collaboration with health sciences librarian (JS and JK). As psychosocial factors can be reported by studies that apply social-cognitive models to explain or predict behaviour, social-cognitive models were included as search terms to create a sensitive and complete search. Search terms (including synonyms and closely related words) were first chosen and used as index terms or free-text words in Pubmed (Table 1). Consequently, the search strategy was adapted and optimised for all consulted databases (available on request). Manual cross-referencing of bibliographies was carried out. Additionally, we utilised indexing sources to retrieve subsequent relevant articles that have cited the included publications [15].

Eligibility criteria

A study was eligible for inclusion if it described the association between psychosocial correlates and oral hygiene behaviour of healthy children with a mean age in the range of 9 to 19. We defined the dependent variable 'oral hygiene behaviours' as oral self-care behaviours which impact or have the potential to impact the oral health of an individual. We included indices of oral hygiene behaviour, if the outcome encompasses one of more oral hygiene behaviours such as tooth brushing, interdental cleaning, fluoride use and flossing behaviour. Studies reporting oral health behaviours like dental visits and sugar consumption were only included if this behaviour was studied in combination with the oral hygiene behaviours mentioned above. Measurement of oral hygiene behaviour could vary from self-report to clinical measurements. The clinical measurements included plaque and gingival indices indirectly measuring the quality oral home care behaviours, a proxy measure of behaviour.

Table 1. Search strategy (in Pubmed)

#1	((correlat*[tiab] OR predict*[tiab] OR factor[tiab] OR factors[tiab] OR determinant*[-tiab] OR "cognition"[Mesh] OR cogniti*[tiab]) AND (dental behavior*[tiab] OR oral health behavior*[tiab] OR oral hygiene behavior*[tiab] OR dental health behavior*[tiab]))
#2	(action planning[tiab] OR action control*[tiab] OR "intention"[Mesh] OR intention*[tiab] OR perceived social pressure*[tiab] OR "internal external control"[Mesh] OR "Attitude to Health"[Mesh] OR "Self Concept"[Mesh] OR preintention*[tiab] OR postintention*[tiab] OR outcome expectanc*[tiab] OR perceived behavioral control*[tiab] OR perceived behavioural control*[tiab] OR self efficac*[tiab] OR positive outcome expectanc*[tiab] OR perceived risk*[tiab] OR risk perception*[tiab] OR health perception*[tiab] OR attitude*[tiab] OR oral health knowledge[tiab] OR belief*[tiab] OR anticipated regret*[tiab] OR social norm*[tiab] OR expected social outcome*[tiab] OR social influence*[tiab] OR self-esteem[tiab] OR cues to action*[tiab])
#3	(parental behavior*[tiab] OR parental behaviour*[tiab] OR parental style*[tiab] OR modeling*[tiab] OR modelling*[tiab] OR perceived susceptibilit*[tiab] OR perceived vulnerabilit*[tiab] OR social cognitive theor*[tiab] OR theory of reasoned action*[tiab] OR ASE model*[tiab] OR planned behavior*[tiab] OR protection motivation theor*[tiab] OR trans-theoretical model*[tiab] OR precaution adoption process*[tiab] OR health belie*[tiab] OR reinforcement sensitivity theor*[tiab] OR injunctive norm*[tiab] OR descriptive norm*[tiab] OR subjective norm*[tiab] OR stages of change[tiab])
#4	(home care dental devices[MeSH Terms] OR floss*[tiab] OR dental compliance[tiab] OR tooth brushing[tiab] OR tooth brushing[tiab] OR interdental cleaning OR interdental brush* OR dental brush* OR oral hygiene[MeSH Terms] OR oral hygiene[tiab] OR dental hygiene[-tiab] OR oral health behavior*[tiab] OR dental behavior*[tiab] OR oral health behaviour*[-tiab] OR dental behaviour*[tiab] OR ((oral health[tiab] OR dental health[tiab]) AND (health behavior[MeSH Terms] OR health behavior*[tiab] OR health behaviour*[tiab] OR complian*[tiab] OR patient compliance[MeSH Terms] OR sugar sweetened beverage*[tiab] OR "Energy Drinks"[Mesh] OR energy drink*[tiab] OR "Fluorides"[Mesh] OR fluorid*[tiab] OR "Diet"[Mesh] OR diet[tiab] OR diets[tiab] OR "intention"[Mesh]))
#5	(child*[tw] OR schoolchild*[tw] OR adolescen*[tw] OR pediatri*[tw] OR paediatr*[tw] OR boy[tw] OR boys[tw] OR boyhood[tw] OR girl[tw] OR girls[tw] OR girlhood[tw] OR youth[tw] OR youths[tw] OR teen[tw] OR teens[tw] OR teenager*[tw] OR puberty[tw])
#6	((#1 OR #2 OR #3) AND #4 AND #5)

[Mesh] = Medical subject headings; [tiab] = words in title OR abstract; [tw] = words in title, abstract, MeSH, other terms

Furthermore, in the event of several publications reporting the outcomes on an identical group of participants, only the most recent publication was included. Studies were excluded, when the study population was exposed to an intervention prior to measurement. In case of an intervention study, data from the baseline measurement prior to the intervention or no-treatment control group was included. Only literature in English, Dutch, and German was included. Qualitative studies, reviews, expert opinion, conference proceedings and case studies were excluded.

Study selection

The study selection was performed in two stages. In the first stage, two persons (JS and EW) independently read the title and abstract of potentially relevant articles against the eligibility criteria. If the abstract contained insufficient information for the decision on whether to include or exclude, the full-text article was obtained and reviewed before a decision was made. In the second stage, full-text articles were obtained and the same two persons independently applied the eligibility criteria to confirm the final selection. If necessary, a third reviewer (PE) was consulted to resolve disagreements or the authors of the included studies were contacted to verify eligibility. Consensus was reached in 100% of the cases.

Data extraction

Two authors (JS and PE) performed the data extraction using a predefined data extraction form. Information was extracted from each included study on authors and year of publication, setting, country, description of the study population (sample size, age and gender), study design, psychological theory or behavioural model used for the design of the study, used definition and measurement of the oral hygiene behaviour under study, the psychosocial correlates assessed, and the reported effect sizes. In addition, we contacted authors of studies to obtain unpublished statistical information or for clarification. To ensure comparability of the psychosocial correlates across studies, measures of the correlates were coded based on actual operationalisations presented in Table 2, rather than the name that the concepts were given in the articles. The psychosocial correlates and outcomes of the included studies were coded so that higher scores indicated greater engagement in oral hygiene behaviour.

Quality assessment of the included studies

The reviewers (JS and EW) independently assessed the methodological quality of the selected articles with a method adapted from Elyasi et al. (2015), which was based on a modified Newcastle-Ottawa Scale [28, 29]. As one item with regard to controlling for confounders was inapplicable, this item was skipped. For cross-sectional studies, a quality score was based on five items of the following categories: group selection, outcome and exposure. For cohort studies, two items were added: duration and adequacy of follow-up. A maximum score of five points for cross-sectional studies and seven points for prospective studies represented the highest methodological quality. Discrepancies between the assessors were resolved via discussion with third reviewer (PE) until reaching a consensus. The report of this procedure is available on request from the corresponding author.

Table 2. Brief definitions of psychosocial correlates

Variable(s)	Brief definition
Action planning	Participants' plan regarding when, where, and how to perform OHB [16].
Coping planning	Participants' anticipation of barriers that might threaten the implementation of the OHB and participants' imagination of ways to overcome them [16].
Intention to practice OHB	Participants' motivation in the sense of his or her conscious decision to exert effort to perform the OHB in the future [17].
Perceived Behavioural Control #	Participants' expectancy that the performance of the behaviour is within his/her control and the participants' perception of the extent to which performance of the behaviour is easy or difficult. 'Perceived behavioural control' is determined by beliefs concerning factors that inhibit or facilitate performance of the behaviour and the perceived power of these factors [17, 47].
• Self-efficacy	Participants' confidence in their ability to perform behaviour [18].
• Perceived Self-efficacy	Participants' beliefs about one's abilities to successfully perform OHB [18].
Social influences	Participants' experiences of pressure that they receive from important others to perform, or not to perform, behaviour. Social influences can be subdivided into 'subjective norm' and 'descriptive norm' [47].
• Subjective norms (or injunctive norm)	Participants' perception whether significant others or peers think he/she should engage in the behaviour and the participants' motivation to comply with those expectations [17].
• Descriptive norms	Participants' perceptions of significant others' attitudes towards OHB and/or OHB [19].
Attitude	Participants' positive or negative evaluation of what it would be like for them to perform OHB. Evaluations of behaviour are determined by beliefs that the behaviour will produce a certain outcome ('outcome expectancies') [17].
• Affective beliefs	Participants' beliefs about considering tooth brushing for affective reasons.
• Perceived barriers	Participants' beliefs about the likelihood of negative consequences of their OHB.
• Perceived benefits	Participants' beliefs about the likelihood of positive consequences of their OHB.
• Cognitive beliefs	Participants' beliefs about considered tooth brushing for cognitive reasons.
• Response-efficacy	Participants' belief in the effectiveness of performing oral hygiene behaviour in preventing oral diseases.
Self-esteem	Participants' overall emotional evaluation of individual's worth and respect for oneself, encompasses beliefs and affect [20, 21].

Locus of control	Participants' beliefs about whether the events affecting their life are causally related to their own behaviour (internal control) or being determined by outside forces, over which the individual has little or no control (external control) [22].
Sense of coherence	Participants' ability to cope with life stress and his/her ability to find an appropriate solution in the face of challenges (mastery orientation) and to stay healthy [23].
Risk perception*	
• Perceived susceptibility	Participants' beliefs about the extent to which they are personally at risk of oral diseases [24].
• Perceived vulnerability	Participants' beliefs about how serious gum and dental diseases would be for them [24].
Life satisfaction*	Participants' perceptions of how they experience their life in terms of being lonely and happy [25].
Depression vulnerability*	Participants' feelings of sadness or hopeless that have caused participants stopped doing usual activities [26].
Health perception*	Participants' perception whether they perceive themselves as healthy or unhealthy [27].

The concept of 'perceived behaviour control' is conceptually related to 'self-efficacy'; * For variables denoted by the sign * applies that these variables were excluded from the analysis, since only one independent correlation ($k < 1$) was available; OHB= Oral hygiene behaviour.

Statistical procedure

Meta-analyses were undertaken using Comprehensive Meta-Analysis (CMA) software (Version 2.0). A weighted average correlation (r_w) and its 95% confidence interval (CI) was calculated per psychosocial correlate and oral hygiene behaviour (range: -1.0 to +1.0) using Fisher's Z-transformations [30]. Pearson and Spearman correlation coefficients (r) were used as the effect size for analyses. When the Odds Ratio (OR) was reported instead of the correlation coefficient, CMA converted the crude OR to a correlation coefficient. CMA computed the oral hygiene behaviour outcome by combining the independent variables of each included study and calculating a mean effect size. Random effects models were chosen due to the heterogeneity across studies caused by various operationalisations of outcomes. Only bivariate analyses were synthesized because multivariate analyses were incommensurable over studies as the studies adjusted for different confounders in their models. This resulted in exclusion of two articles from the analysis [31, 32]. Meta-analyses were only performed if data of two or more independent correlations were available ($k > 1$). This latter resulted in the exclusion of one study from the analysis [27]. If a study reported an effect size for boys and girls, but not for mixed gender, a mean effect size

was computed by CMA. Heterogeneity analyses, Q and I^2 statistics, were conducted to determine whether the variation among correlations was greater than chance [33, 34]. Additionally, subgroup analyses were conducted to test if the study designs (cross-sectional vs. prospective) could explain the observed heterogeneity among effect sizes. If the mixed-effect models revealed significant differences, the results of cross-sectional and prospective design were separately reported. By contrast, if the mixed-effect models revealed nonsignificant differences, a combined effect size was reported to serve as a summary. To assess the extent of publication bias, we calculated the Rosenthal's fail-safe number (FSN), which estimates the number of studies with null findings necessary to nullify the significant weighted effect [35]. A larger FSN value indicates a more robust weighted average effect size. As a rule of thumb, it has been suggested that the recommended tolerance is $5k + 10$, where k is the number of studies retrieved [35]. FSN could only be calculated when $k > 2$. If the FSN is larger than the recommended tolerance, then the results are robust [35].

RESULTS

Study selection

Figure 1 shows the flow diagram presenting the selection process of the included articles. After removing duplicates, a total of 3548 unique articles were found by searching the databases. Screening on title and abstract led to retention of 203 potentially relevant articles. Reading on full-text resulted in exclusion of 179 publications. The flow diagram displays a summary of the excluded papers and the reasoning behind their exclusion. The final sample contained 31 unique data sets (k) reported in 24 articles [20, 21, 25-27, 31,32, 36-52].

Study characteristics

Table S1 (see the Appendix) presents the characteristics and cumulative score of the methodological quality assessment of all studies selected for the systematic review. For cross-sectional studies, the quality assessment scores range from three to five points. Prospective studies scores range from five to six points. Across the studies, the quality scores vary in three items, namely information about the nonrespondents, validation of measurement of the psychosocial factors and assessment of the outcome. The included articles were published from 1972 onwards. Selected studies were conducted in seventeen different countries, located in: Europe ($k=15$), North America ($k=3$), South America ($k=1$), Africa ($k=1$), Asia ($k=8$) and Oceania ($k=3$). In total, the studies sampled 104288 participants. The majority of the studies ($k=25$) focused on self-reported tooth brushing frequency. Five data sets focused on self-reported oral hygiene behaviour, which comprised a set of different activities. Finally, the remaining data sets focused flossing frequency ($k=9$) and/or plaque score ($k=3$). Twenty-nine data sets were cross-sectional in design, including papers that presented baseline results of a longitudinal study. Six data sets were prospective in design. Only 39% of the studies based their research on a behavioural theory, the remaining 61% of the studies did not refer to a specific theoretical framework. The most dominant theoretical framework used for the design in the included studies (25%) was the 'Theory of Planned Behaviour' [17].

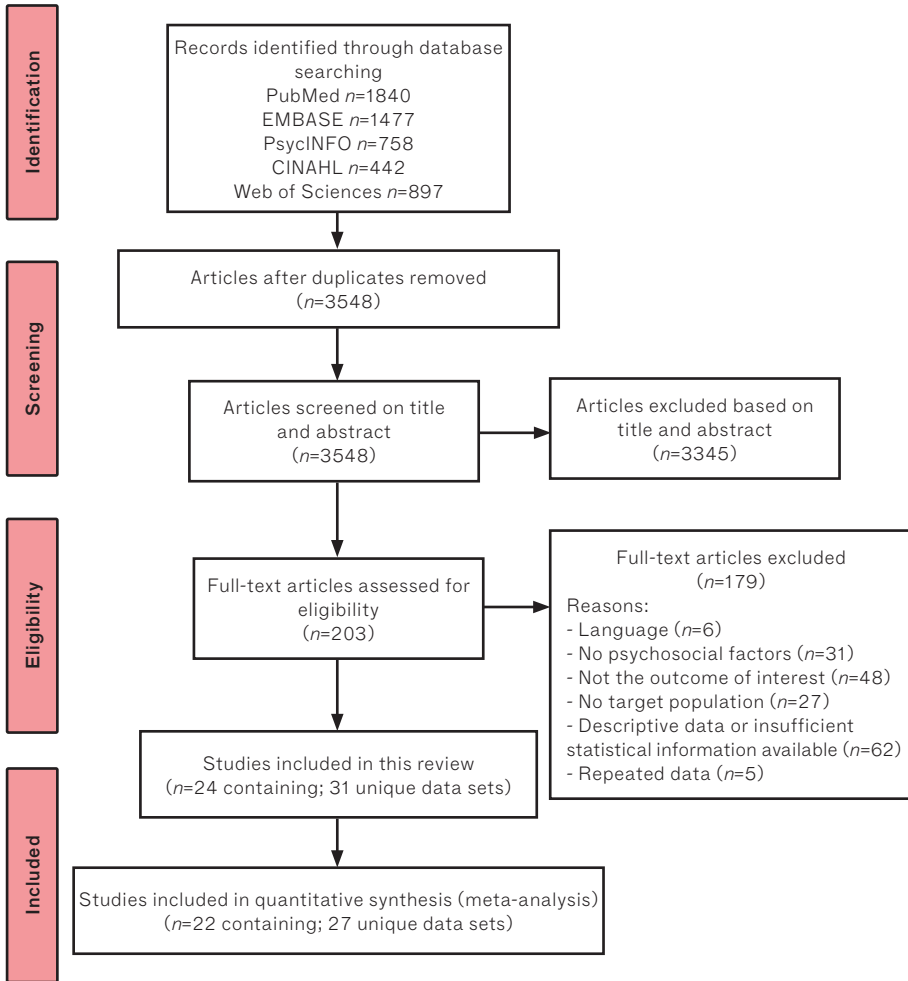


Fig.1. Results of search strategy and screening procedure

Synthesis of results

Twenty-seven unique data sets reported in 22 publications were included in quantitative synthesis (meta-analysis) [20, 21, 25-27, 36-52]. Meta-analyses were performed for the most frequently reported outcome: tooth brushing and for a combined oral hygiene behaviour outcome, which combined various oral hygiene behaviours. The results of the meta-analyses and the heterogeneity analyses for the psychosocial correlates of tooth brushing are presented in Table 3, and for oral hygiene behaviour, in Table 4. The majority of the heterogeneity tests were significant (Table 3 and 4). Nine psychosocial

Table 3. Samples weighted average correlations, confidence intervals and heterogeneity analyses for the psychosocial correlates of tooth brushing

Variable	total n	k	r_+	95% CI	Heterogeneity	
					Q	I ²
Coping planning	1682	2	0.57	[0.54; 0.60]	8.2*	87.8
Action planning	1682	2	0.47	[0.37; 0.56]	6.9*	85.5
Intention	2784	4	0.43	[0.16; 0.64]	122*	97.5
PBC/Self-efficacy	3202	5	0.36	[0.17; 0.52]	127.3*	96.9
Social influences	1533	2	0.32	[0.27; 0.37]	2.6	62.3
Attitude	4217	3	0.18	[-0.04; 0.39]	61.7*	96.7
Self Esteem	12193	7	0.08	[-0.05; 0.10]	32.4*	81.5
Sense of Coherence	2244	3	0.04	[-0.01; 0.09]	2.9	31.5
Locus of Control	5583	6	0.04	[0.02; 0.05]	12.5*	59.9

Note. Total n= total sample size across all the included studies; k= number of independent correlations, which contains prospective and cross-sectional data; r_+ = sample-weighted average correlation; CI = confidence interval; Q between-study heterogeneity, expressed as a Chi-square statistic; I² between-study heterogeneity, expressed as percentage of variation attributable to heterogeneity rather than chance; PBC= Perceived Behavioural Control.* When $p < 0.10$, correlations are heterogeneous.

correlates were addressed across the included studies. These correlates include the following: coping planning, action planning, intention, self-efficacy/perceived behavioural control, social influences, attitude, sense of coherence, self-esteem and locus of control. The results of the meta-analysis for each psychosocial correlate of tooth brushing are described next in order of strength.

Action planning

A significant weighted average correlation of 0.47 was observed for action planning with tooth brushing ($k=2$; $p<0.001$). Mixed-effect models showed significant moderate effects, which indicate that the study design accounted for the heterogeneity in the overall distribution (Q -value=7.9; $p=0.005$). Prospective studies reported stronger correlations for action planning on tooth brushing ($r_+=0.57$; $p<0.001$; $k=2$) than for cross-sectional studies ($r_+=0.35$; $p<0.001$; $k=2$).

Coping planning

Tooth brushing frequency was found to be related positively to 'coping planning' with a r_+ of 0.57 ($k=2$; $p<0.001$).

Table 4. Samples weighted average correlations, confidence intervals, and heterogeneity analyses for the psychosocial correlates of oral hygiene behaviour

Variable	total n	k	r_+	95% CI	Heterogeneity	
					Q	I^2
Intention	4774	7	0.46	[0.29; 0.60]	141.9*	95.8
PBC/Self-efficacy	3966	10	0.44	[0.33; 0.54]	174.1*	94.8
Coping Planning	1842	3	0.43	[0.18; 0.63]	60.8*	96.7
Social influences	2296	5	0.32	[0.28; 0.36]	9.1	45.5
Action planning	1843	3	0.31	[0.05; 0.53]	59.6*	96.6
Attitude	9700	11	0.23	[0.15; 0.30]	119.5*	91.6
Sense of Coherence	2244	3	0.06	[0.02; 0.10]	1.6	37.1
Self Esteem	12193	7	0.05	[0.02; 0.07]	28.6*	79.0
Locus of Control	5583	6	0.01	[0.00; 0.02]	3.6	43.7

Note. Total n= total sample size across all the included studies; k= number of independent correlations, which contains prospective and cross-sectional data; r_+ = sample-weighted average correlation; CI = confidence interval; Q between-study heterogeneity, expressed as a Chi-square statistic; I^2 between-study heterogeneity, expressed as percentage of variation attributable to heterogeneity rather than chance; PBC= Perceived Behavioural Control.* When $p < 0.10$, correlations are heterogeneous

Intention

A significant weighted average correlation of 0.43 was observed for intention with tooth brushing ($k=4$; $p=0.002$; FSN=410).

Self-efficacy or perceived behavioural control

The average weighted correlation between 'self-efficacy' or 'perceived behavioural control' and tooth brushing was estimated at 0.36 ($k=5$; $p<0.001$; FSN=625).

Social influences

A significant weighted average correlation of 0.32 was observed for social influences with tooth brushing ($k=2$; $p<0.001$).

Attitude

The weighted average correlation between attitude and tooth brushing was estimated at 0.18 ($k=3$), which was not significant ($p=0.109$).

Sense of Coherence

A nonsignificant pooled correlation for sense of coherence and tooth brushing was observed ($r_+ = 0.04$; $k=3$; $p=0.092$).

Self-esteem

Self-esteem had a negligible association with tooth brushing in the analysis ($r_+ = 0.08$; $k=7$; $p<0.001$; FSN=235).

Locus of Control

The average weighted correlation between locus of control and tooth brushing was estimated at $r_+ = 0.04$ ($k=6$; $p=0.001$; FSN=13).

Analysis for the outcome oral hygiene behaviour revealed significant positive weighted average correlations for the variables: 'intention' ($r_+ = 0.46$; $k=7$; $p<0.001$; FSN=1000), 'self-efficacy' ($r_+ = 0.44$; $k=10$; $p<0.001$; FSN=2441), 'coping planning' ($r_+ = 0.43$; $k=3$; $p=0.001$; FSN=374), 'social influences' ($r_+ = 0.32$; $k=5$; $p<0.001$; FSN=272), 'action planning' ($r_+ = 0.31$; $k=3$; $p=0.021$; FSN=210), 'attitude' ($r_+ = 0.23$; $k=11$; $p<0.001$; FSN=984), 'sense of coherence' ($r_+ = 0.06$; $k=3$; $p=0.008$; FSN=2), 'self-esteem' ($r_+ = 0.05$; $k=7$; $p=0.001$; FSN=84). A nonsignificant pooled correlation was observed between 'locus of control' and oral health behaviour ($r_+ = 0.01$; $k=6$; $p=0.144$) (Table 4).

DISCUSSION

The present systematic and meta-analytic review of 27 unique data sets aimed to identify psychosocial determinants of oral hygiene behaviour in young people aged 9 to 19. A higher tooth brushing frequency was observed among those with higher 'intention', 'social influences', 'self-efficacy', 'action planning' and 'coping planning', which suggests that these factors are potential psychosocial determinants of tooth brushing. The pooled correlations found for 'intention', 'social influences' and 'self-efficacy' for tooth brushing are in accordance with a previous meta-analysis regarding to other types of health behaviour, for example physical activity and diet behaviours [53]. Little or no associations were found for the factors: 'locus of control', 'self-esteem' and 'sense of coherence'. Our findings indicated that more commonly studied psychosocial factors (e.g. 'locus of control', 'sense of coherence' and 'self-esteem') were less likely to be associated with tooth brushing, whereas factors that illustrated a strong association were relatively understudied (e.g. 'action planning' and 'coping planning'). In addition, it is noteworthy that none of the included studies examined determinants such as 'self-

determination', 'anticipated regret', 'action control' and 'self-identity' that have found to be important in explaining health behaviours [54-56]. Future studies should test for these determinants to advance in the field.

Apart from tooth brushing, we examined whether our findings were consistent for combined oral health behaviour outcome. Generally, the findings were comparable, with exception of 'coping planning' and 'action planning', which showed lower correlations for the combined outcome. The differences between tooth brushing and oral hygiene behaviours for these variables could potentially be explained through to the nature of the behaviour, as the oral hygiene behaviour outcome includes flossing. Flossing is a more complex task, which might require other skills affected by other psychosocial factors. Another reason might be measurement bias, as the method of measuring the psychosocial constructs differed between the studies, that is single items or a more refined assessment tool of five items.

The most frequently used theory for the design of the studies was the 'Theory of Planned Behaviour' (TPB). Nonetheless, the TPB is not without its limitations as highlighted in a recent critique by Sniehotta and his colleagues [57]. They state that TPB does not account for all of the variance in intentions and behaviour. Our findings do suggest that determinants other than TPB variables ('social influences', 'attitude', 'perceived behavioural control' and 'intention') could be relevant to explain oral hygiene behaviour, such as 'action planning' and 'coping planning'. Hence, alternative theories that focus for instance on these and other self-regulatory processes (e.g. Health Action Process Approach [16]), might improve the understanding of tooth brushing or oral hygiene behaviours as well as provide better means for behavioural change.

Prior to discussions of the practical implications, several strengths and limitations should be acknowledged. Random effects models were chosen due to the heterogeneity across studies. This heterogeneity may have been due to different operationalization of the variables, mixed gender, mixed cultures and different definitions of the outcomes across the included studies. As the majority of the studies demonstrated results for mixed gender, it was not possible to test moderation of psychosocial factors with oral hygiene behaviour by gender of participants. However, one of the included studies noticed differences between genders in the psychosocial correlates of oral hygiene behaviour, namely 'locus of control' and 'self-esteem' [21]. Therefore, gender should be given consideration in future studies. In general, the reliance on the availability of published results is a limitation. Studies that show negative or insignificant results are less likely to be published. Therefore, an overestimation of the robustness of the effect sizes may occur due to publication bias. Additional analysis (FSN) was performed to assess the extent of publication bias. All significant effect sizes showed FSN larger than the recommended tolerance, which indicate robust results. Another limitation is the lack of a validated assessment tool to measure the quality of the included studies.

Although no validated checklist exists to assess the risk of bias of the included studies [58], we did measure the quality of their studies by a modified NOS assessment tool adapted by Elyasi et al. (2015) [28]. The majority of the included studies scored low on the outcome measurement, as they assessed oral hygiene behaviour by self-report. It is reasonable to expect inaccuracy of self-reported measures [59]. An attempt should be made to obtain objective measurements of oral hygiene behaviour. Modern technology provides novel ways of collecting reliable data about a person's behaviour, for example registration of behaviour by an electric toothbrush with Bluetooth connectivity. The final limitation is that most studies have used cross-sectional designs, which means that evidence for these correlates to be determinants is somewhat hypothetical [10, 57]. A next step to verify the causal role of these psychosocial factors is to examine them in studies using more complex longitudinal or experimental designs.

The practical implication of the present review is that oral health promotion could be improved by targeting the following potential determinants: 'intention', 'social influences', 'self-efficacy', 'coping planning' and 'action planning'. Two notions should be considered: existing oral health promotion interventions for adolescents rarely targeted these factors, which could explain the generally limited success of oral health promotion programmes [7] and preliminary evidence of intervention studies that have targeted (some of) these determinants have indeed shown that this may result in improved oral hygiene behaviour [4, 40, 60-64].

Behaviour change interventions need to incorporate methods directly targeting these potential determinants. Various methods have previously been defined in relation to these determinants [65]. One could think of skill building as a method to enhance 'self-efficacy' [65]. Skill building comprises the following activities: (i) providing instruction, (ii) demonstrating the behaviour and (iii) guiding practice with feedback and reinforcement [65]. To achieve 'intention' formation, a method might include goal setting, that is prompting planning what a person will do, including a definition of goal-directed behaviours that result in the target behaviour [65]. With regard to 'action planning' and 'coping planning' enhancement, methods might include implementation intentions, that is prompting making if-then plans [65, 66, 67]. A practical application for this method is the use of volitional help sheets [68]. To change 'social influences', a method could be providing information about what others think about the persons' behaviour and whether others will approve or disapprove any proposed behavioural change [65].

In conclusion, this systematic and meta-analytic review highlights the importance of psychosocial factors as potential determinants in explaining oral hygiene behaviour among pre-adolescents and adolescents. In addition, the review identifies various gaps in the literature: (i) psychosocial factors that appear to be the most important received relatively little attention, for instance 'action planning' and 'coping planning';

(ii) psychosocial factors: ‘self-determination’, ‘anticipated regret’, ‘action control’ and ‘self-identity’ that have found to be important in explaining health behaviours and have not been studied in relation to oral health in young people; and (iii) the quality of the study design requires improvement. There is a need for prospective or experimental research. Apart from these improvements, future research should include objective measurement of oral hygiene behaviour. Finally, this review discussed practical implications to optimize and design evidence-based interventions to promote oral hygiene behaviour.

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APPENDIX A

Table S1. Characteristics of the included studies

Study, country, design, (quality assessment score)	Sample (number, gender, age)	Psychosocial correlates (Theoretical framework)	The independent correlations with 95% CI per oral hygiene behaviour outcome
Aleksejuniene et al.2012[36] Lithuania; Cross-sectional study (4 points)	n=235 ^a ; mix ^b aged 12-13 years	1. Locus of control (internal) 2. Locus of control (external)	Plaque score (IQP-index) 1. 0.02(-0.11;0.15) 2. -0.06(-0.18;0.07)
Ayo-Yusuf et al. 2009[26]* South Africa; Prospective study (18 months) (6 points)	n= 526; mix mean age(SD) in years=14.4 (1.5)	1. Sense of coherence 2. Depression vulnerability** 3. Attitude 4. Intention (I-Change Model)	Self-reported tooth brushing frequency 1. na. 2. 0.11(-0.24;0.01)
Cinar et al. 2009[37]* Finland; Cross-sectional study (4 points)	n=338; mix aged 10-12 years	1. Self-efficacy	Self-reported tooth brushing frequency 1. 0.22(0.11;0.32)
Cinar et al. 2009[37]* Turkey; Cross-sectional study (3 points)	n=611; mix aged 10-12 years	1. Self-efficacy	Self-reported tooth brushing frequency 1. 0.28(0.20;0.35)
Dorri et al. 2010[38]* Iran; Cross-sectional study (4 points)	n=911; mix mean age(SD) in years=12,4 (0.8) range=11-16 years	1. Sense of coherence (Salutogenic model)	Self-reported tooth brushing frequency 1. 0.09(0.03;0.15)

Freire et al. 2001[39]* Brazil; Cross-sectional study (3 points)	n=664; mix 15 year olds	1. Sense of coherence (Salutogenic model)	Self-reported tooth brushing frequency 1. 0.01(-0.07;0.08) Plaque score (index of Silnes & Løe) 1. 0.03(-0.05;0.10)
Gholami et al. 2014[40]*; Iran; Cross-sectional study (4 points) nested within a prospective study (1 month) (6 points)	n=156; F aged 11-15 years mean age(SD) in years= 12,5 (1,1)	1. Intention 2. Self-efficacy 3. Action planning 4. Coping planning (HAPA constructs)	Self-reported flossing frequency cross (n=156) pros (n=89) 1. 0.65(0.55; 0.73) 0.34(0.15; 0.51) 2. 0.72(0.64; 0.80) 0.38(0.19; 0.55) 3. 0.09(-0.24; 0.07) -0.01(-0.21; 0.20) 4. 0.04(-0.12; 0.20) -0.03(-0.28; 0.12)
Honkala et al. 2007[25]* Kuwait; Cross-sectional study (3 points)	n=1826; mix; Mean age: 11.9 years (SD ±1.3); age range=11-13 years	1. Self-esteem 2. Life-satisfaction**	Self-reported tooth brushing frequency 1. 0.12(0.08;0.17) 2. 0.10(0.05;0.14) Self-reported flossing frequency 1. 0.16(0.12;0.20) 2. 0.04(0.00;0.08)
Kallestål et al. 2006[20] Sweden; 2 cross-sectional studies within the same study group (4 points)	n=2836; mix mean age in '97 = 14 years mean age in '99 = 16 years	1. Self-esteem 2. Attitude	Self-reported tooth brushing frequency cross 1. 0.02(-0.12;0.15) 0.16(-0.05;0.36) 2. 0.11(0.06;0.17) 0.06(0.00;0.11)
Kamalikhah et al. 2015[41]* Iran; Cross-sectional study (4 points)	n=652; mix; mean age: 16,3 years (SD ±1.02);	1. Self-efficacy 2. Attitude	Self-reported flossing frequency 1. 0.48(0.42;0.54) 2. 0.24(0.16;0.31)

Koerber et al. 2006[42]* United States of America; Cross-sectional study (4 points)	n=575; mix mean age=10.8 years	1. Social influences 2. Self-esteem 3. Self-efficacy (Mixed models – social learning constructs)	Self-reported tooth brushing frequency 1. 0.34(0.27;0.41) 2. 0.16(0.08;0.24) 3. 0.12(0.12;0.28)
Macgregor et al. 1997[21] Study 1 England; Cross-sectional study (3 points)	n=18158; f/m age range=12-13 years	1. Self-esteem 2. Locus of control	Self-reported tooth brushing frequency 1. 0.03(0.02;0.05) 2. 0.02(0.00;0.03) Self-reported flossing frequency 1. 0.00(-0.02;0.02) 2. -0.01(-0.03;0.01)
Macgregor et al. 1997[21] Study 2 England; Cross-sectional study (3 points)	n=4736; f/m age range=13-14 years	1. Self-esteem 2. Locus of control	Self-reported tooth brushing frequency 1. 0.06(0.03;0.08) 2. 0.02(-0.01;0.04) Self-reported flossing frequency 1. -0.01(-0.03;0.03) 2. -0.03(-0.06;0.00)
Macgregor et al. 1997[21] Study 3 England; Cross-sectional study (3 points)	n=15492; f/m age range=14-15 years	1. Self-esteem 2. Locus of control	Self-reported tooth brushing frequency 1. 0.08(0.06;0.09) 2. 0.04(0.03;0.06) Self-reported flossing frequency 1. 0.01(-0.01;0.02) 2. -0.01(-0.03;0.01)

Macgregor et al. 1997[21] Study 4 England; Cross-sectional study (3 points)	n=2756; f/m age range=15-16 years	1. Self-esteem 2. Locus of control	Self-reported tooth brushing frequency 1. 0.07(0.03;0.11) 2. 0.07(0.03-0.10) Self-reported flossing frequency 1. -0.05(-0.08;-0.01) 2. -0.04(-0.08;0.00)
Morowatisharifabad et al. 2007[43] Iran; Cross-sectional study (4 points)	n=300; mix mean age (SD) in years= 17.45 ± 0.54 range=17-19 years old.	1. Perceived self-efficacy 2. Attitude 3. Social influences (Health Promotion Model)	Self-reported oral health behaviour (Brushing and its quality; brushing after consumption of sweets;flossing; use of fluoride mouth wash, and dental visits.) 1. 0.40(0.31;0.50) 2. 0.38(0.27;0.47) 3. 0.28(0.17;0.34)
Pakpour et al. 2012[44] Iran; Cross-sectional study (4 points) nested within a prospective study (1 month) (6 points)	n=721, mix mean age (SD) in years=15.45 (1.18)	1. Intention 2. Attitude 3. Perceived behavioural control 4. Subjective norm 5. Action planning 6. Coping planning (TPB + HAPA constructs)	Self-reported tooth brushing frequency cross 1. 0.50(0.44;0.55) 2. 0.34(0.27;0.40) 3. 0.53(0.47;0.58) 4. 0.26(0.19;0.32) 5. 0.32(0.25;0.38) 6. 0.51(0.46;0.57) pros 1. 0.70(0.66;0.73) 2. 0.46(0.40;0.51) 3. 0.72(0.68;0.75) 4. 0.34(0.28;0.41) 5. 0.51(0.45;0.56) 6. 0.71(0.67;0.74)
Pakpour et al. 2012[45] Iran; Cross-sectional study (4 points) nested within a prospective study (1 month) (6 points)	n=961, mix mean age (SD) in years=15.61 (1.19), range=14-18 years old	1. Intention 2. Perceived behavioural control 3. Action planning 4. Coping planning (TPB + HAPA constructs)	Self-reported tooth brushing frequency cross 1. 0.46(0.41;0.51) 2. 0.34(0.28;0.40) 3. 0.37(0.31;0.42) 4. 0.49(0.44;0.54) pros 1. 0.51(0.46;0.56) 2. 0.47(0.42;0.52) 3. 0.64(0.60;0.68) 4. 0.56(0.52;0.60)

Polk et al. 2014[46] United states of America, prospective study (6 months) (5 points)	n=576; mix aged 9-12 years mean age =10 years	1. Intention	Self-reported tooth brushing frequency 1. 0.50 (0.16;0.73)
Poutanen et al. 2005[47]* Finland; Cross-sectional study (4 points)	n=1464; mix aged 11-12 year old	1. Attitude	Self-reported oral health behaviour (brushing, snacking and xylitol chewing gum) 1. 0.17(0.12;0.22)
Poutanen et al. 2005[47]* Finland; Cross-sectional study (4 points)	n=673; mix; aged 11-12 year old	1. Attitude	Self-reported oral health behaviour (brushing, snacking and xylitol chewing gum) 0.16(0.08;0.23)
Rise et al. 1998[48] Norway; Prospective study (4 weeks) (4 points)	n=163; mix mean age(SD) in years=15.3 (0.3)	1. Attitude 2. Subjective norm 3. Perceived behavioural control 4. Past behaviour 5. Intention (TPB)	Self-reported flossing frequency 1. 0.17(0.02;0.32) 2. 0.30(0.15;0.43) 3. 0.42(0.29;0.54) 4. 0.45(0.32;0.57) 5. 0.50(0.38;0.61)
Schou et al. 1990[27] Scotland; Cross-sectional study (3 points)	n=4935; f/m 11, 13 &15 year olds.	1. Health perception**	Self-reported tooth brushing frequency 1. 0.13(0.11;0.14)
Smyth et al. 2007[47]* Spain; Cross-sectional study (3 points)	n=1105; mix 12 year olds	1. Attitude (KAB model)	Plaque score (index of Silnes & L��e) 1. 0.11(0.05;0.17)

Tolvanen et al. 2012[50]* Finland; Cross-sectional study (4 points)	n=827; mix 15 & 16 year olds	1. Attitude 2. Risk perception** (KAB model)	Self-reported oral health behaviour (tooth brushing, fluoride toothpaste, use of dental floss) 1. 0.35(0.29;0.41) 2. na. (not sign.)
Tran et al. 2006[30] Vanuata Cross-sectional study (3 points)	n=4474; mix age range 11-17 year.	1. Life-satisfaction	Self-reported tooth brushing 1. AOR=0.99(0.85;1.16)
Tran et al. 2006[30] Tonga Cross-sectional study (3 points)	n=1485; mix age range 11-17 year.	1. Life-satisfaction	Self-reported tooth brushing 1. AOR=1.05(0.85;1.28)
Tran et al. 2006[30] Pohnpei, FSM Cross-sectional study (3 points)	n=104; mix age range 11-17 year.	1. Life-satisfaction	Self-reported tooth brushing 1. AOR=1.09(0.69;1.72)
Vakili et al. 2011[51] Iran; Cross-sectional study (4 points)	n=300; mix mean age(SD) in years=16.24 (0.8) age range=15-18 years	1. Self-efficacy 2. Attitude 3. Social influences 4. Intention (Health Promotion Model)	Self-reported oral health behaviour (brushing and its quality, brushing after consumption of sweets, dental visits, flossing, and use of a fluoride mouth wash) 1. 0.53(0.44;0.61) 2. 0.36(0.26;0.45) 3. 0.39(0.29;0.48) 4. 0.32(0.22;0.42)
Verrips et al. 1993[32] the Netherlands Cross-sectional study (4 points)	n=518; mix, 11 year olds.	1. Attitude 2. Descriptive norm (parental)	Self-reported tooth brushing frequency 1. AOR=2.2(1.3;4.0) 2. na.

Williams 1972[52] United States of America; Cross-sectional study (5 points)	n=386; f/m Age: na.; (9th grade students ≈ 14-15 years old)	1. Locus of control (external)	Self-reported tooth brushing frequency 1. 0.07(-0.03;0.18)
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Note. cross: cross-sectional data; pros: prospective data; na.: data not available; AOR: Adjusted Odds Ratio; TPB: Theory of Planned Behaviour ; KAB: Knowledge-Attitude-Behaviour ; HAPA: Health Action Process Approach. a:Smallest number of participants in relevant analyses; b:Mix indicates a mixed sample of female (F) and males (M); For the studies denoted by the sign * applies that (additional) data were supplied by the author. For variables denoted by the sign ** applies that these variables were excluded from the analysis, since meta-analyses were only performed if data of two or more independent correlations were available ($k > 1$). The software Comprehensive Meta-Analysis calculated the presented correlations with confidence interval (CI).

CHAPTER 3

An application of the Health Action Process Approach model to oral hygiene behaviour and dental plaque in adolescent orthodontic patients



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ABSTRACT

Background: The Health Action Process Approach (HAPA) model addresses health behaviours, but it has never been applied to model adolescents' oral hygiene behaviour during fixed orthodontic treatment.

Aim: This study aims to apply the HAPA model to explain adolescents' oral hygiene behaviour and dental plaque during orthodontic treatment with fixed appliances.

Methods: In this cross-sectional study, 116 adolescents with fixed appliances from an orthodontic clinic situated in Almere (the Netherlands) completed a questionnaire assessing oral health behaviours and the psychosocial factors of the HAPA model. Linear regression analyses were performed to examine the factors associated with dental plaque, tooth brushing, and the use of a proxy brush.

Results: Stepwise regression analysis showed that lower amounts of plaque were significantly associated with higher frequency of the use of a proxy brush ($R^2=45\%$), higher intention of the use of a proxy brush ($R^2=5\%$), female gender ($R^2=2\%$) and older age ($R^2=2\%$). The multiple regression analyses revealed that higher action self-efficacy, intention, maintenance self-efficacy and a higher education was significantly associated with the use of a proxy brush ($R^2=45\%$).

Conclusion: Decreased levels of dental plaque are mainly associated with increased use of a proxy brush that is subsequently associated with a higher intention and self-efficacy to use the proxy brush.

INTRODUCTION

In the Netherlands, one out of three young people undergo orthodontic treatment [1]. The insertion of fixed orthodontic appliances (e.g. brackets) complicates dental cleaning and creates extra stagnation areas for plaque, which increases the amount of dental plaque [2]. Dental plaque is a causative factor for oral diseases, and thus, its removal and control are important aspects of oral health maintenance [3,4]. Prolonged plaque accumulation can lead to enamel demineralization and gingivitis, which are the common complications at treatment with orthodontic fixed appliances [5-8]. The severity of enamel demineralization can range from development of opaque white spots lesions, to loss of surface integrity of enamel and cavitation into dentine [9]. The prevalence of demineralization in orthodontically treated patients is higher compared to those without fixed appliances [5]. Richter et al. (2011) [9] showed that 72.9% of the patients developed at least one white spot lesion during fixed orthodontic treatment.

As part of usual dental care, instructions for removing dental plaque are given prior to and during orthodontic treatment in order to maintain good levels of oral hygiene [2]. These instructions are aimed at adequate tooth brushing and the use of dental aids, such as dental floss for interdental cleaning and proxy brushes (also known as interdental brushes) to clean around the brackets [2,10]. Nevertheless, it is estimated that in 5-10% of orthodontic patients, the appliances are prematurely removed before completion of orthodontic treatment, because of high levels of dental plaque caused by poor oral hygiene behaviour [11,12]. To optimize oral hygiene programmes aiming at reduction of dental plaque, it is important to understand the psychosocial factors that could be targeted by interventions. Knowledge about these factors is relevant as it creates an evidence base for the development of oral health promotion programmes [13].

A recent systematic review with meta-analysis provided some insight into psychosocial factors associated with the adolescents' oral hygiene behaviour [14]. It was shown that good oral hygiene behaviour was associated with 'action planning', 'coping planning', 'intention' and 'self-efficacy', factors that are part of a health behaviour change model: the Health Action Process Approach (HAPA). The HAPA model suggests that changing health-related behaviours comprises two consecutive behavioural phases: the motivational and the volitional phase [15]. The motivation (i.e. 'intention') to adopt health behaviour is formed by a growing 'risk perception', 'outcome expectancies', and 'action self-efficacy' (the motivational phase, see the left side of Fig. 1). A minimum level of perceived threat or concern must exist ('risk perception') before people start considering the benefits of possible actions ('outcome expectancies') and think about their competence to actually perform them ('action self-efficacy') [15]. Once intentions are formed, the volitional phase starts (see the right side of Fig. 1). The behavioural 'intention' has to be transformed into specific

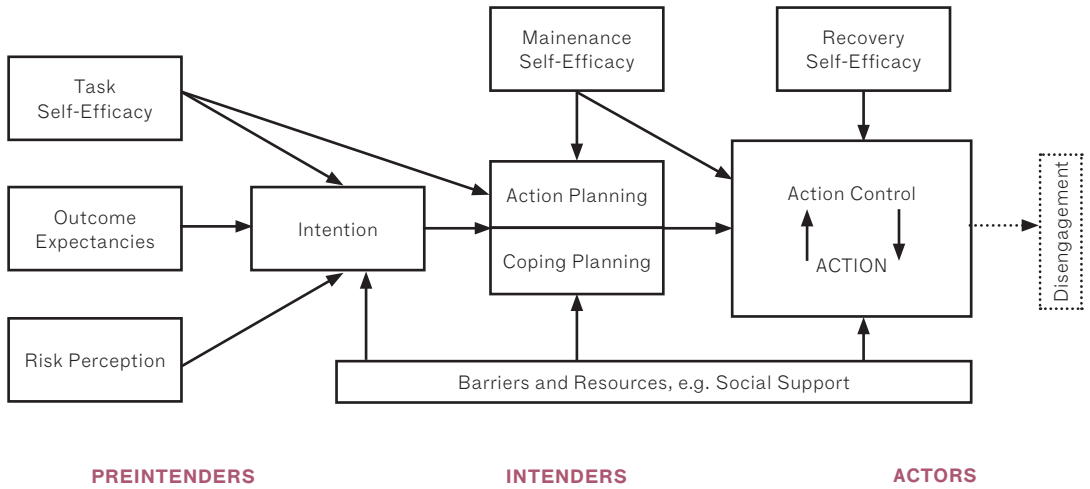


Fig. 1. The Health Action Process Approach Model [1]

planning of when, where, and how to perform the desired action ('action planning') and planning of anticipated barriers and ways to overcome them ('coping planning'). Planning is strongly influenced by 'self-efficacy', because self-efficacious individuals achieve mastery through earlier planning, and they visualize successful scenarios that may guide goal attainment ('maintenance self-efficacy') [15].

Research has not provided a clear picture of the psychosocial factors associated with oral hygiene behaviour and dental plaque for adolescents who have received orthodontic fixed appliances treatment [14]. This study reports factors associated with oral hygiene behaviour and dental plaque in adolescents with fixed orthodontic appliances, for which we applied the HAPA model. The following question guided this cross-sectional study: 'To what extent are the psychosocial factors of the HAPA model associated with tooth brushing, the use of a proxy brush and dental plaque levels in adolescents with fixed orthodontic appliances?'

Table 1. Overview of variables and psychometric data.

Scales	Item example (range response alternatives)	No. of items	Response range	α
Outcome expectancies DC	If I clean my teeth regularly, my breath will be fresh. (totally disagree- totally agree)	6	1-5	0.89
Risk perception TB	If I do not brush my teeth frequently, the risk of caries will be... (very low- very high)	1	1-5	-
Risk perception PB	If I do not frequently use a proxy brush to clean my teeth around my braces, the risk of caries will be... (very low- very high)	1	1-5	-
Action Self-efficacy TB	I am confident that I can brush my teeth every day even when it is time consuming. (totally disagree- totally agree)	4	1-5	0.79
Action Self-efficacy PB	I am confident that I can use a proxy brush every day even when it is time consuming. (totally disagree- totally agree)	4	1-5	0.79
Intention TB	Over the next month I intend to brush my teeth at least twice a day. (totally disagree- totally agree)	1	1-5	-
Intention PB	Over the next month I intend to use a proxy brush to clean my tooth surfaces around the brackets daily. (totally disagree- totally agree)	1	1-5	-
Action Planning DC	I have made a detailed plan regarding when to clean my teeth. (totally disagree- totally agree)	5	1-5	0.90
Coping Planning DC	I have made a detailed plan regarding what to do if I forget to clean my teeth. (totally disagree- totally agree)	4	1-5	0.80
Maintenance Self-efficacy DC	I am confident I can maintain cleaning my teeth, even when it takes a long time to become part of my daily routine. (totally disagree- totally agree)	3	1-5	0.84
The frequency of use of a proxy brush	How many times have you used a proxy brush in the last 4 weeks? (never - 3 times per day or more)*	1	0-24.5	-
Tooth brushing duration	How much time did you spend on brushing your teeth at a time? (less than 1 min. – more than 4 min.):**	2	0-98	-

DC, regarding dental cleaning; TB, regarding tooth brushing; PB, regarding proxy brush; α , Cronbach's α ; *, responses were recoded into weekly frequency; **, responses were recoded into minutes per week.

Table 2. Distribution of dental plaque according the zones to the bracket of the buccal tooth surface.

Mean number (SD) of zones covered with plaque (max. 6)					
	Incisal to the bracket	Gingival to the bracket	Mesial to the bracket	Distal to the bracket	ANOVA <i>F</i> (<i>P</i> -value)
Maxilla – Anterior ^{a,b,c,d,e}	0.37 (1.03)	1.34 (2.13)	2.61 (2.83)	2.97 (2.70)	34.12 (0.001)
Maxilla – Posterior ^{a,b,c,f}	2.69 (2.04)	4.40 (1.76)	4.69 (1.90)	6.00 (1.53)	30.58 (0.001)
Mandibular – Anterior ^{a,b,c,e}	0.53 (1.18)	2.41 (2.44)	2.86 (2.84)	3.17 (2.75)	42.00 (0.001)
Mandibular – Posterior ^{a,b,c}	2.63 (2.16)	4.59 (1.73)	4.72 (1.80)	5.10 (1.48)	46.68 (0.001)

Anterior part of the dentition includes incisors and canines and the posterior part includes first molars and premolars. Significant at $P<0.01$:^a, incisal versus gingival; ^b, incisal versus Mesial; ^c, incisal versus distal; ^d, gingival versus mesial; ^e, gingival versus distal; ^f, mesial versus, distal.

MATERIALS AND METHODS

Participants and procedures

A sample of 116 adolescents (12-15 years) with orthodontic appliances was recruited from an orthodontic clinic situated in the city of Almere, the Netherlands. Adolescents with fixed orthodontic appliances with self-ligating brackets in both arches (which consisted of bonding of the teeth 16 to 26 and 36 to 46) were eligible for inclusion. Furthermore, patients were included if they were without mental and/or physical disabilities, craniofacial anomalies, enamel and/or dentin disorders, no missing teeth, no spacing or crowding greater than three millimetre, no removable or functional appliances and no segmented bonding of fixed appliances. The following exclusion criteria were applied: (1) not able or willing to give informed consent; (2) insufficient command of the Dutch language; (3) the use of concomitant medication which may affect plaque accumulation, for example antibiotics and antibacterial mouth rinses within the last three months. When the fixed orthodontic appliances were inserted, a dental hygienist provided an oral health instruction to the patient using a leaflet with images. Approximately one month prior to the investigation, all adolescents visiting the orthodontic office were informed about the purpose of the study, and invited to participate voluntarily. After having received informed consent from the adolescents and their parents or guardians, participants completed the questionnaire in the orthodontic clinic and a dental hygienist registered the dental plaque index. The Ethical Review Board of VU Medical Centrum (VUMC) Amsterdam approved the study (2016.162).

Clinical measurement

To assess the plaque on the buccal surfaces of the first molars, premolars, canines and incisors, plaque disclosing agent was applied (Gum® Red-Cote® liquid) according to the instructions of the manufacturer. The buccal surfaces of each tooth were divided into four zones mesial, distal, gingival and incisal to the bracket [16]. Each zone was given a score 0 (absence of plaque) or 1 (presence of the plaque). For the analysis, the percentage of zones covered with dental plaque was calculated.

Questionnaire

The self-administered questionnaire contained structured questions concerning oral health behaviours, psychosocial factors and background information, such as gender, education level, ethnicity of adolescents and parents/guardians and smoking status.

Questions concerning oral health behaviour were adapted from a questionnaire of Tolvanen et al. (2012) [17]. Respondents were asked to report the frequency of the use of, respectively, a toothbrush, a proxy brush, dental floss, toothpicks, and mouth rinse,

using a 7-point scale ('1': less than twice a month or never, '2': twice a month, '3': once a week, '4': 2-3 times a week, '5': once a day, '6': twice a day and '7': 3 times a day or more frequently) [17]. For the analysis, these response alternatives were recalculated to describe the weekly frequencies of each of the oral health behaviour (ranging from 0 to 24.5; e.g., three times a day or more frequently was recoded into 24.5 by multiplying its frequency per day (3.5) by 7 days) [17]. Tooth brushing duration was measured by asking "How much time do you spend on brushing your teeth at a time?" with eight-point scale (ranging in increments of 30 s from 0 to 4 minutes). For the analysis, the tooth brushing duration was multiplied by tooth brushing frequency to obtain a single item for the outcome tooth brushing behaviour (ranging from 0 to 89 minutes per week).

The questions concerning the psychosocial factors, 'risk perception', 'action-self-efficacy', 'maintenance self-efficacy' and 'intention' were based on a questionnaire of Schwarzer et al. [18], and items for 'outcome expectancies', 'action planning' and 'coping planning' were adapted from previous studies on oral health [17,19]. All psychosocial factors were assessed using five-point scales, ranging from very low (1) to very high (5) for the item risk perception and ranging from totally disagree (1) to totally agree (5) for the remaining items. Item examples and psychometric data can be found in Table 1. Cronbach's alpha's (α) (see Table 1) were calculated to estimate the lower bound of test-retest reliability. Acceptable values of Cronbach's alpha are reported to be 0.70-0.95 [20]. The questionnaire is available upon request from the corresponding author.

Statistical Analysis

Descriptive statistics were used to summarise the data. Independent sample t-tests were performed to test the differences in the number of zones covered with plaque between the posterior part and anterior part of the dentition of the maxilla and mandibular. One-way ANOVA with multiple comparison *post hoc* Tukey's tests were performed to test the differences in number of zones covered with plaque in relation to the various positions of the zones in relation to the bracket. To examine associations between the psychosocial factors and the outcomes, Pearson's correlation coefficients were calculated. The relative strength of psychosocial factors and oral hygiene behaviours as predictors of dental plaque was evaluated using a stepwise forward and backward selection procedure to construct a linear regression model [21]. The entry probability for each variable was set at 0.05. A linear regression with forced entry of all psychosocial factors was conducted to examine the predictive performance of the HAPA model on the frequency of use of a proxy brush and tooth brushing duration. Prior to the analysis, assumptions for linear regression analyses were checked, which revealed that the data was suitable for parametric analysis. SPSS Statistical Package for Social Sciences (IBM SPSS version 22.0, New York, NY, USA) was used to perform the statistical analyses.

Table 3. Intercorrelations between HAPA variables, the frequency of the use of a proxy brush and tooth brushing duration

Variables	Mean (SD)	OE-DC	RP-TB	RP-PB	ASE-TB	ASE-PB	I-TB	I-PB	AP-DC	CP-DC	MSE-DC	PB	TB	DP
Outcome expectancies of dental cleaning (OE-DC)	4.25 (0.73)	1.00												
Risk perception regarding tooth brushing (RP-TB)	1.51 (0.92)	0.03	1.00											
Risk perception regarding proxy brush use (RP-PB)	2.05 (0.92)	-0.13	0.47*	1.00										
Action Self-efficacy regarding tooth brushing (ASE-TB)	3.95 (0.71)	0.38*	-0.09	-0.16	1.00									
Action Self-efficacy regarding proxy brush use (ASE-PB)	3.58 (0.82)	0.33*	-0.07	-0.23*	0.73*	1.00								
Intention towards tooth brushing (I-TB)	4.53 (0.81)	0.20*	0.17	0.14	0.30*	0.16	1.00							
Intention towards proxy brush use (I-PB)	3.77 (1.11)	0.18	0.07	-0.17	0.31*	0.47*	0.37*	1.00						
Action Planning regarding dental cleaning (AP-DC)	3.76 (0.83)	0.28*	-0.04	-0.15	0.61*	0.38*	0.29*	0.28*	1.00					
Coping Planning regarding dental cleaning (CP-DC)	3.42 (0.73)	0.28*	0.03	-0.19*	0.58*	0.46*	0.18*	0.21*	0.52*	1.00				
Maintenance Self-efficacy regarding dental cleaning (MSE-DC)	3.91 (0.79)	0.33*	-0.10	-0.12	0.61*	0.40*	0.23*	0.26*	0.59*	0.55*	1.00			
The frequency of use of a proxy brush (times per week) (PB)	7.08 (7.28)	0.14	-0.01	-0.22*	0.38*	0.56*	0.10	0.47*	0.20*	0.28*	0.32*	1.00		
Tooth brushing duration (min per week) (TB)	24.21 (13.49)	0.01	-0.05	-0.05	0.29*	0.24*	0.08	0.16	0.13	0.10	0.08	0.23*	1.00	
Dental Plaque (%) (DP)	52.49 (24.56)	-0.22*	-0.03	0.19*	-0.41*	-0.52*	-0.15	-0.52*	-0.22*	-0.26*	-0.35*	-0.67*	-0.28*	1.00

* Correlation is significant at the level 0.05 (two-tailed) (n=116).

Table 4. Stepwise multivariate linear regression analysis of psychosocial and behavioural factors to predict dental plaque in adolescents with fixed orthodontic appliances.

Stepwise multivariate linear regression model				
Variables	β (95% CI)	SE	R^2 Change (%#)	R^2
Frequency of the use of a proxy brush	-0.57 (-2.41;-1.44)*	0.25	0.45* (44.7%)	
Intention towards the use of a proxy brush	-0.25 (-8.67;-2.18)*	1.64	0.05* (5.4%)	
Gender (0=male; 1= female)	-0.17 (-15.09;-2.02)*	3.30	0.02* (2.4%)	
Age	-0.13 (-10.07;-0.16)*	2.50	0.02* (1.7%)	
				0.54 *

β , standardized regression coefficients; CI, confidence interval; SE, Standard Error; * $p < 0.05$; #, % variance explained.

Table 5. Linear regression of the frequency of the use of a proxy brush per week in relation to the HAPA variables as well as gender, age, education level and treatment duration.

Frequency of the use of a proxy brush				
	β (95%CI)	SE	R^2	F
Variables				
Gender (0=male; 1= female)	-0.09 (-3.56;0.95)	1.14		
Age	-0.04 (-2.19;1.26)	0.87		
Education level	-0.20 (-1.31;-0.16)*	0.29		
Treatment duration	-0.07 (-0.10;0.72)	0.10		
Risk perception	-0.08 (-1.78;0.59)	0.60		
Outcome expectancies	-0.03 (-0.32;0.21)	0.14		
Action Self-efficacy	0.38 (0.41;1.26)**	0.21		
Intention	0.25 (0.50;2.74)*	0.56		
Action planning	-0.18 (-0.64;0.03)	0.17		
Coping planning	0.03 (-0.40;0.56)	0.24		
Maintenance Self-efficacy	0.21 (0.01;1.25)*	0.31		
			0.45**	7.68**

SE, Standard Error; R^2 , explained variance; F value (df1=11, df2=104). * $p < 0.05$; ** $p < 0.001$; (n=116) β , standardized regression coefficients;

RESULTS

Descriptive statistics

A total of 116 (45% boys) adolescents with fixed orthodontic appliances, with a mean age of 12.8 years (SD=0.64, ranging from 12 to 15 years) and a mean treatment duration of 9 months (SD=5.8), participated in the study, giving a response rate of 82%. Of the study sample, 99.1% (all but one) was of Dutch nationality, 50% attended higher general secondary education or pre-university education, and 50% attended lower general secondary education. None of the respondents smoked. The mean dental plaque score was 52.5% (SD=24.6); that is, on average, 50 out of the 96 zones were covered by plaque. Table 2 presents the distribution of dental plaque accumulation according to the zones to the bracket of the buccal tooth surfaces. The posterior part of the dentition (premolars and first molars) had significant higher amount of zones covered with plaque than the anterior part of dentition (incisors and the canines) in both the mandibular and maxilla ($p<0.001$). Significant differences in plaque distribution were found between the four zones adjacent to the bracket. The distal zone had the highest mean plaque scores anteriorly and posteriorly in both arches (Table 2).

Intercorrelations between psychosocial variables, tooth brushing, the use of a proxy brush and dental plaque, as well as means and standard deviations, are presented in Table 3. Dental plaque was significantly negatively associated with all psychosocial variables except for 'risk perception' and 'intention regarding tooth brushing'. Self-reported tooth brushing, and the use of a proxy brush were significantly and negatively associated with the dental plaque index. Tooth brushing was only significantly correlated with 'action self-efficacy', suggesting that higher self-efficacy was associated with increased tooth brushing. The use of a proxy brush was significantly correlated with 'risk perception', 'action self-efficacy', 'intention', 'maintenance self-efficacy', 'action planning', and 'coping planning'.

Psychosocial and behavioural factors associated with dental plaque

Table 4 presents the result of the stepwise multivariate linear regression analysis of psychosocial and behavioural factors to predict dental plaque in adolescents with fixed orthodontic appliances. The following factors, including background characteristics, were analysed as independent variables: gender, age, education, treatment duration, frequency of the use of proxy brush, toothpick and floss per week, tooth brushing duration per week, type of toothbrush, and the psychosocial factors with regard to tooth brushing duration and the frequency of the use of a proxy brush including 'risk perception', 'action self-efficacy', 'intention', and psychosocial factors with regard to dental cleaning including 'maintenance self-efficacy', 'action planning' and 'coping

planning'. Forward and backward selection procedures revealed similar results. Stepwise multiple linear regression analysis showed that lower plaque indices were associated with more frequent use of a proxy brush ($\beta=-0.57$, $p<0.001$), higher intention towards the use of a proxy brush ($\beta=-0.25$; $p=0.001$), female gender ($\beta=-0.17$; $p=0.011$), and older age ($\beta=-0.13$; $p=0.043$). The total model accounted for 54% of the variance in dental plaque ($F(4, 111)=32.91$; $p<0.001$), of which the use of a proxy brush explained 44.7% of the variance, a positive intention towards the use of a proxy brush explained an additional 5.4% of the variability, female gender explained 2.4% of the variance and older age brush explained an additional 1.7 % of the variance.

Additional analyses were performed to examine whether there were differences in psychosocial factors predicting the amount of dental plaque of the different zones of the dentition (posterior, anterior, mesial, distal, gingival, incisal, maxilla or mandibular). These analyses did not reveal differences from the analyses with the total plaque index as a dependent variable (data not shown).

Psychosocial factors associated with the use of a proxy brush and tooth brushing

To examine predictive utility of psychosocial factors for the frequency of the use of a proxy brush (Table 5) and subsequently tooth brushing, multiple linear regression analysis was conducted. The multivariate model consisted of gender, age, education, treatment duration, risk perception, action self-efficacy, outcome expectancies, intention, maintenance self-efficacy, action planning and coping planning. The regression equation significantly explained 45% of the variance in the use of a proxy brush ($F(11, 104)=7.68$; $p<0.001$) and 13% of the variance in tooth brushing ($F(11, 104)=1.47$; $p=0.16$). Higher action self-efficacy ($\beta=0.38$ $p<0.001$), intention ($\beta=0.25$ $p=0.005$), maintenance self-efficacy ($\beta=0.21$ $p=0.045$) and a higher education level ($\beta=-0.20$ $p=0.012$), were significantly associated with a higher frequency of the use of a proxy brush. With regard to tooth brushing, only action self-efficacy emerged as a significant predictor ($\beta=0.47$ $p=0.002$).

DISCUSSION

Understanding the determinants of adolescents' oral hygiene behaviour during fixed orthodontic appliances therapy can help to plan oral health education and behaviour change interventions improving oral hygiene. In this study, we applied the HAPA model, to examine to what extent psychosocial factors are associated with the amount of dental plaque, tooth brushing and use of a proxy brush in adolescents with fixed orthodontic appliances. Results of stepwise multivariate linear regression analysis revealed that in this sample, dental plaque could be significantly predicted by the use of a proxy brush, intention towards the use of a proxy brush, gender and age. Patients with low levels of dental plaque used the proxy brush more frequently. This could be explained by the fact that the approximal zones to the brackets are difficult to reach with a toothbrush, and the shape and size of a proxy brush allow cleaning these hard-to-reach areas. The association of the psychosocial factors (such as planning) with dental plaque was markedly attenuated after entering the variable the use of a proxy brush into the regression model. This suggests that oral hygiene behaviour mediates the association between psychosocial factors and dental plaque.

Higher action self-efficacy, intention, maintenance self-efficacy and high education level were significantly associated with the use of a proxy brush and accounted for 45% of the variance in the use of a proxy brush. Merely 'self-efficacy' was significantly associated with tooth brushing, which accounted for 13% of the variance. The differences in variances found for these two oral hygiene behaviours could be explained by the fact that the use of a proxy brush requires more motivation than tooth brushing, as tooth brushing is a standard procedure for the general population and the use of a proxy brush to clean between the brackets is an additional recommendation for orthodontic patients. Another explanation is that other factors, such as 'self-determination', 'action control', and 'anticipated regret', play a role in explaining tooth brushing than the use of a proxy brush [14].

We hypothesized that 'volitional factors', such as 'action planning' or 'maintenance self-efficacy', would show the strongest associations with oral hygiene behaviour as postulated by the HAPA model (see also Scheerman et al. 2016 [14]). Our findings showed, however, that planning did not emerge as a significant predictor of oral hygiene behaviour in our sample. One could argue that measurement bias might have occurred, as the questions with regard to 'action and coping planning' were related to dental cleaning, which comprise both the use of a proxy brush and tooth brushing. Participants might have planned their tooth brushing behaviour, but not the use of a proxy brush, which makes it hard to answer the question whether they have planned to clean their teeth. Differences in the association of planning across oral hygiene behaviours was mentioned by a recent meta-analysis, which showed that 'action

planning' was associated with tooth brushing, but not with flossing behaviour among 9- to 18-year-olds [14]. Future research should measure all psychosocial factors at specific behaviour level, that is tooth brushing separately from the use of a proxy brush, instead of combining all behaviours to one level (i.e., dental cleaning).

The study has some limitations that should be acknowledged. The sample may not be entirely representative of the Dutch 12- to 15-year-olds undergoing fixed orthodontic appliances. The conclusions cannot be generalized to adults wearing fixed braces, as the psychosocial factors may play a different role in adults [22]. Another limitation is that the self-report measures may be potentially biased and often inflated as a result of limitations in recall accuracy or social desirability. Furthermore, due to the cross-sectional nature of the study design, causal inferences cannot be made. This cross-sectional study provides evidence about potential mediators for planning interventions and provides an evidence base for improvement of intervention design by identifying putative determinants. A next step to verify the causal role of the psychosocial factors on oral hygiene behaviour and dental plaque levels during fixed orthodontic treatment is to examine them in intervention trials.

The results have implications for oral health promotion. Increasing the use of the proxy brush may allow for the greatest improvement in dental plaque accumulation. To increase the use of a proxy brush, oral health programmes could target 'intention' and 'self-efficacy' in performing the use of a proxy brush. Gholami et al. [23] found that improvement of 'intention' and 'self-efficacy' by a brief self-regulatory intervention led to higher frequency of dental flossing after one month. Moreover, another study on university students revealed that three weeks after a brief self-regulatory intervention, participants with higher 'self-efficacy' were more engaged in oral hygiene behaviour [24]. Through application of strategies that target the psychosocial factors 'intention' and 'self-efficacy' interventional efforts might be stronger which may result in improved compliances with recommended practices. Guided practice could be a method to enhance 'action self-efficacy' [25]. Guided practice includes prompting individuals to rehearse and repeat the behaviour various times, discuss the experience, and provide feedback [25]. To achieve 'intention' formation, a method might include providing normative information about where and when others perform the behaviour, drawing persons' attention to others' performance (i.e. "most young people clean their teeth in between the brackets with a proxy brush after tooth brushing every day") [23, 27]. A method to enhance 'maintenance self-efficacy' could be self-monitoring, that is keeping records of their behaviours in form of a diary or checkmarks on a calendar [25]. This study shows the usefulness of the HAPA model in explaining oral hygiene behaviour in adolescents with fixed orthodontic appliances.

Bullet points:

Why it is important to paediatric dentists:

1. This article provides information necessary for the planning of behaviour change programs aimed to improve oral hygiene behaviour and dental plaque levels.
2. Patients' intention and self-efficacy are most associated with oral hygiene behaviour in patients with fixed orthodontic appliances.
3. The findings suggest that implementation of behaviour change techniques targeting patient intention and self-efficacy with regard to the use of a proxy brush might be promising to promote oral hygiene in adolescents with fixed orthodontic appliances.

Conflict of interest:

The authors declare no conflict of interest.

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CHAPTER 3

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CHAPTER 4

A mobile app (WhiteTeeth)
to promote good oral health
behavior among Dutch adolescents
with fixed orthodontic appliances:
Intervention Mapping approach.



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ABSTRACT

Background: The insertion of fixed orthodontic appliances increases the risk of dental caries, particularly in adolescents. Caries can be prevented through good oral health behavior. To support adolescents with fixed orthodontic appliances and for promoting oral health behavior, we developed a theory- and evidence based mHealth program, the WhiteTeeth application (app).

Objective: The objective of our paper was to describe the systematic development and content of the WhiteTeeth app.

Methods: For systematic development of the program, we used the Intervention Mapping (IM) approach. In this paper, we present the results of applying the first 5 steps of IM to the design of an mHealth program: (1) identifying target behaviors and determinants through problem analysis, including (I) a literature search, (II) a survey study, and (III) semi-structured interviews to explore adolescent oral health behavior during orthodontic therapy; (2) defining program outcomes and objectives; (3) selecting theoretical methods and translating them into practical strategies for the program design; (4) producing the program, including a pilot test with 28 adolescents testing the acceptability and usability of the WhiteTeeth app; and (5) planning implementation and adoption.

Results: On the basis of our literature search, we identified fluoride use and control of dental plaque levels (e.g. tooth brushing and proxy brush usage) as target behaviors for preventing caries. Next, we identified important and changeable determinants of oral health behavior that fitted the theoretical concepts of the Health Action Process Approach (HAPA) theory. The HAPA theory, the self-regulation theory, and the results of the semi-structured interviews were used to define the program objectives, that is, the performance and change objectives. After defining the objectives, we identified multiple behavior change techniques that could be used to achieve these objectives, such as providing of oral health information and feedback, prompting self-monitoring, coaching of set action and coping plans, and sending reminders. We translated these methods into practical strategies, such as videos and a brushing timer. Next, we combined these strategies into a single program resulting in the WhiteTeeth app (which is available on both iTunes and Google Play stores as "Witgebit"). Adolescents with fixed orthodontic appliances and dental professionals were included in the development process to increase the success of implementation. The pilot test revealed that the app users appreciated and liked the app. The WhiteTeeth app can be integrated into current orthodontic care.

Conclusion: IM allowed us to identify multiple techniques that have been shown to be the most effective in initiating behavior change, but have not yet been incorporated into existing orthodontic apps. The WhiteTeeth app contains all these techniques,

which makes it a unique and promising home-based app for promoting oral health in adolescents with fixed orthodontic appliances.

Keywords: mobile applications; telemedicine; health education; behavior; cognition; health; mHealth; oral health; oral hygiene; dental caries; adolescent; prevention and control; dental plaque; gingiva; health promotion; braces.

INTRODUCTION

Dental caries remains a major public health problem that affects young people and adults [1]. Worldwide, nearly 60%-90% of young people and the majority of adults have dental caries, which often leads to pain and discomfort [2-4]. In several industrialized countries, oral diseases are the fourth most expensive disease to treat [2]. Furthermore, 5%-10% of public health expenditure is devoted to oral health treatment [5-6].

Adolescents with fixed orthodontic appliances are at high risk of developing dental caries [7], as their fixed orthodontic appliances (e.g. brackets) impede oral hygiene procedures and restrict salivary and mucosal self-cleaning capacity, unfavorably altering the balance of oral bacteria and increasing the retention of dental plaque. [8-10]. Prolonged dental plaque accumulation can lead to enamel demineralization, which is an early stage of dental caries. Due to their white appearance, these demineralizations are often referred to as *white spot lesions*, which are a common complication in orthodontics [11]. The incidence of patients who develop at least one new white spot lesion during orthodontic treatment ranges from 68% to 95% [12-14]. White spot lesions may develop around the bracket, their white appearance seriously compromising aesthetics [15,16]. After the removal of fixed orthodontic appliances, white spot lesions often remain permanently visible; along with being unaesthetic, they increase the risk of lesion progression [15,16].

Oral health education is essential for the prevention of dental caries in patients with fixed orthodontic appliances. A central role in such education – which is given both before and during orthodontic treatment [17] – involves oral health behavior that target dental plaque control, dietary behavior and fluoride administration [18-21]. However, it is not always easy to achieve regularity in patient compliance with such oral health behaviors [22]. A recent study among Dutch adolescents with fixed orthodontic appliances showed that they had poor overall oral hygiene and poor compliance with the use of fluoride mouth rinse [23]. This emphasizes the need for interventions that focus on changing in oral health behavior in this group.

As growing numbers of young people now have smartphones, mobile phone apps may be effective means of promoting oral health behavior in orthodontics [24-26]. As a delivery method, apps have many advantages: they are constantly accessible,

can be adjusted to the needs of the user, can provide tailored feedback, are more anonymous than face-to-face contact, can send cues to action (i.e. reminders), and have a wide reach and interactive features, such as animations [27-29].

To promote good oral health behavior among adolescents with fixed orthodontic appliances, we decided to develop a smartphone app, the WhiteTeeth app (Dutch name: WitGebit app). To ensure that this app would be both theory- and evidence-based and also be feasible for use in orthodontic clinics, we used the IM protocol [30] for its systematic development. This paper provides a detailed description of the development and content of the WhiteTeeth app.

METHODS

4

Intervention Mapping Protocol

IM is a protocol for the planning and development of theory- and evidence-based health promotion programs [30]. The IM process comprises six steps: Step 1, identifying target behaviors and determinants through problem analysis; Step 2, specifying program outcomes and objectives; Step 3, selecting theoretical methods and practical strategies for the program design; Step 4, producing the program; Step 5, planning the implementation and adoption; and Step 6, planning for evaluation [30]. Each step has a defined end product and consists of various tasks that are required for the systematic integration of theoretical and empirical information. The product of a preceding task or tasks guides the developmental activities for the subsequent step or steps.

To guide the developmental process for this intervention, we established a multi-disciplinary planning group consisting of an orthodontist, a dental hygienist, two dentists, a smartphone application developer, a health psychologist, two health scientists, and a child psychologist with communication expertise.

Step 1: Problem analysis

The first step of the IM process was to conduct a problem analysis, which included the identification of determinants related to the problem and the specific health-related behaviors. This IM process is based on the assumption that health outcomes can be improved by targeting health behavior and their determinants [30]. To explore the oral health behaviors of adolescents during treatment with fixed appliances, we conducted semi-structured interviews with adolescents with such appliances (n=20), asking them about their oral health behavior. These semi-structured interviews were performed after a regular orthodontic check-up in a private room at the Academic Centre for Dentistry Amsterdam (ACTA). Adolescents with fixed orthodontic appliances were

purposely sampled to ensure that the patient group ranged in gender, educational level, ethnicity and dental hygiene level. The clinicians told adolescents about the aim of the study and the voluntary nature of participation. Their parents or legal representative were given written information about the study. Informed consent was obtained from both the adolescents and their parents. During the interview, we asked adolescents about their beliefs and motivations concerning the performance of oral health behavior during fixed orthodontic treatment. Interview topics relevant to the adolescents' oral health behaviors consisted of: (1) oral hygiene practices; (2) reasons or motives for performing oral health behaviors; (3) awareness and knowledge of dental health and recommendations on oral health (see Table 1); and (4) personal strategies and reported barriers; (5) role of the social environment; (6) facilities (accessibility). The adolescents were individually interviewed using open-ended questions to guide the interview. The audiotaped interviews were anonymously transcribed verbatim and transported to a software program "NVivo" to analyze the transcripts. After 20 interviews saturation was attained, i.e. no new relevant information emerged in subsequent interviews. The Medical Ethics Committee of the University of Amsterdam approved this qualitative study (VUMC - 2014-577).

After exploring adolescent oral health behavior during orthodontic treatment through these semi-structured interviews, we searched the literature to identify behavioral determinants and theoretical constructs to explain this behavior. We therefore conducted a systematic literature review with a meta-analysis [33]. Since the findings of this review applied to young people in general, not specifically those with fixed orthodontic appliances, we conducted a survey among adolescents undergoing fixed orthodontic therapy (n=116) [23]. This survey study aimed to explain oral health behavior and the presence of dental plaque during orthodontic treatment. A sample of 116 adolescents (12-15 years) with fixed orthodontic appliances was recruited from an orthodontic clinic situated in Almere (the Netherlands) and the respondents completed a questionnaire to map their oral health behavior. In addition, a dental hygienist measured their dental plaque levels. Linear regression analyses were performed to examine the factors associated with dental plaque and specific oral health behaviors [23].

Next, the planning group selected important and changeable determinants of oral health behaviors. According to IM, the importance of determinants is related to the strength of the relationship between the determinants and oral health behavior. The changeability of the determinants that can be achieved by an intervention and the importance of the determinants were established by the development group on the basis of the available scientific literature [23, 30, 33-40] and consensus judgments.

Table 1. Oral health recommendations for patients with fixed orthodontic appliances from the Academic Centre for Dentistry Amsterdam, (ACTA).

- To control dental plaque levels, it is recommended to brush the teeth at least twice a day according to the “5-step method” and to use dental aids (such as a proxy brush to clean the tooth surfaces around the brackets and/or to maintain gingival health). The “5-step method” consists of brushing (1) the gums; (2) above and (3) under the bracket on the buccal sites of the teeth; (4) the chewing surfaces and (5) the lingual or palatal sites of the teeth. This 5-step procedure takes approximately three minutes to fulfill [31].
- Daily use of fluoride mouth rinse and toothpaste during orthodontic treatment is strongly advised for the prevention of dental caries [20, 31]
- The consumption of sugars, refined carbohydrates and or, dus acid or soft drinks should be limited [32].

Step 2: Identification of program outcomes and objectives

Step 2 involved a detailed specification of program outcomes and objectives indicating those behaviors that needed to change to achieve the overall goal of the program, i.e. to prevent dental caries in adolescents during orthodontic treatment and to prevent existing dental caries from getting worse. The performance objectives formalized the behavioral changes that adolescents with fixed orthodontic appliances needed to make to achieve the behavioral goals of the program (the program outcomes). Per program outcome, two researchers (JS and PvE) defined performance objectives on the basis of the following question: “To perform the desired behavior, what, in concrete terms, do participants in this program need to do?” Next, the same two researchers identified specific determinants that would be deemed useful in changing each performance objective. For example, if a performance objective was “to decide to prevent dental diseases and to change their tooth brushing behavior”, appropriate behavioral determinants may be “risk perception”, “knowledge”, “outcome expectancies” and “self-efficacy”. Subsequently, we formulated change objectives that stated what needs to change in determinants to achieve the performance objectives. The change objectives were the result of combining performance objectives with the changeable determinants of oral health behavior. Thus, to give an example, the determinant was adolescents’ “self-efficacy”, and the performance objective was “adolescents decide to prevent dental diseases and to change their tooth brushing behavior”. In this example, the change objective would be for “adolescents with fixed orthodontic appliances [to] feel able to prevent dental diseases and [to] gain confidence in their ability to brush their teeth twice daily according to the 5-step method”. The first author constructed a matrix (as explained by IM [30]) specifying performance objectives, behavioral determinants and change objectives, which were subsequently validated by the planning group.

Step 3: Program design: Selecting theoretical methods and practical strategies for program design

The third step of IM comprised two phases. In the first phase, we identified and selected theoretical methods. Theoretical methods or behavior change techniques are considered general techniques or processes that have been shown to enable change in one or more behavioral determinants, and which have their origins in behavioral and social sciences theories. One example of a theoretical method is modeling, which is frequently used to facilitate behavior change [30]. For each behavioral determinant and in conjunction with the change objective, two researchers (JS and PvE) selected theoretical methods on the basis of the literature on existing dental and orthodontic health promotion interventions [36-52] and behavior change techniques [30, 53, 54]. For example, to reach the change objective “adolescents monitor their tooth brushing behavior and dental plaque levels”, we selected the methods “self-monitoring of behavior” and “self-monitoring of the outcome of behavior” for changing the determinant “action control”.

In the second phase, we assessed the conditions under which the methods are shown to be effective and translated the selected methods into practical strategies. A practical strategy is “a specific application of a theoretical method, adjusted to the intervention setting, tailored to the target population, and applied considering parameters for effective use of the methods” [30]. For example, the selected method “self-monitoring of behavior” was translated into the practical strategy “adolescents enter into the app whether or not they accomplish their daily oral health tasks”. The planning group decided if the methods and strategies were suitable for the target population and appropriate for designing a smartphone app. When necessary, small changes were made, resulting in strategies that were easier to implement.

Step 4: Program production

In the fourth step, we combined the chosen strategies into a coherent program leading to the development of the WhiteTeeth app. First, the strategies were clustered to create a program plan, which described the intervention components and presented the wireframe drafts. To ensure that the program met the users’ needs and expectations, we organized meetings with the target audience to obtain feedback on the program plan. Helen Parkhurst, a high school in Almere, the Netherlands, allowed us to organize two meetings with 30 adolescents (most had current or previous orthodontic appliances) attending preuniversity technology classes. The first author showed the wireframe drafts and offered a brief demonstration of the main functionalities of the app. As an assignment for a technology class, adolescents were asked to give feedback on the program plan and to design an app. During the second meeting, adolescents presented their app design. New ideas or suggestions

for improvements to optimize the program plan were discussed with the planning group. Based on the adjusted version of the program plan, the first author created an adapted version of the app wireframes to increase the app's acceptability and usability. These adapted wireframes were then improved by a user experience designer. The WhiteTeeth app was developed by ACTA in collaboration with Inholland University of Applied Sciences and TNO Research group. A programmer at ACTA programmed the WhiteTeeth app using Ionic software (ionicframework.com), which enabled the app to function on two operating systems: IOS ≥ 7 and Android ≥ 4.1 .

To identify aspects of the program that could be improved, the WhiteTeeth app 1.0 was pilot tested. It was first tested for bugs (i.e. system errors) by the planning group (resulting in WhiteTeeth 1.1). Second, to increase the app's acceptability and usability, it was pilot-tested for two weeks by 28 adolescents with fixed orthodontic appliances, who then provided feedback on its acceptability and usability in an online survey containing 49 questions. The survey measured perceived usefulness, attractiveness and ease of use, and included the System Usability Scale (SUS) for measuring the app's usability [55]. The SUS scale ranged from 0 to 100, with response ranges from strongly agree to strongly disagree. A SUS score above 68 would be considered above average. This questionnaire has been published elsewhere [56]. The results of the pilot test were used to refine the WhiteTeeth app (resulting in WhiteTeeth 1.2).

Step 5: Program implementation plan

The previous steps of IM were focused on ensuring the effectiveness of the program. The purpose of the penultimate step of IM is to ensure that the program reaches the intended population by preparing for the adoption and implementation of the program [30]. The planning began by identifying who would use the program: who would adopt it, who would implement it, and who would be responsible for sustaining the program over time. The best way to increase the chances for successful implementation is collaborating with future program implementers from the start of the planning process, thereby linking program developers with program implementers. Dental health professionals were therefore involved throughout the entire process. The planning group discussed the adoption and implementation of the app.

Step 6: Evaluation plan

In the final step of IM, an evaluation plan was created. As this final IM step for is not within the scope of this paper, it is reported in detail elsewhere [56].

RESULTS

Step 1: Problem analysis

Semi-structured interviews with adolescents with fixed orthodontic appliances provided insight into their oral health behavior. These interviews revealed that recommended dental aids, such as proxy brushes, were used only occasionally. Although most respondents stated that they brushed their teeth twice a day as a matter of routine, they often failed to brush for as long as recommended. These respondents had little awareness of the benefit of fluoride and fluoride mouth rinses were not a preventive measure they chose consciously. The dietary recommendations were familiar to most respondents, but many of them did not fully adhere to these recommendations. The main reasons for performing desired or undesired oral health behaviors are listed in Table 2. Respondents shared the opinion that their parents (especially mothers) were helpful with dental care, since they influenced the availability of dental aids and supported the adolescents by reminding them to clean their teeth.

The relevant literature was systematically reviewed to identify those behavioral determinants and theoretical constructs that best explained adolescent oral health behavior. The results of this systematic literature review with meta-analysis revealed that the psychosocial factors most strongly correlated with oral health behavior were “self-efficacy”, “intention”, “social influences”, “coping planning” and “action planning”. These factors that are part of the Health Action Process Approach (HAPA) theory [33]. The findings of this review applied to the oral health behaviors of young people in general.

Our survey study (n=116) revealed that the HAPA theory could be applied to explain the differences in oral health behaviors in adolescents with fixed orthodontic appliances [23]. According to this theory, behaviors are established in two subsequent phases: (1) a motivational, intention-forming phase, and (2) a volitional phase in which intention is translated into action [57]. Regarding the motivational phase, the motivation (i.e. intention) to adopt health behavior is formed by a growing “risk perception”, “outcome expectancies”, and “action self-efficacy”. A minimum level of threat must exist (“risk perception”) before people start considering the benefits of possible actions (“outcome expectancies”) and think about their competence to actually perform these (“action self-efficacy”) [57]. Once intentions are formed, the volitional phase starts. The behavioral intention has to be transformed into specific planning of when, where, and how to perform the desired action (“action planning”) and planning of anticipated barriers and ways to overcome them (“coping planning”). Planning is strongly influenced by self-efficacy because self-efficacious individuals achieve mastery through planning, and they visualize successful scenarios that may guide goal attainment (“maintenance or coping self-efficacy”). Persons with confidence in their ability to cope with setbacks will

Table 2. Main reasons or motives for performing desired or undesired oral health behaviors during fixed orthodontic therapy

Oral health behavior	Reasons for performing, or not performing, the oral health behaviors
Brushing as recommended	Personal appearance and attractiveness (white teeth without discoloration and bad breath).
Not brushing as recommended	Lack of time, forgetfulness, no prioritization, and tiredness.
Using dental aids	The necessity they perceived for removing food residues between the brackets.
Not using dental aids	They believed that it was unnecessary to follow recommendations with respect to use of these aids: in their view, some dental aids had the same function as the toothbrush.
	Forgetfulness and uncertainty about their ability to use them correctly.
Rinsing with fluoride mouth rinse	Freshness of breath, better oral health, perceived attractiveness to others due to fresh breath and cleanliness.
Not using fluoride mouth rinse	Forgetfulness, not being familiar with the guidelines, or unavailability of mouth rinse at home.
Following dietary recommendations	Oral health reasons.
Ignoring dietary recommendations	Dietary habits among young people, and social pressure from friends.
	Misperceptions about the recommendations – e.g. perceptions regarding the negative effects of soft drinks.

quickly recover when running into unforeseen difficulties (“recovery self-efficacy”). When the behavior has been initiated, self-regulatory cognitions to control and maintain the behavior must be activated (“action control”) [57].

Next, the planning group selected important and changeable determinants of oral health behaviors, which are presented in Table 3.

Step 2: Identification of program outcomes and objectives

The results of the problem analysis were used to specify the program outcomes, performance objectives and change objectives, which are described below.

The program outcomes were specified as follows:

- (1) Adolescents control their dental plaque levels by improving:
 - (a) their tooth brushing frequency and duration, that is, by brushing their teeth consistently and correctly (5-step method, see Table 1) at least twice daily; and
 - (b) cleaning around the brackets with a dental aid (e.g., a proxy brush).
- (2) Adolescents increase their exposure to fluoride (i.e., a fluoride mouth rinse).

Table 3. Our selection of significant determinants of oral health behaviors

Determinants	Importance	Changeability	Evidence for importance
Personal:			
Knowledge and awareness	+	+++	$r=0.20$ $p<0.001$
Risk perception	+	+	Precondition for personal relevance
Attitude and expectancies	++	+	$r=0.20$ $p<0.001$
Subjective norm	++	+	$r=0.26$ $p<0.001$
Self-efficacy	+++	+	$r=0.37$ $p<0.001$
Intention	+++	+	$r=0.40$ $p<0.001$
Planning (action and coping)	+++	+	$r=0.52$ $p<0.001$
Self-regulatory skills, such as action control and goal commitment	+++	+	Maintaining behavior
Motor skills	++	+	Precondition for improvement in self-efficacy
Habit	+++	+	Making a certain behavior automatic
External:			
Social influences:			
- Parental behavior	+++	+	$r=0.41$ $p<0.001$
- Dental professional	+	+	
Cues	+++	+	Most direct environmental influence
Access /Availability	+++	+	Making healthy behavior easier

Note: importance = the strength of the evidence for the relationship between the determinant and oral health behavior we want to change; changeability = the strength of the evidence that the proposed change can be realized by a program; + = not very important, not easy to change; ++ = important, changeable; +++ = very important or easy to change. Correlation and significant levels are based on results from previous studies on oral health and behavior change [23, 30, 33-40]

Table 4. Seven performance objectives (PO1-PO7) and 23 change objectives (CO1-CO23) pertaining to program outcome 1a “Adolescents control their dental plaque levels by improving tooth-brushing”.

Performance objective (PO)	Determinant	Change objective (CO)
PO1: Adolescents decide to prevent dental diseases and to change their tooth brushing behavior.	Risk perception	CO1: Are aware of their susceptibility to dental diseases
	Awareness	CO2: Are able to describe their tooth brushing behavior
	Knowledge	CO3: Know what good oral health is and its association with dental plaque
	Risk perception, Expectancies	CO4: Acknowledge the risk of not brushing teeth as recommended and its consequences
	Expectancies	CO5: Know the benefits of maintaining good oral health
	Knowledge	CO6: Know how to brush teeth according to the 5-step method.
	Self-efficacy	CO7: Feel able to prevent dental diseases and gain confidence in ability to brush teeth twice daily according to the 5-step method
	Skills	CO8: Develop tooth brushing skills (5-step method) to remove all dental plaque
PO2: Adolescents choose or plan how to improve their tooth brushing behavior	Goal-commitment, Self-efficacy	CO9: Choose a change about which they feel self-efficacious
	Skills	CO10: State a clear tooth brushing or oral hygiene goal
PO3: Adolescents prepare strategies to establish how they will change their tooth-brushing behavior.	Action planning	CO11: Plan in terms of when and where to brush their teeth
	Attitude	CO12: Show commitment to their goals
PO4: Adolescents change their tooth brushing behavior.	Support	CO13: Receive support during brushing on where and for how long to brush teeth
	Cues to action	CO14: Receive cues to tooth brushing
PO5: Adolescents evaluate their tooth brushing behavior, their dental plaque levels, and the effect of brushing on these levels.	Self-regulatory skills – action control	CO15: Monitor their tooth brushing behavior and dental plaque levels
	Self-regulatory skills, Awareness	CO16-CO17: Examine how well their performance corresponds to agreed goals, and consider modifying goals accordingly
PO6: If adolescents have difficulty attaining their tooth-brushing/dental plaque goal, adolescents identify possible solutions.	Coping-planning, Action control	CO18: Identify and anticipate barriers and ways to overcome them
	Self-efficacy	CO19: Gain confidence to deal with possible barriers
	Social influences	CO20: Enlist others to help overcome barriers
PO7: Adolescents maintain the desired tooth brushing behavior.	Self-efficacy	CO21: Gain confidence in maintaining tooth brushing behavior
	Expectancies	CO22: Feel positive about tooth-brushing
	Attitude	CO23: Believe that long-term benefits can be achieved by maintaining tooth brushing over time

The next stage was to stipulate the performance and change objectives for each of the specific program outcomes. The results of the semi-structured interviews (see step 1), in combination with the frameworks of the HAPA[57] and self-regulatory theory [58] were used to define the performance objectives. Self-regulation theory provides an understanding of the behavioral processes needed for adequate self-management in order to obtain a behavioral goal. As such, it is very useful to define subsets of behaviors. Once the performance objectives had been specified, we created a matrix of change objectives by linking performance objectives to behavioral determinants. In order to design the program, 21 performance objectives and 69 accompanying change objectives were defined. Due to the similarities between the performance objectives for all program outcomes, a selection is presented in Table 4. Table 4 presents 7 performance objectives (PO1-PO7) and 23 change objectives (CO1-CO23) pertaining to program outcome 1a (“Adolescents control their dental plaque levels by improving tooth brushing”).

Step 3: Program design: selection of theoretical methods and practical strategies

After careful consideration of parameters for use, theoretical methods and practical strategies addressing the determinants were selected to achieve the change objectives. The determinants and change objectives, their linked theoretical methods and practical strategies for program outcome 1 “adolescents control their dental plaque levels by improving their tooth brushing frequency and duration” are presented in Table S1 (see Appendix A).

The following paragraphs present the selected theoretical methods and their translation into practical strategies for the same seven performance objectives (POs) (Step 2).

PO1 – Providing health risk information, personal advice and instructions

Suitable methods for supporting decision-making on oral health behavior include providing health risk information on oral health behavior, and giving personal advice and instructions (targeting determinants: “risk perception”, “outcome expectancies”, and “knowledge”) [53]. To personalize dental advice and instructions, the app collects information on adolescents’ oral health behavior and dental plaque levels. Adolescents were asked to answer questions covering their tooth brushing frequency, their use of fluoride mouth rinse and dental cleaning aids, the duration of their brushing sessions, and the type of toothbrush they used. Next, they were asked to use disclosing tablets in order to visualize their dental plaque. The app then showed an example of a selfie, asked them to take a selfie of the teeth where plaque was visualized, and also asked them to indicate the plaque by clicking

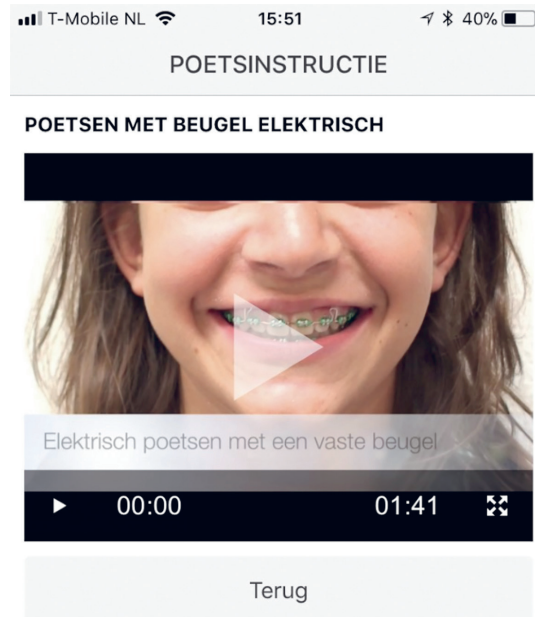


Fig. 1. Screenshot of a movie of the WhiteTeeth app. Taken on an iPhone, this movie shows users a peer model who demonstrates how to use an electric toothbrush to brush teeth fitted with fixed orthodontic appliances.

on the selfie (the app is installed in the orthodontic clinic, where a dental hygienist provided instructions on using the disclosing tablets and using the smartphone to take a selfie of the teeth). Based on the number of clicks (i.e. the amount of plaque) and answers to the questions, the app provided personal advice on oral health behavior (see Table 5 for the algorithm). If an adolescent did not adequately control his or her plaque levels or if his or her oral health behavior was poor, health risk information was offered via a short animated movie, which depicted the likely development of white spot lesions. This, and an image of beautiful white teeth, were shown as outcomes resulting from complying with oral health recommendations – and thus provided adolescents with two motivation for performing the desired oral health behavior.

Our semi-structured interviews showed that doubts about personal oral hygiene skills and the perceived complexity of the techniques were important barriers to the use of dental cleaning aids. To target adolescents' self-efficacy, movies of a peer model were shown (adolescent with fixed orthodontic appliances), demonstrating how to clean teeth correctly (according the 5-step method - see Table 1) that have fixed orthodontic appliances (Fig. 1). This demonstration was tailored to the kinds of toothbrushes the adolescents used.

Table 5. The algorithm of personal recommendations that were provided based on the plaque assessment and answers to the registration questions.

Flow	Answer options (the answer)	Interpretation of the answers and personal recommendations
1.1	<p>Question A: Tooth brushing frequency <2 times/day (0/1), OR</p> <p>Question B: Tooth brushing duration <3 min/day (0/1/2), OR</p> <p>Dental plaque is visible on the selfie.</p>	<p>The user does not follow the tooth brushing recommendations and/or dental plaque is present.</p> <p>The app provides information on health risk plus recommendations and instructions. It helps to set goals for increasing brushing frequency and duration. It advises users to use the brushing timer and to monitor their tooth brushing frequency daily.</p>
1.2	<p>Question A: Tooth brushing frequency >2 times/day (2/3 or more often), AND</p> <p>Question B: Tooth brushing duration ≥3 min/day (3/4 min or longer), AND</p> <p>Dental plaque is or is not visible on the selfie.</p>	<p>The user follows the tooth brushing recommendations and dental plaque is absent or present.</p> <p>Continue to question C – flow 2</p>
2.1	<p>Question C: Proxy brush usage <1 time/day (0), AND</p> <p>Dental plaque is or is not visible on the selfie.</p>	<p>The user does not follow the proxy brush recommendations and/or dental plaque is present.</p> <p>The app provides information on health risk plus recommendations and instructions. It helps to set goals for increasing the use of a proxy brush and for increasing tooth brushing frequency and duration. It advises users to use the brushing timer and to monitor their tooth brushing frequency and proxy brush usage.</p>
2.2	<p>Question C: Proxy brush usage 1 time/day (1/2 or more often), AND</p> <p>Dental plaque is visible on the selfie.</p>	<p>The user follows the proxy brush recommendations, but dental plaque is present.</p> <p>Idem as flow 2.1.</p>
2.3	<p>Question C: Proxy brush usage 1 time/day (1/2 or more often), AND</p> <p>Dental plaque is not visible on the selfie.</p>	<p>The user follows the proxy brush recommendations and dental plaque is absent.</p> <p>Continue to question D – flow 3</p>
3.1	<p>The user does not have 3 fluoride moments per day:</p> <p>Question A: Tooth brushing frequency <3 times/day (0/1/2), OR</p> <p>Question D: Fluoride mouth rinse usage <1 time/day.</p>	<p>The user does not follow the fluoride recommendations.</p> <p>The app provides information on health risk plus recommendations and instructions. It helps to set goals for increasing the use of fluoride mouth rinse. It advises users to monitor their fluoride mouth rinse usage.</p>
3.2	<p>The user has 3 fluoride moments per day:</p> <p>Question A: Tooth brushing frequency ≥3 times/day (3 or more often), OR</p> <p>Question D: Daily fluoride mouth rinse usage.</p>	<p>The user follows all recommendations.</p> <p>Positive reinforcement.</p>

PO2 – Goal setting

Goal setting can help adolescents to choose how to improve their oral health behavior (targeting the determinant: “skills”) [34]. Important conditions for the success of goal setting are the adolescent’s commitment to the goal and the fact that the goals are challenging, but lie within the adolescent’s abilities to achieve them. To ensure their commitment, adolescents chose a health behavior goal that best matched their preferences and abilities. In a series of questions, the app guided them through the process of defining one or more oral health goals. The adolescents then selected an oral health behavior he or she would like to change, for example, improving the frequency and duration of tooth brushing and the use of a proxy brush or a fluoridated mouth rinse. The answers were presented as clear goals on the main page of the app.

PO3 – Planning and behavioral contracting

Planning (i.e., formulating action plans) and contracting were identified as methods for preparing oral health behavior change (targeting determinants: “action planning” and “attitude”) [37-39, 44-46]. The app asked questions, which guided the adolescents in the creation of action plans by specifying goals in terms of when and where they should act. The answers were presented as their action plan, which would state where and when they would brush their teeth. This action plan was formulated as an implementation intention (“If situation X arises, then I’ll do Y”). When one or more goal were formulated, the adolescent agreed to the overall action plan by signing a contract in the app. This was saved on its main page. The action plan was linked to the option for setting reminders.

PO4 – Practical support (The Brushing timer)

To establish oral health behavior change, practical support was identified as a useful method [53]. To provide practical support, the app incorporated a brushing timer, which users could turn on when they decided to brush (targeting determinants: “support”). The timer showed how much time had elapsed. Throughout brushing, it also supported good brushing, according to the 5-step method, by showing where to brush (location in the mouth). Figure 2 shows a screenshot of the brushing timer. When brushing with the brushing timer was completed, the app congratulated the user on fulfilling the task.

PO4 – Prompt cues (Reminders)

Since numerous studies have shown that sending short message service (SMS) text messages as prompt cues is an effective way for establishing behavior changes and improving oral hygiene during fixed orthodontic treatment [48-50], the app also provided an option for setting reminders for oral health behavior tasks (including monitoring of behavior and dental plaque) and the use of the brushing timer (targeting determinants: “cues to action or habit formation”). The reminders were sent as push notifications.

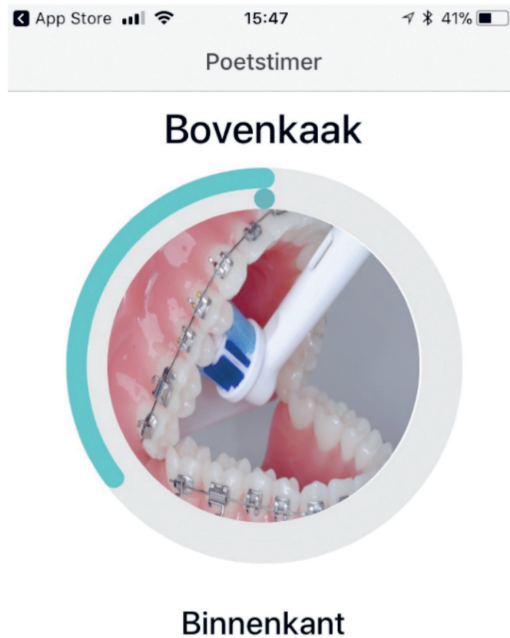


Fig. 2. Screenshot of the brushing timer. Taken on an iPhone, it shows how adolescents can use the brushing timer (poetstimer) to see how much time has elapsed and also where to brush (in this case the inside (binnenkant) of the maxila (bovenkaak)).

PO5 – Prompt self-monitoring

We identified prompt self-monitoring as a suitable method for evaluating tooth brushing behavior and dental plaque levels (targeting determinants: “self-regulatory skills or action control” and “awareness”) [36, 40, 51, 52, 59]. The use of disclosing agents provided a suitable method of monitoring plaque levels and thereby improved oral hygiene [59]. When the app was installed in the orthodontic clinic, a dental hygienist explained how oral health behavior and plaque levels should be monitored. The next day, the app sent a push notification that urged the adolescents to monitor their oral health behavior daily by entering into the app whether they accomplished their daily dental activities. If they failed to complete the monitoring, a push notification was sent the next day. Each week, adolescents were asked via the app to evaluate their dental plaque levels and review their behavioral goals. For this purpose, they were asked to use a disclosing tablet to visualize the dental plaque, to take a selfie of the result and to indicate the visualized dental plaque. On the basis of the information

on the selfie and the activities performed that week, the app concluded whether the adolescent's goals had attained. It then congratulated the adolescent for using the app, and, if necessary guided him or her in setting goals or adapting existing ones, and in creating coping plans.

PO6 – Prompt barrier identification to establish coping plans (Volitional sheets)

We identified prompt barrier identification and the creation of coping plans as suitable methods for helping adolescents to identify possible ways of achieving their oral health goal if they encountered difficulties (targeting determinants: “self-regulatory skills or action control”, “coping self-efficacy” and “coping planning”) [40, 60, 61]. If adolescents failed to attain their goals, coping plans could be formulated [57]. These plans use “if-then” formulations to specify how they would deal with difficult situations. However, although adults realized positive effects for if-then planning (i.e., implementation intentions [60-61] on oral health behavior were undertaken with adults [40], it is possible that planning interventions would be less suitable for adolescents, who may be less familiar with creating behavioral coping plans. To mitigate this, the app therefore incorporated volitional help sheets [62] – a tool for constructing effective (if-then) coping plans – by asking participants to link difficult situations (where “if” indicates barriers against performing the desirable behavior) with a behavioral response (where “then” indicates solutions) [47]. For example, “If I often forget to brush my teeth, then I ask someone at home to remind me to brush my teeth.” Table 6 shows the content of a volitional help sheet intended to establish coping plans for tooth brushing behavior. The content of the volitional help sheets was informed by the results of the semi-structured interviews (performed in step 1). To remind the adolescents of their coping plans, the plans were saved on the main page of the app, and thus were visible when the app was opened.

PO7 – Providing positive reinforcement (Coaching text messages)

Maintaining oral health behavior requires long-term commitment. Providing reinforcement by sending coaching SMS text messages was identified as a suitable method of motivating adolescents to maintain the desired behavior (targeting determinants: “attitude” and “maintenance self-efficacy”) [53]. To personalize coaching SMS text messages, adolescents were asked what outcomes motivated them to maintain good oral health. They could select from pre-established motives such as “keeping my gums healthy,” “getting fresh breath,” or “white teeth.” If desired, these notifications could be switched off.

Table 6. An example of the content of the volitional help sheet used to establish coping plans for tooth brushing behavior.

(A) Think about difficult situations that hinder tooth brushing and possible solutions to them. Please select the difficult situations and solutions that fit you best.	
Difficult situations	Possible solutions
<input type="checkbox"/> (If) I am too tired to brush my teeth	<input type="checkbox"/> Then I think of the dentist who has to fill all the cavities
<input type="checkbox"/> (If) I don't feel like tooth-brushing	<input type="checkbox"/> Then I think of the brown spots and cavities I might get if I don't brush my teeth
<input type="checkbox"/> (If) I want to skip tooth brushing because I'm in a hurry	<input type="checkbox"/> Then I think about how fresh and clean my teeth will feel after brushing
<input type="checkbox"/> (If) want to skip tooth brushing because I've got something much more fun to do	<input type="checkbox"/> Then I ask someone at home to remind me to brush my teeth
<input type="checkbox"/> (If) I often forget to brush my teeth	<input type="checkbox"/> Then I think about what the orthodontist or assistant told me about brushing my teeth
<input type="checkbox"/> (If) I'm so busy that I don't have time for tooth-brushing	<input type="checkbox"/> Then I think about the bad breath I can get if I don't brush my teeth
<input type="checkbox"/> (If) I prefer not to brush my teeth because they're sensitive or painful	<input type="checkbox"/> Then I set a reminder
<input type="checkbox"/> (If) I don't want to brush my teeth because it's too difficult	<input type="checkbox"/> Then I think of tooth brushing giving me fresh breath and white teeth
<input type="checkbox"/> (If) I prefer not to brush my teeth because my gums are bleeding	<input type="checkbox"/> Then I look in the mirror and say to myself: "I can do it! Every day!"
<input type="checkbox"/> (If) I'm too tired to brush my teeth in the evening	<input type="checkbox"/> Then I watch the movie about tooth brushing in the app
<input type="checkbox"/> (If) I (option to fill in)	<input type="checkbox"/> Then I'll brush my teeth right after dinner
	<input type="checkbox"/> Then (option to fill in)

Step 4: Program production

The practical strategies were clustered into 4 main program components: (1) Registration to help adolescents to decide to change their oral health behavior, to choose how to change it, and to plan appropriate actions; (2) behavior change to help adolescents to actually change their behavior with respect to their daily oral health routines; (3) evaluation to help adolescents to evaluate their behavior change over the past week and to adapt goals weekly and; (4) maintenance to help adolescents to maintain their behavior. Table 7 shows an overview of the flow of the program.

Table 7. An overview of the flow of the WhiteTeeth app: targeted performance objectives.

(1) Registration – First day (PO^a1-PO3)
Users are required to respond to registration questions and provide some personal information.
The app asks users to visualize dental plaque using disclosing tablets and to indicate the plaque, on the selfie.
On the basis of the information collected on their oral health behavior and dental plaque the app then provides health risk information, personal advice and instructions in short videos.
Next, it helps the users to customize their personal oral health goals, creating action plans and setting reminders.
At the end of installation, it encourages them to use the brushing timer and monitor their oral health behavior every day.
(2) Behavior change - Every day (PO4)
When they decide to brush, they have the option of turning on the timer. Afterwards, the app provides positive reinforcement.
Users receive a push notification on a daily basis to monitor their behavior.
(3) Evaluation - Every week (PO5, PO6)
Users are asked by the app to evaluate their dental plaque levels, to review their behavioral goals, and to create coping plans if needed.
(4) Maintenance – Every 3 days (PO7)
Users receive coaching SMS text messages.

^aPO: performance objective

The final program: the WhiteTeeth app

The app was listed on both iTunes and Google Play stores as the “WitGebit” app. The WhiteTeeth (“WitGebit”) app was made available free of charge for IOS ≥ 7 and Android ≥ 4.1 operating systems.

Pilot test of the WhiteTeeth app

The most important finding of the pilot test was that adolescents with fixed orthodontic appliances liked and appreciated the WhiteTeeth app, particularly the movies with instructions on how to use of proxy brushes. The mean SUS score was 77, indicating an acceptable score for usability. Since the app users suggested changing the amount of storage of the WhiteTeeth app, we compressed the movies to reduce the storage of the app to 52.8MB. The app users also suggested improving the instructions for the brushing timer and the statistics for evaluating their behavior. Even though the users requested to include gamification, this could not be included due to financial limitations. The program was adapted using their feedback

Step 5: Program implementation plan

The planning group agreed to deliver the intervention through dental professionals that already had regular contact with adolescents receiving orthodontic therapies, thereby allowing the app to be implemented within existing oral health care processes. One of the barriers to implementation perceived by the dental professionals was the limited time they had during appointments. They therefore recommended that we created an app that could operate as a stand-alone program. To encourage adolescents to use the WhiteTeeth app, several practical strategies were planned. For example, if the adolescents did not use the app for 3 days, the app used the registration information to send personalized SMS text messages reminding them to use the app, such as “Brushing your teeth will help to keep them healthy and beautiful.”

DISCUSSION

This paper describes the development process and content of the WhiteTeeth app. The WhiteTeeth app was developed to promote oral health behavior among adolescents with fixed orthodontic appliances who were at high risk of developing dental caries. We used an IM protocol as a tool for the systematic development of the app [30]. IM linked the phases of intervention development to theory and empirical evidence and made the process of program development transparent. IM was proven to be a suitable method for developing health promotion programs for various health issues [63-65].

In the field of orthodontics, authors did not describe the process of program development explicitly in their publications [41, 42, 48-50, 66-70]. This limited opportunities for comparison. Mapping the development and contents of an intervention, as in this study, is useful because it allows researchers to faithfully replicate effective programs, or make attempts to design programs that are even more effective [71]. In contrast to other studies, our study used theory to inform the program design. The use of theory was necessary to ensure that the factors related to achieving change were addressed [72, 30]. When reviewing the few available orthodontic apps promoting oral health, we concluded that the integration of behavior change techniques was limited in these apps [25, 69, 70, 73, 74]. However, a meta-analysis revealed that programs with a larger differentiation of behavior change techniques tended to have larger effects on behavior than programs that incorporated fewer techniques, which may be a consequence of the fact that different techniques target different aspects of the behavior change process [72]. In addition to this matter, behavior change techniques were the most effective for initiating behavior change, such as creating action and coping plans, [72, 75] were not incorporated into these

apps. Our app contains multiple proven techniques that focus on the motivation and initiation of oral health behavior changes. We believe this makes it a unique and promising mHealth program for oral health promotion.

Our work represents a major contribution to the field of oral health care, as it is the first study to systematically develop an mHealth program based on sound evidence and theory. The involvement of dental professionals and adolescents enabled us to develop a feasible program which offered ample opportunities for effective implementation in the future. To increase the likelihood that the app would meet the preferences of the target group, we invited a user experience designer to participate in the app development and also included future users through semi-structured interviews and a pilot test. Interaction with the adolescents enabled us to create program materials, such as volitional sheets that listed barriers and solutions, suited to the individual situations of the target members. Our problem analysis helped us to identify important determinants that were not addressed by the existing oral health programs, such as volitional factors that are outlined in the HAPA theory [57]. Using the IM protocol ensured that all important app objectives were addressed in the WhiteTeeth program, based on the theoretical insights and methods, empirical findings and practical strategies.

However, there were some limitations that should be highlighted. Despite the value of this robust development process, IM is very time-consuming. Our experience in this regard was similar to that of other researchers who used the IM protocol [76-80]. Our development process required more time than expected because we had to carry out additional research to gain insights into oral health behaviors and its determinants during orthodontic treatment (step 1), as there was little information available on these topics.

Another challenge regarding IM, as others have acknowledged [78-81], was the complexity of detailing the performance and change objectives. Program developers and researchers recognized that targeting multiple complex behaviors may create a high degree of complexity since data obtained during the development process can become cumbersome and overwhelming [79, 81]. In our study, the creation of matrices of change objectives was particularly time-consuming and resulted in an overwhelming amount of information about what should be targeted by the program. During our development process we excluded an important target behavior, intake of sugar-sweetened beverages, in order to manage the data of our study and the complexity of our program [82].

The use of IM enabled us to create the WhiteTeeth app, a unique and promising mHealth intervention for Dutch adolescents with fixed orthodontic appliances. This app incorporated several behavior change techniques, such as self-monitoring, goal setting and volitional sheets. The app simultaneously targeted important

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determinants of oral health behavior change. The lessons learned from using the IM process have relevance for researchers and practitioners, especially considering the current paucity of evidence-based oral health promotion programs for orthodontic patients and their failure to incorporate important behavior change techniques addressing meaningful behavioral determinants. Our future randomized controlled trial will indicate whether the app is effective in improving adolescent oral health.

Conflicts of interest

None declared.

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ABBREVIATIONS

ACTA: Academic Centre for Dentistry Amsterdam

App: mobile phone application

CO: Change Objective

HAPA: Health Action Process Approach

IM: Intervention Mapping

mHealth: mobile health

PO: Performance Objective

RCT: Randomized Controlled Trial

SUS: System Usability Scale

Appendix 1: [Performance objectives, selected change objectives, theoretical methods and practical strategies for program outcome 1 “adolescents control their dental plaque levels by improving their tooth brushing frequency and duration”.]

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Table S1. Performance objectives, selected change objectives, theoretical methods and practical strategies for program outcome 1 “adolescents control their dental plaque levels by improving their tooth brushing frequency and duration”.

PO1 Adolescents decide to prevent dental diseases and to change their tooth brushing behavior.			
Change objectives (determinant)	Theoretical methods/ BCTs	Requirements	Practical strategies
Adolescents are aware of their susceptibility to dental diseases (risk perception).	- Providing feedback on behavior (BCT 2.2): i.e., monitoring and providing informative or evaluative feedback on performance of behavior [34, 35].	Adolescents need to possess some sub-skills (they need to know how to use the disclosing tablets and take a selfie).	In the orthodontic clinic (upon installing the app), a dental hygienist demonstrates how to use the disclosing tablets to visualize plaque and how to take a selfie.
Adolescents are able to describe their tooth brushing behavior (awareness).	- Using disclosing tablets to visualize and evaluate dental plaque [33]. - Providing feedback on outcome (BCT 2.7): i.e., monitoring and providing feedback on the outcome of the behavior [34, 35].	Feedback needs to be personal and specific.	To provide feedback, information on adolescents' oral health behavior and dental plaque levels will be collected. Adolescents will first be asked to answer to questions with regard to their oral health behavior. Next, adolescents are asked to use disclosing tablets to visualize the dental plaque. After they use the tablets, they are asked to take a selfie of their teeth with the visualized plaque (red color). The app presents an example of a selfie and the selfie will be stored on the main page of the app. The app asks them to click where the plaque is present on the selfie. Based on the number of clicks and registration questions, the app provides feedback on their dental plaque levels and oral health behavior, and provides oral health advice.

<p>Adolescents know what good oral health is and its association with dental plaque (knowledge). Adolescents acknowledge the risk of not brushing teeth as recommended and its consequences (risk perception & outcome expectations). Adolescents know the benefits of maintaining good oral health (outcome expectancies).</p>	<p>- Providing information on health consequences (BCT 5.1) (e.g. written, verbal, visual): i.e., providing information on health consequences of performing the behavior) [35]. - Belief selection: i.e., using messages designed to strengthen positive beliefs, weaken negative beliefs, and introduce new beliefs [34]. - Providing scenario-based risk information: i.e., providing information that may aid the construction of an image of the ways in future loss or accident might occur [34]. - Providing reinforcement: i.e., linking a behavior to any consequence that increases the rate, frequency and probability of the behavior [34].</p>	<p>There must be a plausible scenario with a cause and an outcome. The message must be easy to understand: any use of imagery or movies must be relevant and must not diverge too much from the target group's experience.</p>	<p>The app provides information on the importance on tooth brushing as recommended in a short animated movie. The movie explains that not brushing teeth can increase the risk of getting dental diseases (how plaque can cause dental diseases) and can also affect appearance. The movie provides information on the positive outcomes of maintaining good oral health. It shows two scenarios: (1) bad oral hygiene causes white spot lesions/dental caries; (2) good oral hygiene causes white and beautiful teeth.</p>
<p>Adolescents know how to brush teeth according to the 5-step method (knowledge). Adolescents feel able to prevent dental diseases and gain confidence in ability to brush teeth twice daily according to the 5-step method (action self-efficacy) Adolescents develop tooth brushing skills (5-step method) to remove all dental plaque (skills).</p>	<p>- Providing instructions on how to perform the behavior (BCT 4.1): advise or agree on how to perform behavior (includes "skills training") [35]. - Demonstrating the behavior (BCT 6.1): i.e., providing an observable sample of the performance of the behavior, directly in person or indirectly (e.g. through film) (includes "modeling" [34,</p>	<p>The adolescents must identify with the model (use a coping model instead of mastery model).</p>	<p>The app provides a movie in which a peer model (adolescent with fixed orthodontic appliances) demonstrates how to brush teeth correctly twice daily according to the 5-step method. The demonstration is tailored to the kind of toothbrush they use, i.e., electric or manual.</p>
P02 Adolescents choose/plan how to improve their tooth brushing behavior.			
<p>Change objectives (determinant) Adolescents choose a change about which they feel self-efficacious (goal-commitment & action self-efficacy</p>	<p>Theoretical methods/ BCTs</p> <ul style="list-style-type: none"> - Prompting intention formation: i.e., encouraging the person to decide to act or set a general goal [27]. - Setting graded tasks: i.e., setting easy tasks, and increasing difficulty until target behavior is performed [34]. 	<p>Theoretical requirements</p> <p>The target behavior can be reduced to easier but increasingly difficult sub-behaviors.</p>	<p>Practical strategies</p> <p>The app allows the adolescents to choose the tooth brushing duration and/or frequency they would like to change and they think they can change.</p>

Adolescents state a clear tooth brushing or oral hygiene goal (skill).	- Goal setting (behavior) (BCT 1.1): i.e., setting or agreeing a goal defined in terms of behavior to be achieved [35].	Guided by questions in the app, adolescents set a clear goal. The answers are presented as clear goals, which are stored on the main page of the app.
PO3 Adolescents prepare strategies to establish how they will change their tooth brushing behavior.		
Change objectives (determinant)	Theoretical methods/ BCTs	Theoretical requirements
Adolescents plan in terms of when and where to brush their teeth (action planning).	- Prompt action planning (BCT 1.4): i.e., prompting detailed planning of performance of the behavior (must include at least one of context, frequency, duration and intensity) [35]. (This includes implementation intentions: prompting making if-then plans that link situational cues with responses that are effective in attaining goals or desired outcomes [34]).	Adolescents need to have a positive intention.
		Practical strategies
		The app incorporates a program that helps the adolescents to form action plans. Guided by questions in the app, adolescents can specify when and where they will brush their teeth. The answers are presented as their action plan, which will state where and when they will brush their teeth. This action plan is formulated as an implementation intention ("If situation X arises, then I'll do Y") (The action plan is linked to the option for setting reminders).
PO4 Adolescents change their tooth brushing behavior.		
Change objectives (determinant)	Theoretical methods/ BCTs	Theoretical requirements
Adolescents receive support during brushing on where and for how long to brush teeth (facilitator/support).	- Providing practical support (BCT 3.2): i.e., advising on, arranging, or providing practical help for performance of the behavior [35]. - Providing technical assistance: i.e., providing technical means to achieve desired behavior [34].	The technical assistance must fit the recipient's needs and resources.
		Practical strategies
		The app provides technical means for achieving the desired tooth brushing behavior, i.e., it incorporates a brushing timer. This provides practical support with brushing according to the 5-step method, showing each step during brushing.
Adolescents receive cues to tooth brushing (cues to action, habit formation).	- Prompts/cues: i.e., introducing or defining environmental or social stimulus with the purpose of prompting or cueing the behavior. The prompt or cue would normally occur at the time or place of performance (BCT 7.1) [35].	The app has an option for setting reminders, which are sent as push notifications that function as "cues to action". The adolescents will be reminded to brush their teeth at a time that fits in with their daily routine.

PO5 - Providing technical assistance: i.e., providing technical means to achieve desired behavior [34].			
Change objectives (determinant)	Theoretical methods/BCTs	Theoretical requirements	Practical strategies
Adolescents monitor their tooth brushing behavior and dental plaque levels (awareness, self-regulatory skills/action control).	<ul style="list-style-type: none"> - Self-monitoring of the behavior (BCT 2.3): i.e., the person monitors and records their behavior as part of a behavior change strategy [35]. - Self-monitoring of the outcome of behavior (BCT 2.3): i.e., the person monitors and records the outcome of their behavior as part of a behavior change strategy [35]. 	<p>Commitment and motivation are required to use the self-monitoring part of the app.</p> <p>The data must be interpreted and used.</p>	<p>Upon installing the app in the orthodontic clinic, a dental hygienist briefly shows the adolescent how to monitor their tooth brushing and dental plaque levels.</p> <p>Adolescents fill out their tooth brushing frequency in the app every day. If they fail to complete the monitoring, a prompt message is sent the next day.</p>
Adolescents examine how well their performance corresponds to agreed tooth brushing goals, and consider modifying goals accordingly (skills and goal pursuit).	<ul style="list-style-type: none"> - Reviewing behavior goal(s) (BCT 1.5): i.e., reviewing behavior goal(s) jointly with the person and considering modifying goal(s) or behavior change strategy in the light of achievement. This may lead to re-setting the same goal, to a small change in that goal, or to setting a new goal rather than (or in addition to) the first; or to no change [35]. <p>Discrepancy between the current behavior and goal (BCT 1.6): i.e., drawing attention to discrepancies between a person's current behavior (in term of the form, frequency, duration, and intensity of that behavior) and the person's previously set outcome goals or action plans (goes beyond self-monitoring of behavior).</p>	<p>Requires awareness of the oral health recommendations</p>	<p>Based on the information obtained from the brushing timer and the self-monitoring records, the app provides personal feedback once a week on whether the person's performance corresponds to the agreed goals and asks them to consider modifying goals accordingly.</p>

<p>Adolescents monitor their dental plaque levels (awareness, self-regulatory skills) and compare it with goal (awareness, self-regulatory skills).</p>	<ul style="list-style-type: none"> - Using disclosing tablets to visualize and evaluate dental plaque [35]. - Prompting self-monitoring of the outcome of the behavior (BCT 2.4): i.e., establishing a method for the person to monitor and record the outcome(s) of their behavior as part of a behavior change strategy [35]. - Providing feedback on the outcome of behavior (BCT 2.7): i.e., monitoring and providing feedback on the outcome of the behavior [34, 35]. 	<p>Adolescents need to possess the sub skill: identifying which dental surfaces are clean and which are covered with dental plaque.</p>	<p>Once a week the app asks adolescents to use disclosing tablets to visualize the dental plaque and to take a selfie of the results (this is the same procedure as during registration). It then asks them to designate the position of the dental plaque on the selfie by clicking on the screen. Based on the number of clicks, the app compares the number of clicks (plaque levels) with the results of the previous week, and provides feedback accordingly.</p>
<p>PO6 If they have difficulty attaining their tooth-brushing/dental plaque goal, adolescents identify possible solutions.</p>			
<p>Change objectives (determinant)</p> <p>Adolescents identify and anticipate barriers and ways to overcome them (coping planning, action control)</p> <p>Adolescents gain confidence to deal with possible barriers (coping self-efficacy).</p>	<p>Theoretical methods/BCTs</p> <ul style="list-style-type: none"> - Problem solving/prompt barrier identification (BCT 1.2): i.e., analyzing, or prompting the person to analyze, factors influencing the behavior; and generating or selecting strategies that include overcoming barriers and/or facilitators (includes “relapse prevention” and “coping planning”)[34, 35]. - Setting implementation intentions: i.e., prompting the making of if-then plans that link situational cues with responses that are effective in attaining goals or desired outcomes [34]. 	<p>Theoretical requirements</p> <p>Barrier identification without solutions is not sufficient.</p> <p>Requires identification of the barriers and possible solutions/coping responses.</p>	<p>Practical strategies</p> <p>If a person’s goal has not been achieved, volitional help sheets will be presented to help them identify barriers preventing them from proper tooth brushing and their possible solutions. The results of this volitional help sheets are presented as their coping plan, which will be stored at the main page of the app. This coping plan is formulated as an implementation intention (“if difficult situation X arises, then I’ll do Y”).</p>
<p>Adolescents enlist others to help overcome barriers (social influences)</p>	<ul style="list-style-type: none"> - Mobilizing social support: i.e., advising on, arranging, or providing social support for performance of the behavior [34]. 	<p>Adolescents are motivated to ask significant others.</p>	<p>If needed, adolescents are guided in asking significant others to support tooth brushing. When necessary, the app suggests asking parents and/or orthodontists for support, e.g., helping or demonstrating how to brush teeth.</p>

PO7 Adolescents maintain the desired tooth brushing behavior.			
Change objectives (determinant)	Theoretical methods/BCTs	Theoretical requirements	Practical strategies
Adolescents gain confidence in maintaining tooth brushing behavior (maintenance self-efficacy).	<ul style="list-style-type: none"> - Belief selection: i.e., using messages designed to strengthen positive beliefs, weaken negative beliefs, and introduce new beliefs [34]. - Framing: Using gain-framed messages emphasizing the advantages of performing the healthy behavior[34]. 	Before choosing the beliefs on which to intervene, the individual's current attitudinal, normative, and efficacy beliefs should be investigated. Gain-framed messages are more readily accepted and prevent defensive reactions.	The app provides positive personal text messages about favorable outcomes and the benefits of tooth brushing, (i.e., personal motives which are asked by the app when starting the app).
Adolescents feel positive about tooth brushing (outcome expectancies).			
Adolescents believe that long term benefits can be achieved by maintaining tooth brushing over time (attitude).			

BCT: Behavior Change Technique [35]; PO: Performance objectives.

CHAPTER 5

Study protocol of a randomized controlled trial to test the effect of the WhiteTeeth app



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Study protocol of a randomized controlled trial to test the effect
of a smartphone application on oral health behavior and oral hy-
giene in adolescents with fixed orthodontic appliances. BMC Oral
Health, 2018;18(1):19. PMID: 26952723

ABSTRACT

Background: Adolescents with fixed orthodontic appliances are at high risk of developing dental caries. To date, new smartphone technologies have seldom been used to support them in the preventive behavior that can help prevent dental caries. After an Intervention Mapping process, we developed a smartphone application (the WhiteTeeth app) for preventing dental caries through improved oral health behavior and oral hygiene. The app, which is intended to be used at home, will help adolescents with fixed orthodontic appliances perform their oral self-care behavior. The app is based on the Health Action Process Approach (HAPA) theory, and incorporates several behavior change techniques that target the psychosocial factors of oral health behavior. 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 to 16 with fixed orthodontic appliances.

Methods/design: 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. In the western part of the Netherlands 146 participants will be recruited from four orthodontic clinics. Data will be collected during three orthodontic check-ups: baseline (T0), 6 weeks of follow-up (T1) and 12 weeks of follow-up (T2). The primary study outcomes are the presence of dental plaque (measured with a modified Silness and Loe Plaque Index); and gingival bleeding (measured with the Bleeding on Marginal Probing Index). Secondary outcomes include changes in self-reported oral health behaviors and their psychosocial factors identified by the HAPA theory, such as outcome expectancies, intention, action self-efficacy, coping planning and action control.

Discussion: Since the intervention was designed to target psychosocial factors in the motivational and volitional components of the behavior change process, we hypothesize that the app will cause greater improvements in oral health behavior and oral hygiene more than traditional oral health promotion programs (i.e., care as usual).

Trial registration: The trial has been registered with the Dutch Trial Register (www.trialregister.nl NTR6206: 20 February 2017).

Keywords: study protocol, behavioral intervention, app, M-health, prevention, oral health promotion, oral health behavior, and oral hygiene.

BACKGROUND

In 2011, 60% of young Dutch adults had had orthodontic treatment during adolescence [1]. Despite its functional and esthetic benefits, fixed-appliances therapy is associated with an increased risk of dental caries, mainly in the form of white spot lesions, whose estimated prevalence ranges from 50% to 90% [2-5]. After orthodontic treatment, the lesions can become an esthetic problem, and may progress to more extended caries lesions [6,7].

Although fluoride administration (e.g. fluoride mouth rinses) and the regular and effective removal of plaque from all tooth surfaces are essential to preventing oral diseases [8,9], patients undergoing fixed orthodontic treatment have difficulty reducing dental plaque, as fixed orthodontic appliances (brackets) impede cleaning [10]. Previous studies also showed that only 50% of patients used fluoride mouth rinses as prescribed [11,12]. Over 60% of orthodontists in the Netherlands stated that patients' oral hygiene deteriorates during orthodontic treatment [13]. A majority of orthodontists indicated that 5%-10% of patients interrupt orthodontic treatment prematurely due to poor oral hygiene [13, 14]. A recent cross-sectional study in the Dutch city of Almere showed that most young orthodontic patients had low levels of oral hygiene and did not follow oral health recommendations [15]. This emphasizes the need for intervention strategies to improve oral hygiene in young people with such appliances.

Today's use of smartphones offers new opportunities for developing oral health interventions. This high use – particularly by young people – could ensure comprehensive access to adolescents with fixed orthodontic appliances [16-18]. Smartphones may thus be an appropriate medium for providing oral health care information, changing oral health behavior and improving oral hygiene.

For this reason, we used the intervention mapping protocol [19] to develop a smartphone application (the WhiteTeeth app) intended to prevent dental caries by improving adolescents' oral health behavior and oral hygiene during fixed orthodontic treatment. As part of the intervention mapping process, we conducted a systematic review with meta-analysis and a cross-sectional study in which we analyzed oral health behaviors and psychosocial factors (i.e. intervention targets) in adolescents [15, 20]. The results of this suggested that the Health Action Process Approach (HAPA) theory would be an appropriate theory for underpinning the present intervention [21]. Incorporating several behavior change techniques that target the psychosocial factors identified by the HAPA theory, the WhiteTeeth app thus focuses (1) on controlling dental plaque levels through improved dental cleaning and (2) on increasing the use of fluoride mouth rinse.

In this article we describe the design of a randomized controlled trial (RCT) to compare the effectiveness of the WhiteTeeth app with that of care as usual. The

primary objective of the study is to determine whether the use of the WhiteTeeth app by orthodontic patients aged 12 to 16 improves oral health behavior and oral hygiene. The primary outcomes of this RCT are changes in dental plaque levels, and gingival bleeding upon marginal probing. The secondary outcomes are changes in oral health behaviors, including tooth-brushing, the use of dental cleaning aids, and fluoride mouth rinse, and also psychosocial factors of oral health behavior. We will test the mediating effects of psychosocial factors on changes in oral health behaviors and oral hygiene. Our hypothesis is that the use of the WhiteTeeth app in the intervention group will improve oral health behavior and oral hygiene more than usual care does (the control group). We expect changes in the psychosocial factors to be associated with the factual changes in oral health behavior.

METHODS / DESIGN

This study is a multicenter, parallel, randomized controlled trial with two conditions: an experimental group that will receive the WhiteTeeth app in addition to care as usual, and a control group that will receive only care as usual. Data will be collected during three orthodontic check-ups: baseline (T0), 6 weeks of follow up (T1) and 12 weeks of follow up (T2) (Fig. 1).

Participants and recruitment

One hundred forty-six orthodontic patients aged 12 to 16 will be recruited in four orthodontic clinics in the western Netherlands. The study sites will be eligible if (1) standard oral health instructions are administered according to the clinical guidelines of the department of orthodontics at the Academic Centre for Dentistry Amsterdam (ACTA) (See paragraph 'Care as usual'); if (2) the clinicians are orthodontists registered in the Dutch orthodontic specialist register, or are postgraduate orthodontic students supervised by a registered orthodontist; if (3) the orthodontists are willing not to change their method of providing oral health education or instructions during the study period (care as usual); if (4) there is scope for the researcher to inform patients about treatment allocation and the app (in the case of participation in the intervention group); and if a dental chair is available for the oral health assessments. We will include the same number of participants from each study site.

CHAPTER 5

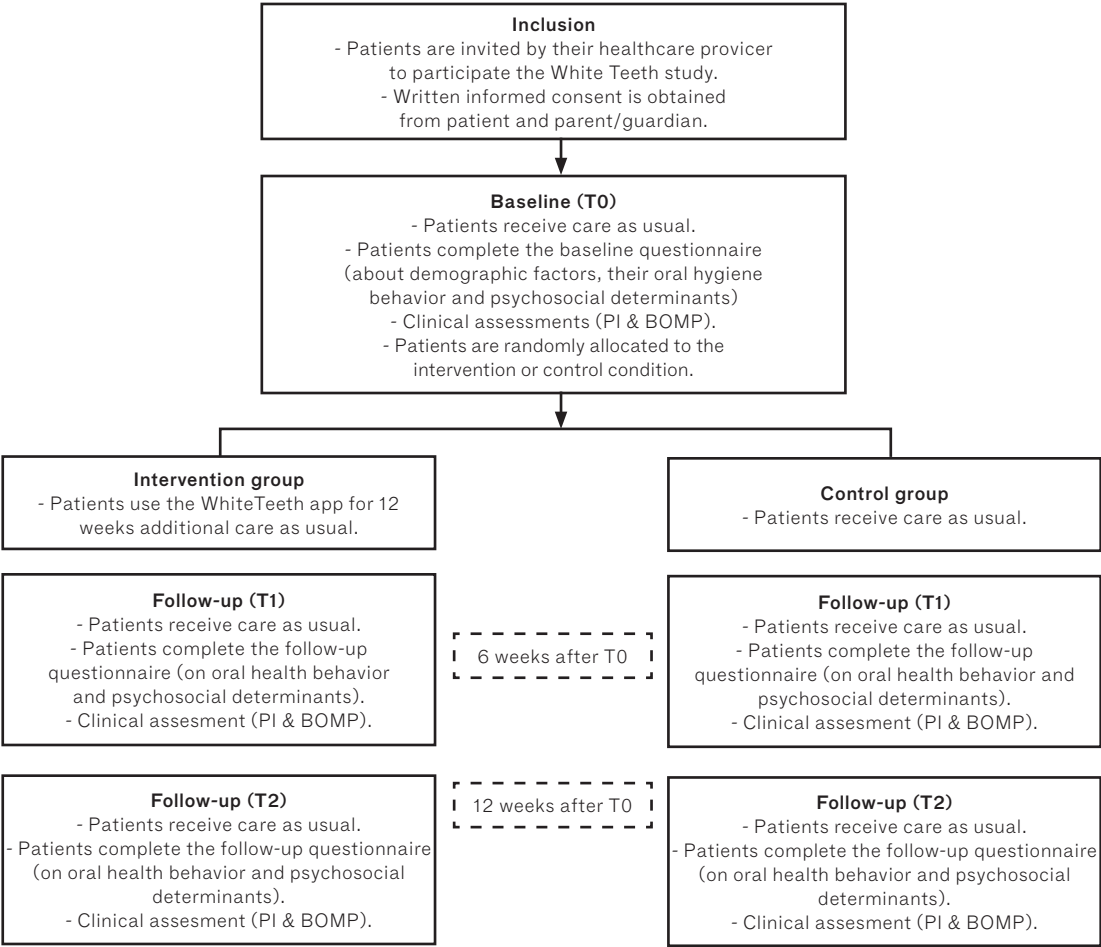


Fig.1 An overview of the study procedures and design.

Before the study starts, a presentation on it will be given at the eligible clinics. Patients who meet the eligibility criteria (table 1) will be informed about the study by their clinician. They will then receive an information letter and an informed consent form, and have two visits before the baseline measurements. The letter will include information on the intervention, the study design, and ethics. Patients will be recruited over a 3-month period. The baseline assessment will be scheduled after patients' and their parents' written informed consent has been received.

Table 1. Eligibility criteria

Patients will be eligible for the study if they meet the following criteria:
- Boys or girls aged 12 to 16.
- For at least 6 weeks, they must have maxillary and mandibular fixed orthodontic appliance therapy, which consists of bonding at least premolar-to-premolar with edgewise appliances and their modifications.
- They have not been scheduled for removal of fixed orthodontic treatment before the end of the study.
- They have no physical and/or mental disabilities that will impede their ability to perform their own oral hygiene activities.
- They are not engaged in other oral health education or research program.
- They do not have enamel and dentine dysplasia and/or craniofacial malformation (e.g. cleft).
- They have a sufficient command of the Dutch language.
- They possess a smartphone with software IOS ≥7 or Android ≥ 4.1.
- Patients and their parents are able or willing to give informed consent.
- Patients must not use medication that may affect plaque accumulation, for example antibiotics and antibacterial mouth rinses.

RANDOMIZATION

Randomization to the intervention group or control group will be performed at the patient level. A co-author who is not involved in data collection or analysis will use a random sequence generator (<http://www.random.org>) to allocate patients in a random sequence to the intervention or control group. In a separate room after completion of the baseline measurements, an independent researcher will tell individual participants to which group they have been allocated. If this is the intervention group, the researcher will help them install and unlock the app on their smartphone, and will also provide information on how to use it. To identify dental plaque during the intervention period, participants in the intervention group will receive twelve disclosing tablets (Gum® Red-Cote®). 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.

Care as usual

Care as usual will be provided according to the orthodontic protocol at the Academic Centre for Dentistry Amsterdam (ACTA). Whether in the intervention group or control

group, all patients will receive oral health education and instructions on plaque control at each visit.

Approximately every 6 weeks, orthodontists will invite their patients for a check-up visit, when they will adjust the braces, evaluate dental hygiene and the progress of the teeth, and, if necessary, provide oral health education. On the basis of the ACTA guidelines, they will recommend the following oral health behavior to their patients.

First, to control dental plaque levels, patients will be recommended to brush their teeth with fluoride-containing toothpaste at least twice a day according to the 5-step method. Thus, (1) after brushing the gingival sites, they should brush (2) above and then (3) under the bracket on the buccal sites of the teeth. They should end by brushing (4) the occlusal sites and (5) the lingual or palatal sites of the teeth. These five steps take approximately three minutes to fulfill [11]

Next, to ensure proper plaque removal, the orthodontists will recommend the use of dental aids (e.g. a proxy brush to clean the tooth surfaces around the brackets). To prevent dental caries during orthodontic treatment, they will also highly recommend the daily use of fluoride-containing mouth rinse and toothpaste [9, 11]. Finally, they will recommend patients to limit their consumption of sugars, refined carbohydrates and acid drinks/soft drinks [22].

The behavioral intervention: WhiteTeeth app.

The app is intended for use at home as an add-on intervention to care as usual. The intervention is based on the Health Action Process Approach (HAPA) theory (Fig. 2), which has demonstrated its usefulness to understanding oral hygiene behaviors in adolescents with fixed orthodontic appliances [15, 21]. The theory classifies the establishment of behavior into two phases: a motivational, intention-forming phase, and a volitional phase in which intention is translated into action [21]. The WhiteTeeth app integrates several behavior change techniques (BCTs) that target these motivational and volitional behavior change processes [23, 24]. BCTs addressing the factors of the motivational phase include: providing information on health consequences, visualizing dental plaque with disclosing tablets [25], and demonstrating the desired behavior [24]. BCTs addressing factors in the volitional phase include self-monitoring [26], Goal setting and implementation intentions [27, 28], coping planning (via volitional sheets) [29], and behavioral goal reminders [30, 31]. For the experimental group the WhiteTeeth app is available in the App Store for IOS $\geq 7+$ and in the Play Store for Android ≥ 4.1 as 'Witgebit' (free of charge).

Upon installing and opening the WhiteTeeth app, participants in the intervention group will be required to respond to registration questions and to provide some personal details. These questions will cover the frequency of tooth brushing, the use of fluoride mouth rinse and dental cleaning aids, the length of brushing sessions, and

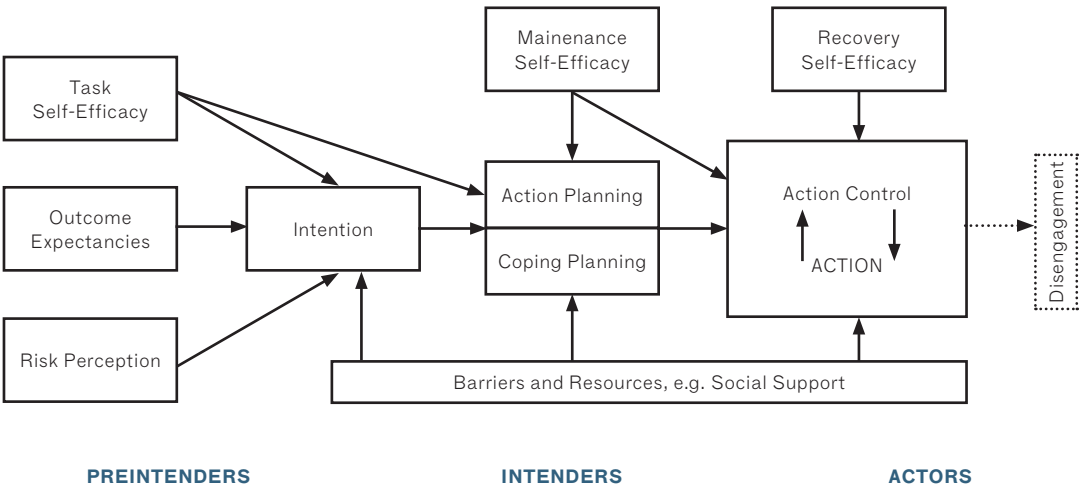


Fig. 2. Health Action Process Approach Model

the type of toothbrush. The personal details pertain to outcomes that motivate them to maintain good oral health. Adolescents can select from pre-established outcome expectancies, such as gum health, fresh breath, plaque removal and whitening. Messages can thus be individualized. In the next part of the registration process, which is intended to help adolescents identify their dental plaque levels, they will be asked to use the disclosing tablets and to take a selfie of their teeth on which dental plaque is visualized by the disclosing tablet. 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. Adolescents will then set a particular goal with regard to tooth brushing frequency and duration, the use of a proxy brush and/or fluoride mouth rinse (Goal setting). Next, they will be required to formulate when and where they will perform the oral health behavior (formulating “if-then” goals or an implementation intention). As part of the

implementation planning, the app will provide an option for setting reminders for oral health behavior tasks. The action plans formulated will be saved on the main page of the app. At the end of the installation process, the app will encourage adolescents to use the brushing timer daily and to monitor their oral health behavior by registering in the app whether they have performed their tasks.

Every day throughout the 12-week intervention period, push notifications will be sent instructing adolescents to use the app to enter whether or not they have accomplished their daily dental activities, and to remind them to use the brushing timer when brushing their teeth (at installation, adolescents set the time at which they would like to receive this notification). When adolescents decide to brush, they have the option of turning on the timer. 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. When adolescents have completed brushing, the app provides positive reinforcement.

Each week, adolescents will be asked via the app to evaluate their dental plaque levels and review their behavioral goals. For this purpose, they will use a disclosing tablet to visualize the dental plaque. They will also be asked to take a selfie of the result and to indicate the visualized dental plaque (following the same procedure as in the registration phase). On the basis of the information both on the selfie – which indicates an increase or decrease in the number of clicks and thus the amount of plaque – and on the activities performed that week, the app concludes whether the adolescent's goals have been attained. It then compliments the adolescent for using the app, and, if necessary, helps him or her to set new goals or to adapt the existing ones. If adolescents have failed to attain their goals, they can formulate coping plans, i.e., “if-then” plans specifying how they can deal with difficult situations. To establish these, they use volitional sheets, i.e., sheets with pre-established difficult situations and solutions, such as “If I’m too tired to brush my teeth in the evening, then I’ll brush my teeth right after dinner.” These coping plans will be saved on the main page of the app, so adolescents will be reminded of them when they open the app.

If the adolescent does not use the app, it will send personalized text messages every three days reminding them to use it. These messages will be based on information obtained during installation of the app. For example, “Brushing will help to keep your teeth healthy and beautiful.”

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.

Data collection

Figure 1 presents an overview of the data collection procedures. Before the orthodontic check-ups at T0, T1 and T2, all participants will fill in a digital questionnaire on the tablet (Ipad® Air 2.0) in a separate room at the clinic. Next, before the orthodontic check-up, the clinical measurements will be made.

Demographic or background information

The first part of the self-administered digital questionnaire includes questions on the participants' demographic background and any possible confounding variables (age, sex, education level, nationality, cultural background, and smoking status (see additional file 1 for questionnaire part I). Information will be retrieved from the orthodontic files about the date on which treatment with fixed orthodontic appliances started and about the type of orthodontic bracket (e.g., self-ligating or conventional appliances, and the presence of elastic hooks and/or looped wires).

Self-reported oral health behavior and its psychosocial factors

The second part of the self-administered digital questionnaire contains questions with both single-response and multiple-response items on oral health behaviors and their psychosocial factors (HAPA factors) (see additional file 2 for questionnaire part II). This questionnaire was derived from earlier studies on oral health [15, 32, 33, 34]. The additional file specifies which questions were derived from which original questionnaire. First, to ensure that the integrity of the content was maintained, the original questions were translated into Dutch and then back-translated to English. Next, to ensure that the questions are comprehensible, the questionnaire was piloted.

The questionnaire asks respondents to report the frequency with which they use a toothbrush, a proxy brush, dental floss, toothpicks, mouth rinse, and other dental aids. It used the following 7-point scale: 1: less than twice a month or never, 2: twice a month, 3: once a week, 4: two to three times weekly, 5: once daily, 6: twice daily, and 7: three times daily or more. For the analysis, these response options will be recalculated to establish the weekly frequencies of each of the oral health behaviors. Self-reported tooth brushing frequency and tooth brushing duration will both be measured in one open question, i.e., "In the last four weeks, how many times have you brushed your teeth per day?" and "How much time do you spend on brushing your teeth at a time?". For the analysis, these two items will be multiplied to obtain a single item: self-reported tooth brushing duration (minutes per day).

With regard to the psychosocial factors relevant to tooth brushing and the use of a proxy brush, the questionnaire includes questions on "risk perception", "action-self-efficacy", "intention", "maintenance self-efficacy", "recovery self-efficacy", "action control", "social influences" (including parental support, descriptive and subjective

norm), “action planning” and “coping planning”. Next, the questionnaire includes questions on adolescents’ outcome expectancies regarding dental cleaning, and questions about “action-self-efficacy” and “intention” regarding the use of mouth rinse. All psychosocial factors will be assessed on 5-point scales ranging from “very low” (1) to “very high” (5) for risk perception, and from “totally disagree” (1) to “totally agree” (5) for the remaining items. To obtain a single score per psychosocial factor for tooth brushing and the use of a proxy brush, the scores will be summed. The headers in the questionnaire (see additional file 2 for questionnaire part II) show the items that are summed to generate the score for each psychosocial factor.

Clinical measurements

At baseline and at 6 and 12 weeks’ follow-up, the state of adolescents’ oral hygiene will be determined by the amount of plaque and gingival bleeding at the buccal surfaces of the first premolars, canines and incisors. These elements were chosen on the basis of the finding by Chapman et al. (2010) that the maxillary lateral incisor was the tooth most frequently and severely affected by white spot lesions; it was followed by the maxillary canine, premolar, and central incisor [2]. To achieve this, the following clinical assessments will be carried out:

Modified Silness and Loë Plaque Index

A systematic review conducted by Al-Anezi concluded that the modified Silness and Loë plaque index by Williams (1991) is the most valid and discriminatory index for measuring plaque accumulation in orthodontic patients [35, 36]. Using a mouth mirror and a probe, we will therefore use this index to establish the amount of plaque on the buccal surfaces of the first premolars, canines and incisors. According to the position of the orthodontic bracket, the buccal surface of each tooth is divided into four zones, i.e., those mesial, distal, gingival and incisal to the bracket [35, 36]. Each of the four sites of the buccal tooth surface is given a score from 0 to 3, where 0 indicates the absence of plaque; 1 indicates no plaque visible, but an accumulation of soft deposit on a probe when used to clean the surface; 2 indicates a moderate accumulation of soft deposit on the tooth which can be seen with the naked eye; and 3 indicates an abundance of soft matter on the tooth. For the analysis, values are summed to obtain a total score per participant.

Bleeding upon Marginal Probing (BOMP)

Gingival bleeding will be assessed with the Bleeding on Marginal Probing index (BOMP). This will be used to score the condition of the gingiva according to the method described by Van der Weijden et al (1991). In summary, a periodontal probe (tapered tine, tip diameter 0.5 mm; Hu-Friedy, Liemen, Germany) runs

along the soft tissue wall at the orifice of the pocket – i.e., the marginal gingiva – at an angle of approximately 60° to the longitudinal axis of the tooth [37]. To determine whether probing elicited marginal bleeding (score 1) or not (score 0), we will assess the mesio-vestibular, vestibular, disto-vestibular sections of the vestibular surfaces of the first premolar, canines and incisors. The presence or absence of bleeding will be scored within 30 seconds of probing. To obtain a total number of bleeding sites per participant, all scores for the analysis will be summed.

To ensure the reliability of the clinical measurements, the clinical examiners at each site (a dentist and student dental hygienists) will be trained and calibrated by an experienced ACTA University examiner two weeks before the start of the study. The calibration will involve a separate group of ten people.

It will not be possible to determine inter-rater reliability by performing the clinical measurements twice, as the first set of measurements will affect the results of the second: plaque will be removed by the probe used to determine the plaque score, and more marginal bleeding might be elicited by the second probing of marginal gingiva. For this reason, one examiner will perform the clinical measurements and another examiner will observe them, and then give a second independent judgement. The inter-rater reliability will thus be determined by comparing the scores made by both examiners. This will be done in a random sample of 10% of the measurements. To determine the inter-rater reliability of the primary outcome measures the Intra-class Correlation Coefficients (ICC) will be calculated.

Process evaluation

A process evaluation will be performed to examine intervention fidelity (i.e., the extent to which participants comply with the intervention); and participants' experiences with the intervention program, including the perceived effectiveness of various components of the WhiteTeeth app.

Information on intervention fidelity will be collected through the app. For medical-ethical reasons, the app users' data will not be uploaded automatically. Instead, participants will have to send it themselves from their smartphone to the database. During intervention allocation, participants will be informed about the collection of their users' data, and will be asked to send it via the app each week. At 6 and 12 weeks follow-up, all participants will be reminded to send their user's data via the app. User's data consists of (1) the week that the users' data is sent, (2) the login code of the app, (3) the total number of selfies, (4) the total number of clicks on the selfie, (5) the total number of times that the brushing timer is opened, (6) the average number of minutes brushed registered by the brushing timer, (7) the action plans that are entered into the application, (8) the goals that were set, (9) the number of times that they watch a video about (I) dental plaque and cleaning their teeth either with (II) a

manual toothbrush, an (III) electric toothbrush, or (IV) interdental brushes; and (10) their initial motives for cleaning their teeth.

At 12 weeks follow-up, the participants' experiences with the intervention program will be examined in a short questionnaire consisting of open and closed questions (See additional file 3 for questionnaire part III).

To maximize retention of participants, all participants will receive a letter at baseline on the importance of adhering to the intervention and on participation in the follow-up measurements. To promote their active participation in the study, participants will receive monetary compensation (€10) at the end of the trial.

Data-management

All data will be recorded using FileMaker Pro© 15 database. Separate FileMaker Pro forms have been designed for both the clinical measurements and the questionnaires.

The researchers will register clinical data on tablets. To fill in all questionnaires, participants will use the tablets in a separate room. To ensure that appropriate help and guidance can be given when needed, this will be done in the presence of one of the researchers. To minimize data-entry errors, the forms have inbuilt check-and-skip rules. FileMaker Pro will allow us to export the data safely from tablets to SPSS Statistics database. For participants who withdraw from the trial, any data collected up to the withdrawal date will be retained and included in the analyses.

Names, mobile phone numbers and addresses will not be recorded in the same forms as sensitive data. Each participant will be given a unique identification number. Each participant will send their weekly user's data to a secure server owned by ACTA University. Only the principal and the co-principal researchers will have access to the participants' personal data. All data will be saved on password-protected computers and tablets. When the study has been completed, all personal identifiers will be deleted. Data will be kept in stored digitally at the coordinating center (ACTA) for 5 years after completion of the study.

Blinding

The participants in this study cannot be blinded for the intervention allocation after randomization. To ensure the blindness of assessors and clinicians, the principal researcher will ask the participants not to communicate with outcome assessors or their clinicians on whether they use the app.

Sample Size

The sample size calculation will be based on the primary outcome measure, the modified Silness and Løe plaque index. Between treatment groups we have assumed a 0.35 difference in mean change at week 12 [38]. The required sample size is 2×63

patients (setting $\alpha = 5\%$ (two-tailed), a standard deviation (s) of 0.7, and the power $(1-\beta) = 0.80$) [39]. Allowing for an expected loss of 15%, a sample of 73 patients is needed in each group.

Statistical analysis

All statistical analysis will be based on the intention-to-treat (ITT) principle. The participants' characteristics will be summarized using descriptive statistics (mean, standard deviation, frequency). Baseline data will be used to investigate the characteristics of any participants who discontinue or deviate from the trial and/or intervention. The magnitude of change over time across study groups will be examined by linear mixed models for continuous primary and secondary outcome variables, controlling for baseline variables and other covariates that may relate to the outcome.

To take account of the correlated observations within the participant, mixed-model analyses will be used. Two analyses will be performed: 1) to evaluate the overall intervention effect, 2) to evaluate the intervention effect at different follow-up times. This will be done by adding time and the interaction between time and intervention group variable into the linear mixed models. For mediation analysis, we will perform linear regressions based on Baron and Kenny's recommendations [40]. A Sobel test will be used to test the mediating effect. A z-value greater than 1.96 and a p-value lower than 0.05 will indicate a significant mediating effect [41].

Benefits and harms

Participants in the experimental condition might benefit from the intervention by achieving better oral health. Since no harmful consequences are expected from exposure to the intervention, a data-monitoring committee is not needed. Unanticipated problems or adverse events that are likely to be related to the trial will be recorded and reported to the METC at VU Medical Centre Amsterdam. Authorship of the publications emerging from the study will be decided on the basis of the guidelines of the International Committee of Medical Journal Editors.

Dissemination plan

This protocol was written according to the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) guidelines [42]. The research findings will be disseminated through reports, presentations, and scientific articles in peer-reviewed journals. Findings will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines [43]. Important protocol modifications will be reported when findings are disseminated.

DISCUSSION

This paper describes the protocol for an RCT to evaluate the effectiveness of the WhiteTeeth app, which is intended to prevent dental caries in adolescents with fixed orthodontic appliances by improving oral health behavior and oral hygiene more than care as usual does. By making our study objectives and methods known, the publication of this study protocol will improve the eventual usefulness of our study [44].

The WhiteTeeth app was developed systematically on the basis of the Intervention Mapping protocol [19]. This protocol guides the linking of theory to specific behavior change targets and their associated behavior change techniques and delivery methods [19]. The WhiteTeeth app is based on the HAPA theory, in which changing health-related behaviors comprises two consecutive behavioral phases that are essential to achieving behavior change: a motivational phase and a volitional phase. As the systematic theoretical underpinnings of WhiteTeeth allow additional questions to be addressed regarding the influence of mediating factors on outcomes, we will be able to increase our understanding of the extent to which the outcomes in dental hygiene can be explained by some or all of the underlying psychosocial and behavioral factors (mediators). The process evaluation will provide additional insight into the effective ingredients of the intervention and into the feasibility of the intervention for the target group. Understanding of these issues will underlie the post-trial adjustments necessary to enhancing the effectiveness of WhiteTeeth before any larger scale roll-out.

We should note some weaknesses in the design of the intervention. First, data on oral health behaviors and its psychosocial factors will be self-reported. Self-reported measures are prone to bias, such as social desirability bias. As far as possible, we will therefore use the users' data for several components of the app to evaluate whether the self-reported behavior corresponds to this data. For example, the mean brushing duration collected by the brushing timer of the app will be compared with the self-reported tooth brushing duration.

A second limitation is that the participants in the control group might also undergo changes in oral health behavior, which may conceivably be induced by questions about their behavior. Wilding et al. (2016) have shown that participants' behavior can be increased or changed simply if questions are asked about their behavior [45]. In our study, there is thus a chance that the effects of asking people about their behavior will reduce any differences between the intervention and the control groups, and thereby the possibility of finding a significant effect.

Although the intervention has been developed to prevent dental caries, this specific health outcome will not be measured in this RCT. Dental caries is nonetheless strongly associated with the outcome measures in the present study: oral health behavior and oral hygiene measures [11, 46]. 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. We assume that if the WhiteTeeth app is effective in improving adolescents' oral health behavior and oral hygiene status, it is also likely to affect caries development.

Thus, if our study confirms the effects we hypothesize on oral health behavior and oral hygiene status, we will recommend that long-term studies are carried out with dental caries as a primary long-term outcome. On the hypothesis that our preventive oral health intervention reduces orthodontic patients' long-term health costs, such long-term follow-up studies should also incorporate health care costs.

Trial status

Recruitment started in November 2016 and was continuing when the manuscript was submitted. Inclusion is estimated to finish in October 2017.

List of abbreviations

ACTA: Academic centre for Dentistry Amsterdam; App: Application; BCTs: Behavior Change Techniques; BOMP: Bleeding On Marginal Probing index; CONSORT: Consolidated Standards of Reporting Trials; HAPA: Health Action Process Approach; METC: Medical Ethics Committee; RCT: Randomized Controlled Trial; PI: Modified Silness and Løe Plaque Index; SPIRIT: Standard Protocol Items: Recommendations for Intervention Trials.

Declarations

Ethics approval and consent to participate – All procedures will be carried out in compliance with the Helsinki Declaration. The study was approved by the Medical Ethics Committee (METC) at VU Medical Centre Amsterdam (protocol. nr. 2016.162). Before the start of the study, written informed consent will be obtained from each patient and one of their parents (or guardians). All information about the participants will be kept strictly confidential. Clinicians will inform the patients and their parents that participation in the study is entirely voluntary and that, if they refuse, their decision will not affect the care as usual they receive. All patients will also be informed of their right to withdraw from the trial whenever they desire without giving the researchers any reason for their decision.

Consent for publication

Not applicable.

Availability of data and materials

Upon reasonable request, the data sets used during the current study will be available from the corresponding author.

Competing Interests

The authors declare that they have no competing interests.

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APPENDIX A

ADDITIONAL FILE 1:

Questionnaire Part I: DEMOGRAPHIC AND BACKGROUND VARIABLES

How to answer the questions in this questionnaire:

1. Answer the questions on your own. Don't discuss them with others!
2. Answer all questions honestly.
3. There are no right or wrong answers; it's about what *you* think or what *you* do.

1	Are you a boy or a girl?	
	<input type="checkbox"/> 0	Boy
	<input type="checkbox"/> 1	Girl
2	How old are you? years	
3	What level of education are you attending right now?	
	<input type="checkbox"/> 1	Primary education
	<input type="checkbox"/> 2	Practical pathway or pre-vocational education (PP VMBO)
	<input type="checkbox"/> 3	Theoretical pathway or pre-vocational education (TP VMBO)
	<input type="checkbox"/> 4	Senior general secondary education (HAVO)
	<input type="checkbox"/> 5	Pre-university education (VWO)
	<input type="checkbox"/>	Other:
4	To which culture do you feel you belong?	
	<input type="checkbox"/> 1	Dutch
	<input type="checkbox"/> 2	Turkish
	<input type="checkbox"/> 3	Moroccan
	<input type="checkbox"/> 4	Surinamese
	<input type="checkbox"/> 5	Other culture (please fill in below):
5	Do you smoke?	
	<input type="checkbox"/> 1	Yes
	<input type="checkbox"/> 0	No
6	What kind of toothbrush do you use to brush your teeth?	
	<input type="checkbox"/> 1	Manual toothbrush
	<input type="checkbox"/> 2	Electric toothbrush
	<input type="checkbox"/> 3	Manual toothbrush and electric toothbrush
7	<p>To measure how often between meals your teeth are exposed to the acids or sugars in foods and/or drinks, we would like you to count the number of times you eat or drink between meals in an average day (for example yesterday). If you eat and drink at the same time, it counts as 1 time. If there is more than half an hour between the eating or drinking, it counts as 2 times.</p> <p>Please tell us the number of times you drink and/or eat between the main meals. Drinks include lemonade, iced tea, energy drinks or orange juice. Do not count water, coffee or tea without sugar. Sugar-free chewing gum does not count as eating. But please count coffee or tea with sugar.</p> <p>How often do you drink and/or eat anything in between your main meals on an average day?</p> <p>..... per day</p>	

ADDITIONAL FILE 2:

Questionnaire Part II: ORAL HEALTH BEHAVIOR & PSYCHOSOCIAL FACTORS

The headers in the questionnaire indicate what constructs will be measured. We will remove the numbers indicating the range of the score and the headers from the questionnaire when used.

Abbreviations: TB = regarding Tooth Brushing; PB = regarding Proxy Brush; MR = regarding Mouth Rinse; DC = regarding Dental Cleaning, q=question.

ORAL HEALTH BEHAVIOUR (q1-5); TOOTH BRUSHING (q6, q1/q7/q10), PROXY-BRUSH USE (q2/q8/q11) AND FLUORIDE MOUTH RINSE USE (q4/q9/q12) [1,2]								
How many times in the last 4 weeks have you used the products or dental aids listed below?								
		3 times per day or more	Twice a day	Once a day	2 to 3 times a week	Once a week	Twice a month	Less often or never
1	Toothbrush	<input type="checkbox"/> 24.5	<input type="checkbox"/> 14	<input type="checkbox"/> 7	<input type="checkbox"/> 2.5	<input type="checkbox"/> 1	<input type="checkbox"/> .45	<input type="checkbox"/> 0
2	Proxy brush (also known as interdental brush/small brush)	<input type="checkbox"/> 24.5	<input type="checkbox"/> 14	<input type="checkbox"/> 7	<input type="checkbox"/> 2.5	<input type="checkbox"/> 1	<input type="checkbox"/> .45	<input type="checkbox"/> 0
3	Toothpick	<input type="checkbox"/> 24.5	<input type="checkbox"/> 14	<input type="checkbox"/> 7	<input type="checkbox"/> 2.5	<input type="checkbox"/> 1	<input type="checkbox"/> .45	<input type="checkbox"/> 0
4	Fluoride mouth rinse	<input type="checkbox"/> 24.5	<input type="checkbox"/> 14	<input type="checkbox"/> 7	<input type="checkbox"/> 2.5	<input type="checkbox"/> 1	<input type="checkbox"/> .45	<input type="checkbox"/> 0
5	Other dental aids, (please specify) (e.g., Dental floss)	<input type="checkbox"/> 24.5	<input type="checkbox"/> 14	<input type="checkbox"/> 7	<input type="checkbox"/> 2.5	<input type="checkbox"/> 1	<input type="checkbox"/> .45	<input type="checkbox"/> 0
Please fill in your tooth brushing duration, e.g., 2.5 minutes.								
6	Each time you brush your teeth, how much time do you spend on brushing?					Minutes per brushing	

How often did you...	3 times or more	Twice	Once	I didn't do this
7 brush your teeth yesterday?	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
8 use the proxy brush yesterday?	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
9 use fluoride mouth rinse yesterday?	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
In the last 4 weeks, how many times have you...				
10 brushed your teeth?			per day
11 used the proxy brush?			per day
12 used fluoride mouth rinse?			per day
If you use a proxy brush regularly, please answer the question below. If not, skip this question. (This will be done automatically in the digital questionnaire.)				
Do you use the proxy brush to clean the space...	Yes	No		
11b in between the teeth?	<input type="checkbox"/> 1	<input type="checkbox"/> 0		
11c in between the brackets?	<input type="checkbox"/> 1	<input type="checkbox"/> 0		

INTENTION TB (q13) & PB (q14a) & MR (q14b) [2]					
How true are the following statements?					
In the next 4 weeks I intend to...	Totally untrue	Untrue	Maybe true, maybe untrue	True	Totally True
13a brush my teeth daily at least twice a day.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
13b brush my teeth daily for at least 3 minutes each time.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
14a use the proxy brush to clean my teeth daily.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
14b use fluoride mouth rinse daily.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

(TASK/) ACTION SELF-EFFICACY TB (q15-18) & PB (q19-21) & MR (q21b) [3]					
How true are the following statements?					
I am confident that I can...	Totally disagree	Disagree	Don't agree, don't disagree	Agree	Totally agree

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15	brush my teeth daily for at least 3 minutes.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
16	brush my teeth at least twice a day.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
17	attentively brush my teeth daily.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
18	brush my teeth daily, even the surfaces that are hard to reach.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
19	use the proxy brush daily.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
20	attentively clean my teeth with a proxy brush daily.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
21	clean my teeth with a proxy brush daily, even the surfaces that are hard to reach.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
21b	use fluoride mouth rinse daily.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

MAINTENANCE SELF-EFFICACY TB (q22-25) [3]					
I am confident that I can brush my teeth for 3 minutes at least twice a day...	Totally disagree	Disagree	Don't agree, don't disagree	Agree	Totally agree
22 even when I do not see immediate results.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
23 even when I don't feel like doing it.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
24 even when I'm in a hurry.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
25 even if it takes a lot of time.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

MAINTENANCE SELF-EFFICACY & PB (q26-29) [3]					
I am confident that I can clean my teeth with a proxy brush daily...	Totally disagree	Disagree	Don't agree, don't disagree	Agree	Totally agree
26 even when I do not see immediate results.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
27 even when I don't feel like doing it.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
28 even when I'm in a hurry.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
29 even if it takes a lot of time.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

RECOVERY SELF-EFFICACY TB (q30) & PB (q31) [3]						
Even in the long term, I'm confident that I can...		Totally disagree	Disagree	Neither agree nor disagree	Agree	Totally agree
30a	brush my teeth at least twice a day.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
30b	brush my teeth daily for at least 3 minutes at a time.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
31	use the proxy brush to clean my teeth daily.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

ACTION PLANNING TB (q32-34) & PB (q35-37) [2]					
Please answer the following questions.					
Do you have a clear plan for...		No plan	Vague plan	Clear plan	Very clear plan
32	when to brush your teeth?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
33	where to brush your teeth?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
34	how much time to spend on brushing your teeth?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
35	when to clean your teeth with a proxy brush?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
36	where to clean your teeth with a proxy brush?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
37	how much time to spend on cleaning your teeth with a proxy brush?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

COPING PLANNING TB (q38-39, q42) & PB (q40-41, q43) [2]					
Do you have a clear plan for...					
		No plan	Vague plan	Clear plan	Very clear plan
38	something hinders brushing?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
39	you forget to brush your teeth?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
40	something hinders using the proxy brush?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
41	you forget to clean your teeth with a proxy brush?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

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	Do you have a plan on how to motivate yourself when you don't feel like...	No plan	Vague plan	Clear plan	Very clear plan
42	brushing?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
43	using the proxy brush?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

OUTCOME EXPECTATIONS DC (q44-49) [1]						
By cleaning my teeth regularly...		Totally disagree	Disagree	Neither agree nor disagree	Agree	Totally agree
44	I avoid getting cavities.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
45	my breath is fresh.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
46	I avoid discoloration of my teeth.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
47	I feel fresh.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
48	I keep my gums healthy.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
49	I look better.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

RISK PERCEPTION TOWARDS ORAL DISEASES (q50-53), TB (q54-56) & PB (q57-59) [3]						
What is your risk of getting...		Very low	Low	Not low, not high	High	Very high
50.	a cavity?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
51.	gum inflammation?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
		Very low	Low	Not low, not high	High	Very high
52.	a cavity is:	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
53.	a gum inflammation is:	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
If I don't brush my teeth often, the risk of getting...		Very low	Low	Not low, not high	High	Very high
54	a cavity will be:	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
55	a gum inflammation will be:	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
56	discoloration of my teeth will be:	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

	If I don't clean my teeth daily with a proxy brush, the risk of getting:	Very low	Low	Not low, not high	High	Very high
57	a cavity will be:	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
58	a gum inflammation will be:	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
59	discoloration of my teeth will be:	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

SOCIAL INFLUENCES DC (PARENTAL SUPPORT (q60) & DESCRIPTIVE NORM (q61-63) SUBJECTIVE NORM (q64-66) [1]						
My parents...		Totally disagree	Disagree	Neither agree nor disagree	Agree	Totally agree
60	often remind me that I need to clean my teeth properly.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
61	brush their teeth at least twice a day.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
I think that other young people with fixed braces...		Totally disagree	Disagree	Neither agree nor disagree	Agree	Totally agree
62	brush their teeth for 3 minutes at least twice a day.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
63	use the proxy brush to clean their teeth daily.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
The following people think that I should clean my teeth properly:		Totally disagree	Disagree	Neither agree nor disagree	Agree	Totally agree
64	My friends	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
65	My dental healthcare provider.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
66	My parents or guardian.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

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ACTION CONTROL TB (q67-68, q70) & PB (q69, q71) [3]						
In the last week ...		Totally disagree	Disagree	Neither agree nor disagree	Agree	Totally agree
67	I have regularly checked how often I have brushed my teeth.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
68	I have regularly checked my daily tooth brushing duration.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
69	I have regularly checked how often I used the proxy brush.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
70a	I have really tried hard to brush my teeth twice a day.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
70b	I have really tried hard to brush my teeth for at least 3 minutes at a time.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
71	I have really tried hard to clean my teeth with a proxy brush every day.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

This is the end of the questionnaire. Thanks for your collaboration!

ADDITIONAL FILE 3:

Questionnaire Part II: PARTICIPANTS' EXPERIENCES WITH THE WHITETEETH APP

The headers in the questionnaire indicate what constructs will be measured. We will remove the numbers indicating the range of the score and the headers from the questionnaire when used.

ACCEPTABILITY (q1,15) OPERABILITY (q2-3), ATTRACTIVENESS (q4, q21-23) OF THE APP; USERS' PERCEPTIONS OF SEVERAL COMPONENTS OF THE APP (q5-14); INTENTION TO USE THE APP (q16); PERCEIVED EFFECTIVENESS (q17); USABILITY (q20, q26-34) - questions are adapted from the system usability scale (SUS) [1,2,3,4].						
The following questions concern your opinion of the WhiteTeeth app. Indicate per statement whether you think it's good or bad.						
What did you think about....	Very bad	Bad	Neither good, nor bad	Good	Very good	Not applicable
1 The app in its entirety?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>
2 The app's loading time when you opened it?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>
3 The app's speed when it was opened?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>
4 The app's layout?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>
5 The brushing timer?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>
6 The Goal setting option?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>
7 The tutorial at the start of the app?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>
8 The option for setting reminders for your tasks?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>
9 The reminders you received that reminded you of your tasks (pop-ups/ notifications on your smartphone)?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>
10 The pop-ups/notifications you received that reminded you to check off your tasks?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>

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11	The option for monitoring your progress using the “statistics screen” in the app?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>		
12	The duration of the brushing timer?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>		
13	The overview of the selfies?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>		
14	The option for finding solutions to problems that kept you from achieving your goals?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/>		
To what extent do you agree with the following statements?									
		Totally disagree	Disagree	No opinion	Agree	Totally Agree			
15	I would recommend the app to others.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5			
16	I plan to use the app for at least 4 more weeks.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5			
17	The app stimulated me to take better care of my teeth.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5			
18	I have truthfully indicated whether I did or did not do my tasks (brushing, proxy brushes, and mouth rinse).	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5			
19	I have truthfully indicated which factors influenced whether or not I achieved my goals.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5			
20	The app is well designed.	<input type="checkbox"/> 0	<input type="checkbox"/> 2,5	<input type="checkbox"/> 5	<input type="checkbox"/> 7,5	<input type="checkbox"/> 10			
21	The apps layout looks good.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5			
22	The animations appeal to me.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5			
23	The app looks childish.	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1			
24	What score (scaling from 1 to 10) would you give the app?								
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

25	Do you have any tips on improving the app, or any questions or remarks about this re-search? If so, please write them here.																																																																					
<div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div>																																																																						
To what extent do you agree with the following statements?																																																																						
	<table><tr><td></td><td>Totally disagree</td><td>Disagree</td><td>No opinion</td><td>Agree</td><td>Totally Agree</td></tr><tr><td>26</td><td>I found the app un-necessarily complex</td><td><input type="checkbox"/>10</td><td><input type="checkbox"/>7,5</td><td><input type="checkbox"/>5</td><td><input type="checkbox"/>2,5</td><td><input type="checkbox"/>0</td></tr><tr><td>27</td><td>I thought the app was easy to use</td><td><input type="checkbox"/>0</td><td><input type="checkbox"/>2,5</td><td><input type="checkbox"/>5</td><td><input type="checkbox"/>7,5</td><td><input type="checkbox"/>10</td></tr><tr><td>28</td><td>I think that I would need the support of a technical person to be able to use this app</td><td><input type="checkbox"/>10</td><td><input type="checkbox"/>7,5</td><td><input type="checkbox"/>5</td><td><input type="checkbox"/>2,5</td><td><input type="checkbox"/>0</td></tr><tr><td>29</td><td>I found the various functions in this app were well integrated</td><td><input type="checkbox"/>0</td><td><input type="checkbox"/>2,5</td><td><input type="checkbox"/>5</td><td><input type="checkbox"/>7,5</td><td><input type="checkbox"/>10</td></tr><tr><td>30</td><td>I thought there was too much inconsis-tency in this app</td><td><input type="checkbox"/>10</td><td><input type="checkbox"/>7,5</td><td><input type="checkbox"/>5</td><td><input type="checkbox"/>2,5</td><td><input type="checkbox"/>0</td></tr><tr><td>31</td><td>I would imagine that most people would learn to use this app very quickly</td><td><input type="checkbox"/>0</td><td><input type="checkbox"/>2,5</td><td><input type="checkbox"/>5</td><td><input type="checkbox"/>7,5</td><td><input type="checkbox"/>10</td></tr><tr><td>32</td><td>I found the app very cumbersome to use</td><td><input type="checkbox"/>10</td><td><input type="checkbox"/>7,5</td><td><input type="checkbox"/>5</td><td><input type="checkbox"/>2,5</td><td><input type="checkbox"/>0</td></tr><tr><td>33</td><td>I felt very confident using the app</td><td><input type="checkbox"/>0</td><td><input type="checkbox"/>2,5</td><td><input type="checkbox"/>5</td><td><input type="checkbox"/>7,5</td><td><input type="checkbox"/>10</td></tr><tr><td>34</td><td>I needed to learn a lot of things before I could get going with this app</td><td><input type="checkbox"/>10</td><td><input type="checkbox"/>7,5</td><td><input type="checkbox"/>5</td><td><input type="checkbox"/>2,5</td><td><input type="checkbox"/>0</td></tr></table>		Totally disagree	Disagree	No opinion	Agree	Totally Agree	26	I found the app un-necessarily complex	<input type="checkbox"/> 10	<input type="checkbox"/> 7,5	<input type="checkbox"/> 5	<input type="checkbox"/> 2,5	<input type="checkbox"/> 0	27	I thought the app was easy to use	<input type="checkbox"/> 0	<input type="checkbox"/> 2,5	<input type="checkbox"/> 5	<input type="checkbox"/> 7,5	<input type="checkbox"/> 10	28	I think that I would need the support of a technical person to be able to use this app	<input type="checkbox"/> 10	<input type="checkbox"/> 7,5	<input type="checkbox"/> 5	<input type="checkbox"/> 2,5	<input type="checkbox"/> 0	29	I found the various functions in this app were well integrated	<input type="checkbox"/> 0	<input type="checkbox"/> 2,5	<input type="checkbox"/> 5	<input type="checkbox"/> 7,5	<input type="checkbox"/> 10	30	I thought there was too much inconsis-tency in this app	<input type="checkbox"/> 10	<input type="checkbox"/> 7,5	<input type="checkbox"/> 5	<input type="checkbox"/> 2,5	<input type="checkbox"/> 0	31	I would imagine that most people would learn to use this app very quickly	<input type="checkbox"/> 0	<input type="checkbox"/> 2,5	<input type="checkbox"/> 5	<input type="checkbox"/> 7,5	<input type="checkbox"/> 10	32	I found the app very cumbersome to use	<input type="checkbox"/> 10	<input type="checkbox"/> 7,5	<input type="checkbox"/> 5	<input type="checkbox"/> 2,5	<input type="checkbox"/> 0	33	I felt very confident using the app	<input type="checkbox"/> 0	<input type="checkbox"/> 2,5	<input type="checkbox"/> 5	<input type="checkbox"/> 7,5	<input type="checkbox"/> 10	34	I needed to learn a lot of things before I could get going with this app	<input type="checkbox"/> 10	<input type="checkbox"/> 7,5	<input type="checkbox"/> 5	<input type="checkbox"/> 2,5	<input type="checkbox"/> 0
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CHAPTER 6

The effectiveness of the WhiteTeeth app, a theory-based oral health promotion program for adolescent orthodontic patients



Scheerman JFM, van Meijel B, van Empelen P,
Verrips GHW, van Loveren C, Twisk JWR,
Pakpour AH, van Den Braak MCT, Kramer GJC.

The effectiveness of the WhiteTeeth app, a theory-based oral health promotion program for adolescent orthodontic patients – A Randomized Controlled Trial. To be submitted to the Journal of Medical Internet Research.

ABSTRACT

Background: The aim of this study was to evaluate the effectiveness of the WhiteTeeth smartphone app, a theory-based mobile health (mHealth) program for oral health behavior and oral hygiene in adolescent orthodontic patients. Integrating several behavior change techniques targeting oral health behaviors and their psychosocial factors, the app combined oral health education with an automatic coaching program.

Methods: In this parallel randomized controlled trial, adolescents with fixed orthodontic appliances were recruited from two orthodontic clinics in the Netherlands. 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). After baseline assessment, randomization was performed at patient level. 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 (measured according to a modified Silness and Loe Plaque Index); and the total number of sites with gingival bleeding (measured according to the Bleeding on Marginal Probing Index). Oral health behavior and its psychosocial factors (secondary outcomes) 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. At both follow-ups, significant effects were found in favor of the intervention group for the intention to use mouth rinse (T1 B=0.56; 95%CI 0.15 to 0.96; T2: B=0.42; 95%CI 0.01 to 0.83) and coping planning regarding tooth brushing (T1 B=0.56; 95%CI 0.15 to 0.96; T2 B=0.27; 95%CI 0.03 to 0.51).

Conclusion: The results show that adolescents with fixed orthodontic appliances can be helped to improve their oral hygiene when usual care is combined with a smartphone app that provides oral health education and automatic coaching. After the intervention period, however, adolescents' oral health behavior and oral hygiene was still not optimal in either group. This indicates the need for improved interventions for promoting better oral health behavior and oral hygiene.

Netherlands Trial Registry Identifier: NTR6206: 20 February 2017.

Keywords: app, mHealth, oral health promotion, oral health behavior, and oral hygiene.

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 [1]. Failure to practice good oral hygiene results in prolonged accumulation of biofilm (dental plaque), which potentially increases levels of cariogenic bacteria such as *Streptococcus mutans*. These produce acids that cause enamel demineralization [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 [4-8].

To prevent the development and/or 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 [9]. However, adherence to these recommendations is low, and oral hygiene in adolescent orthodontic patients is often inadequate [10,11]. This indicates a need for interventions to improve oral health behavior and oral hygiene in this special risk population.

Many health promotion programs that successfully changed health behavior included methods that targeted different stages of the behavior change process, i.e. the process of behavioral initiation and maintenance [12,13]. Examples of methods targeting behavior initiation include providing health risk information and demonstrating how to perform the behavior. Examples of methods targeting the process of behavioral maintenance are: self-monitoring of behavior and behavioral outcomes, prompting barrier identification, setting action and coping plans, and reviewing behavioral goals [12-15]. However, these methods have only rarely been applied in orthodontics [11]. In orthodontics, studies have combined mobile-health technology with oral health behavioral support—particularly sending text messages to deliver prompts or oral health information. These interventions had a positive effect on oral hygiene during fixed orthodontic treatment [16-23]. In our study we chose a combination of changing health behavior and using mobile health technology. We took a systematic approach to designing the WhiteTeeth app, a smartphone-delivered oral health promotion program for adolescents with fixed orthodontic appliances [12]. Combining behavioral change methods with the advantages of mobile technology, the app provided oral health education and an automatic coaching program intended to help these users maintain good oral health behavior 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 behaviors 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.

METHODS

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 [24]. The study was approved by the Medical Ethics Committee (METC) at VU Medical Centre in Amsterdam (protocol. nr. 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 [27].

Participants

The study population consisted of adolescents with fixed orthodontic appliances visiting orthodontic clinics in Alkmaar and Leiden, two cities in the Netherlands. These adolescents could participate in the study if they met the eligibility criteria (see Table 1). 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. Those who were willing to participate received an invitation letter containing information on the study and an informed consent form. Baseline assessments were scheduled after adolescents and their parents had returned the informed consent form. Data collection took place in the period from February 2017 to October 2017. 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.

Table 1. Eligibility criteria.

Adolescents could participate if they met the following eligibility criteria:
- They were boys or girls aged 12 to 16.
- For at least 6 weeks, they had had maxillary and mandibular fixed orthodontic-appliance therapy, which consisted of bonding at least premolar-to-premolar with edgewise appliances and their modifications.
- They had not been scheduled for removal of fixed orthodontic treatment before the end of the study.
- They had no physical and/or mental disabilities that impeded their ability to perform their own oral hygiene activities.
- They had not been engaged in any other oral health education or research program.
- They did not have enamel or dentine dysplasia and/or craniofacial malformation (e.g. cleft).
- They had a sufficient command of the Dutch language.
- They possessed a smartphone with IOS ≥ 7 or Android ≥ 4.1 software.
- Patients and their parents were willing and able to give informed consent.
- Patients did not use medication such as antibiotics or antibacterial mouth rinses that might affect plaque accumulation.

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. This was achieved through the use of two separate rooms: while the outcome assessors performed their examinations in the first room, an independent researcher allocated the intervention in the second room. Per visit, researchers requested the adolescents not to talk with the assessors and dental-care providers about their treatment allocation.

The intervention: the WhiteTeeth app

It is increasingly recognized that interventions should be based on theory, and should therefore be guided by intervention mapping [26, 27]. Intervention mapping is a protocol for developing theory-based and evidence-based health promotion programs, whose function is to help health promoters develop the best possible intervention [26]. 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 [12]. A detailed description of the systematic development and of the content and preliminary testing of the WhiteTeeth app has been published elsewhere [12].

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 behaviors of adolescents with fixed orthodontic appliances [10,28]. Using behavior change techniques (BCTs) that target the psychosocial factors outlined by the HAPA theory, the app focused mainly on improving oral health behavior, and thereby reducing dental plaque levels and gingival bleeding.

Participants randomized to the intervention group were asked to download the WhiteTeeth 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 WhiteTeeth app, participants were required to answer registration questions and to provide personal details on their oral health behavior 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 (which were provided at baseline) 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 behavioral outcomes* [29,30]). 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' behavior, as oral health education, and/or as instructions in short videos (*BCT: providing information on health consequences, and demonstrating the desired behavior* [31,32]).

Next, the app invited the participants to set a particular goal regarding oral health behavior (*BCT: Goal setting* [33]) and to formulate when and where they would perform the oral health behavior (*BCT: implementation intentions* [34]). 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 behavior tasks, and then to monitor them (*BCT: behavioral goal reminders* [16-18]).

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 behavior tasks (*BCT: self-monitoring of behavior* [35,36]), 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 [12], the timer showed the time elapsed during

brushing (*BCT: practical support* [32]). 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 behavioral outcomes* [36]). 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, i.e., "if-then" plans specifying how they could deal with difficult situations (*BCT: coping planning* [37]). For this purpose, the app contained volitional sheets, i.e., sheets outlining pre-established difficult situations and solutions.

Outcome measures

The outcome measures were collected through clinical assessments and self-administered digital questionnaires. At baseline (T0), and at six weeks (T1) and twelve 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. A modified Silness and Loe plaque index was used to measure the amount of plaque on the buccal surfaces [38]. 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 bracket (Fig. 1) [38]. Each of the four sites of the buccal tooth surface was given a score ranging from 0 to 3, where 0 indicated the absence of dental plaque, 1 indicated no plaque visible but an accumulation of soft deposit on a probe when used to clean the surface, 2 indicated a moderate accumulation of soft deposit on the tooth that could be seen with the naked eye, and 3 indicated an abundance of soft matter on the tooth.

For the analysis, the scores per site were summed to obtain a total score for the amount of dental plaque accumulation per patient. Higher scores indicated greater accumulation. The range was from 0 to 192 (16 elements*4sites*3 scores). To explore the effect on the presence of plaque in the mesial, distal, gingival and incisal sites, we dichotomized the plaque scores, with 0 indicating the absence of dental plaque and 1 indicating the presence of dental plaque. The score for the number of sites covered with plaque ranged thus from 0 to 16 (16 elements) per site and from 0 to 64 per patient (16 elements*4 sites).

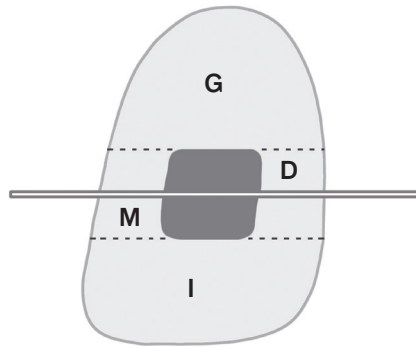


Fig.1. The buccal surfaces of the first premolars, canines and incisors were divided into four sites in relation to the position of the orthodontic bracket (G gingival, M mesial, D distal, I incisal).

Gingival bleeding was assessed using the Bleeding on Marginal Probing index (BOMP), the condition of the gingiva being scored according to the method described by Van der Weijden et al (1991) [39]. The mesio-buccal, buccal and disto-buccal sites of the buccal surfaces of the first premolar, canines and incisors were assessed to determine whether probing elicited marginal bleeding (score 1) or not (score 0). For the analysis, all scores were summed to obtain the total number of bleeding sites per patient. Higher scores indicate more gingival bleeding. The outcome variable ranged from 0 to 48 (16 teeth * 3 sites).

To ensure the reliability of the clinical measurements, the clinical examiners were trained and calibrated by an experienced examiner. Inter-examiner reliability was assessed using the intra-class correlation coefficient (ICC) with a two-way random-effects model. As a measurement of inter-examiner agreement, the ICCs in 10% of the measurements of the study population were 97.6% for the mean plaque score per patient and 93.2% for the mean bleeding score.

The secondary study outcomes were self-reported oral health behaviors and their psychosocial factors (HAPA factors). To measure these outcomes, we used a self-administered digital questionnaire containing questions with both single and multiple response items (see the study protocol for the full questionnaire) [24]. The questionnaire included questions on the frequency of oral health behaviors with which the following were used: a toothbrush, a proxy brush, a toothpick, mouth rinse, and other dental aids (such as dental floss). It used the following 7-point scale: 1: less than twice a month or never, 2: twice a month, 3: once weekly, 4: two to three times weekly; 5: once daily, 6: twice daily, and 7: three times daily or more. For the analysis,

these response options were recalculated to establish the weekly frequencies of each of the oral health-related activity (ranging from 0 to 24.5). Subsequently, the weekly frequencies for the use of each of the dental aids or products were summed to obtain a total oral health behavior score that ranged from 0 to 122.5. Higher scores indicate a higher frequency of oral health-related activities. Self-reported tooth brushing frequency and tooth brushing duration were measured on the basis of two open questions, i.e., “In the last four weeks, how many times have you brushed your teeth per day?” and “How much time do you spend on brushing your teeth at a time?”. The following psychosocial factors—HAPA factors—were assessed: risk perception, action self-efficacy, intention, maintenance self-efficacy, recovery self-efficacy, action control, action planning, and coping planning, social influences, outcome expectancies. Risk perception was assessed on 5-point scales ranging from “very low” (1) to “very high” (5). Coping planning and action planning were assessed on 4-point scales ranging from “no plan” (1) to “a very clear plan” (4). For 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) [40].

Covariates

The following variables were regarded as potential confounders or effect modifiers and collected at baseline: 1.) age (in years); 2.) sex (boy/girl); 3.) level of education (primary education, prevocational education; senior general secondary or pre-university education); 4.) cultural background (Dutch or other); 5.) smoking status (smoker or non-smoker); and 6.) 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: 7.) the type of orthodontic bracket used (e.g. self-ligating or conventional brackets); 8.) the treatment duration (in days).

Use of the WhiteTeeth app and its usability

App usage data was collected during the 12-week intervention period. Participants were asked to use the WhiteTeeth app to send their user data weekly from their smartphone via to the database. At 6-week 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 [41]. The SUS-scale ranges from 0-10, 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 [24].

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 drop-outs and completers in the total sample. Linear mixed models were used to analyze the effects of the WhiteTeeth app and to take account of the correlated observations within the participant. To compare the outcome (dental plaque, gingival bleeding, oral health behaviors and their psychosocial factors) 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. Two models were constructed: (1) crude models; (2) models adjusted for covariates. Since linear mixed model analysis handles missing observations caused by drop-out, no additional action were 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, Armonk, NY, USA).

RESULTS

As figure 2 shows, 132 of the 230 eligible adolescents with fixed orthodontic appliances agreed to participate; they provided informed consent, attended baseline, and were randomly assigned to one of the two experimental arms (response rate 57%). Five patients dropped out of the intervention group, and three patients 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 ($p=0.997$). 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 ($p=0.962$).

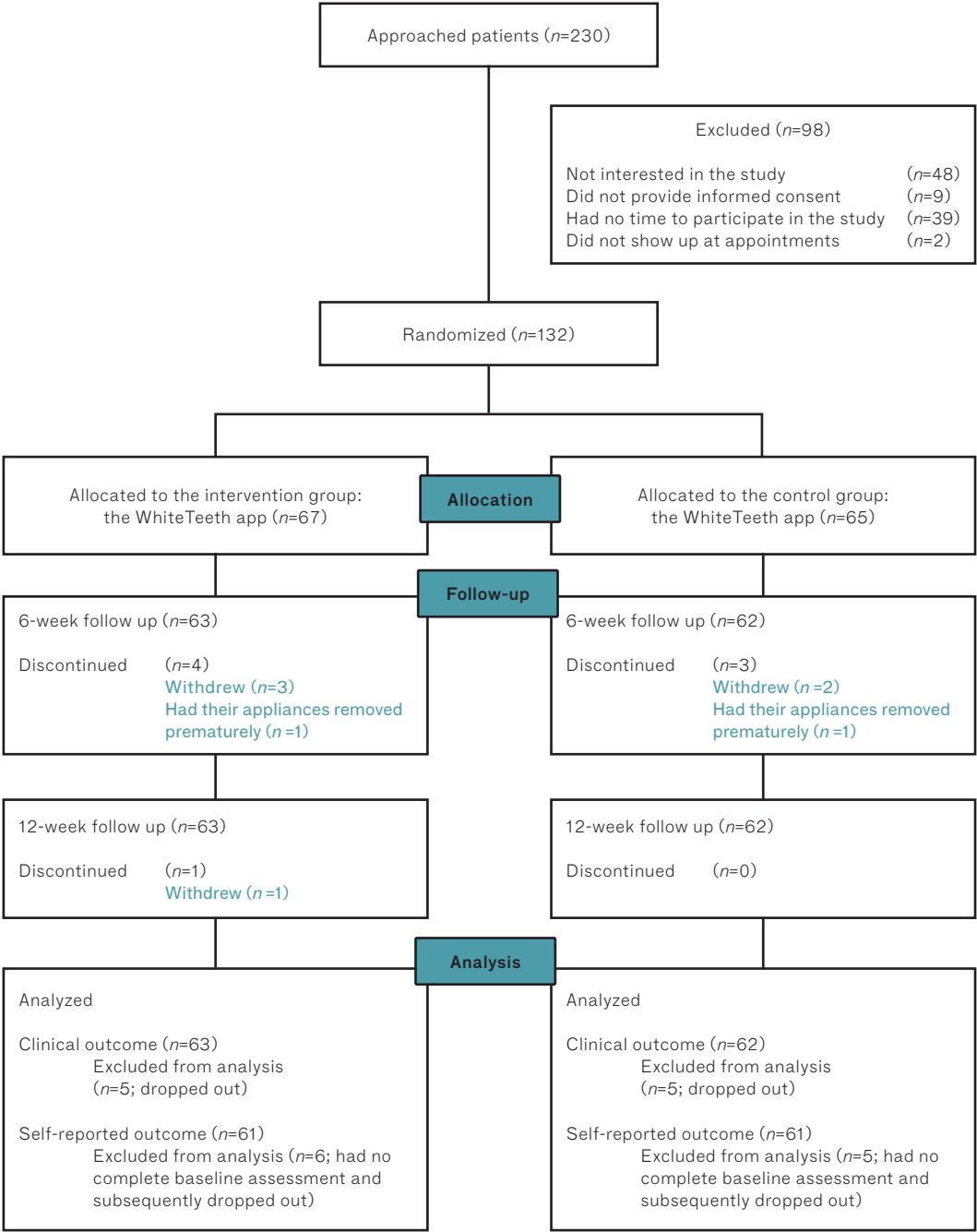


Fig. 2. Flowchart of the participants throughout the trial.

Table 2. Patients' characteristics at baseline.

Characteristic	Intervention group (n=67)	Control group (n=65)
Age (years) ^a	13.2 (1.01)	13.5 (0.97)
Girl (yes) ^b	41 (61.2%)	32 (49.2%)
Education level ^b (<i>Using the standard Dutch abbreviations</i>)		
- Primary education	7 (10.4%)	2 (3.1%)
- Prevocational education - Practical pathway (PP VMBO)	7 (10.4%)	6 (9.2%)
- Prevocational education - Theoretical Pathway (TP VMBO)	16 (23.9%)	14 (21.5%)
- Senior general secondary education (HAVO)	17 (25.4%)	23 (35.4%)
- Pre-university education (VWO)	20 (29.9%)	20 (30.8%)
Cultural background ^b		
- Dutch	63 (94.0%)	56 (86.2%)
- Moroccan	4 (6.0%)	5 (7.7%)
- Other	0 (0%)	4 (6.2%)
Smoking (no) ^b	67 (100%)	65 (100%)
Conventional brackets (yes) ^b	16 (24.6%)	22 (32.8%)
Exposure to the acids and/or sugars in foods and/or drinks between main meals (times per day)	3.6 (1.80)	3.5 (2.16)
Duration at baseline of treatment with fixed orthodontic appliances (days) ^a	401.0 (212.1)	419.0 (277.2)
Oral health behavior score (0-122.5) ^a	20.9 (9.3)	20.1 (8.2)
Plaque index (S&L; 0-192) ^a	70.8 (29.6)	75.3 (34.3)
Number of gingival bleeding sites (0-48) ^a	27.8 (8.9)	28.1 (8.3)

^a mean (SD), ^b n (%)

Due to technical complications, occasional malfunctions meant that the user data—including selfies—was not always sent during the intervention period. For this reason, less user data was 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 7 participants for brushing, by 9 participants for rinsing, by 16 for self-monitoring of behavioral 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 proxy 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 2 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 out before the last assessment show that completers scored significantly higher on the oral health behavior score (mean (SD) total sample = 20.67 (8.97); Drop-out= 17.88 (2.67); $p=0.04$).

The intervention effects on oral hygiene

Table 3 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; 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 in 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).

The intervention effects on oral health behavior and its psychosocial factors

Table 4 shows the descriptive information and the results of the mixed model analyses for the oral health behaviors. The only significant intervention effect was for fluoride use at the 6-week follow-up; it favored the intervention group ($B=1.93$; 95%CI 0.36 to 3.50). No significant intervention effects were found for the oral health behavior score, tooth brushing (frequency and duration) and proxy 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; $p=0.028$) 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).

DISCUSSION

This randomized controlled trial aimed to test the effect of the WhiteTeeth app on oral health behavior and oral hygiene in adolescents with fixed orthodontic appliances. The app incorporated many behavior change techniques, targeting not only oral health behavior but also the psychosocial factors that are associated with this behavior and had been identified through the HAPA theory [12]. The behavior change techniques it incorporated included coaching to set goals, action plans and reminders; self-monitoring of oral health behavior and dental plaque; providing feedback and practical support; reviewing behavioral 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 smartphone app for oral health promotion in orthodontic patients [22, 23]. In the first, Zotti et al. [22] 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 ($p < 0.0001$) and gingival index ($p < 0.05$), 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%; $p < 0.0001$).

Table 3. 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).

Mean (Standard deviation)					T1			T2			
Outcome measures (scale)	T0	T1	T2	Effects	B	95% CI	p	B	95% CI	p	
Total amount of dental plaque accumulation according the modified Sillness and Loë score (0-192)	Intervention	70.79 (29.56)	52.41 (29.02)	54.63 (26.93)	Crude ^a	-7.95	-16.81; 0.90	0.078	-13.49	-22.37; -4.62	0.003
	Control	75.34 (34.27)	62.97 (25.71)	70.42 (30.72)	Adjusted ^b	-6.86	-16.05; 2.34	0.143	-11.32	-20.57; -2.07	0.017
Total sites covered with plaque (0-64)	Intervention	45.04 (12.43)	38.02 (15.73)	39.66 (14.93)	Crude	-4.94	-9.44; -0.44	0.032	-6.91	-11.42; -2.40	0.003
	Control	45.40 (14.35)	43.39 (12.20)	46.76 (12.03)	Adjusted	-4.83	-9.69; 0.04	0.052	-6.77	-11.67; -1.87	0.007
The number of mesial sites covered with plaque (0-16)	Intervention	12.77 (3.55)	11.30 (4.42)	11.53 (4.10)	Crude	-1.33	-2.57; -0.09	0.036	-1.88	-3.13; -0.64	0.003
	Control	12.98 (3.78)	12.81 (3.36)	13.58 (3.36)	Adjusted	-1.36	-2.71; -0.01	0.048	-1.85	-3.22; -0.49	0.008
The number of incisal sites covered with plaque (0-16)	Intervention	6.55 (4.34)	5.35 (4.43)	6.02 (4.24)	Crude	-0.86	-2.29; 0.57	0.237	-1.20	-2.63; 0.23	0.101
	Control	7.26 (4.70)	6.45 (4.19)	7.44 (4.37)	Adjusted	-0.87	-2.44; 0.69	0.271	-1.25	-2.82; 0.32	0.118
The number of distal sites covered with plaque (0-16)	Intervention	13.45 (2.94)	11.86 (4.45)	11.90 (4.45)	Crude	-1.35	-2.63; -0.07	0.039	-1.82	-3.11; -0.54	0.006
	Control	13.18 (3.67)	13.15 (3.09)	13.63 (3.35)	Adjusted	-1.11	-2.53; 0.32	0.127	-1.53	-2.96; -0.91	0.037
The number of gingival sites covered with plaque (0-16)	Intervention	12.27 (3.69)	9.51 (4.47)	10.21 (4.25)	Crude	-1.46	-2.79; -0.14	0.031	-2.06	-3.39; -0.73	0.003
	Control	11.97 (3.95)	10.98 (3.96)	12.11 (3.49)	Adjusted	-1.51	-2.93; -0.09	0.038	-2.15	-3.58; -0.71	0.004
Bleeding on marginal probing (0-48)	Intervention	27.81 (8.94)	23.46 (9.34)	24.61 (10.07)	Crude	-2.32	-5.31; 0.67	0.128	-2.44	-5.45; 0.56	0.110
	Control	28.11 (8.25)	26.48 (10.12)	27.63 (8.60)	Adjusted	-3.74	-6.84; -0.65	0.018	-1.89	-5.00; 1.22	0.232

B: mean difference in outcome between the two groups; CI: confidence interval. ^a The crude effects are adjusted for baseline values of the outcome of interest; ^b The adjusted effects are adjusted for baseline values of the outcome of interest and for sex, age, education level, type of toothbrush, oral health behavior, cultural background and the duration of orthodontic treatment.

Table 4. Descriptive information and the effects of the intervention on oral health behaviors (n=121).

Outcome measures (scale)		Mean (standard deviation)			T1			T2		
		T0	T1	T2	Effects	B	95% CI	p	B	95% CI
Oral health behavior score (0-122.5)	Intervention	20.89 (9.24)	22.60 (12.06)	22.50 (10.59)	Crude ^a	2.37	-0.72; 5.46	0.131	0.59	-2.51; 3.66
	Control	20.08 (8.21)	20.74 (9.27)	22.00 (8.88)	Adjusted ^b	2.67	-0.72; 6.06	0.191	0.93	-2.48; 4.34
Tooth-brushing frequency (times per day)	Intervention	1.90 (0.40)	1.92 (0.41)	1.93 (0.36)	Crude	-0.04	-0.15; 0.08	0.530	-0.01	-0.12; 0.10
	Control	1.90 (0.40)	1.97 (0.39)	1.97 (0.36)	Adjusted	-0.07	-0.18; 0.04	0.233	-0.02	-0.14; 0.09
Tooth-brushing duration (minutes per session)	Intervention	2.58 (1.04)	2.79 (1.09)	2.74 (1.02)	Crude	0.26	-0.02; 0.55	0.073	0.16	-0.13; 0.45
	Control	2.50 (1.01)	2.50 (0.98)	2.43 (0.87)	Adjusted	0.29	-0.03; 0.60	0.071	0.13	-0.19; 0.45
Proxy brush use (times per week)	Intervention	4.24 (5.22)	3.74 (5.29)	4.28 (5.55)	Crude	0.30	-0.96; 1.56	0.641	1.13	-0.14; 2.39
	Control	3.26 (4.46)	2.83 (3.73)	2.48 (3.42)	Adjusted	0.65	-0.65; 1.95	0.326	0.19	-0.18; 1.58
Fluoride mouth rinse use (times per week)	Intervention	2.73 (4.78)	4.08 (4.97)	3.46 (4.27)	Crude	1.72	0.20; 3.23	0.026	0.17	-1.35; 1.69
	Control	2.41 (4.04)	2.94 (5.07)	3.63 (5.64)	Adjusted	1.93	0.36; 3.50	0.017	0.36	-1.22; 1.94

B: mean difference in outcome between the two groups; CI: confidence interval. ^a Crude effects are adjusted for baseline values of the outcome of interest;

^b Adjusted effects are adjusted for baseline values of the outcome of interest and sex, age, education level, cultural background and the orthodontic treatment duration.

In the second study, a mobile app had been designed by Alkadhi et al.: it consisted of videos of oral hygiene instructions and text messages encouraging patients to practice oral hygiene tasks [23]. 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 ($p < 0.05$) after 4 weeks of follow-up than verbal oral hygiene instructions had [23].

While our study corroborates these findings, it also goes beyond previous studies by using behavioral theory for the program design, and thus by targeting the underlying factors of oral health behavior and by evaluating the effects on these factors. By doing so, this study contributes to research involving the understanding of oral health behavior. 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 behavior change techniques [12]. 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 programs that are even more effective [11].

The evaluation of orthodontic oral health promotion programs has focused mainly on preventing demineralisation by improving oral hygiene procedures during fixed appliance orthodontic treatment [11,22,23]. 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.

Unfortunately, due to technical problems that occurred during the intervention period, data on the use of the various components was not reliable, as we did not receive all user's data. For example, data on creating coping plans regarding fluoride mouth rinse was 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 e-mail function on their phone. These malfunctions prevented us from detecting the extent of compliance with the intervention components and from identifying which component or behavior change technique was responsible for producing changes in the outcomes, or whether there was a synergistic effect of all behavior change techniques working together. Since the launch of our app in 2016, the consumer market for oral health apps has expanded, bringing many new features, such as connections to a toothbrush via blue-tooth 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 behavior change techniques. 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 behavior [42]. 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.

Conclusion

The use of a smartphone app as an adjunct to usual care may be a viable method of improving oral health promotion in adolescent orthodontic patients. The findings of our randomized controlled trial show that the WhiteTeeth app was effective in reducing dental plaque in adolescents with fixed orthodontic appliances. However, after the intervention period, the oral hygiene of patients in usual care and the app group was still not optimal. This indicates the need to improve oral hygiene programs for adolescent orthodontic patients.

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CHAPTER 7

Summary Samenvatting



SUMMARY

Chapter 1 introduces this dissertation, demonstrating its aim, importance and innovative character.

The main objectives of orthodontic treatment are to achieve pleasant smile aesthetics with a stable occlusal relationship and masticatory function. However, treatment with fixed orthodontic appliances (brackets) also involves some risks: the appliances increase the number of sites that retain biofilm or dental plaque, impeding cleaning of the area surrounding the brackets and thus hampering the maintenance of proper oral hygiene. As a result of prolonged plaque accumulation surrounding the bracket, biofilm-related complications, such as gingival inflammation and decalcifications (i.e., white spot lesions), are prevalent during fixed orthodontic therapy, especially among adolescents. White spot lesions can remain visibly unaesthetic all a person's life. For these patients, existing oral health promotion programs have clearly been ineffective.

Oral health promotion programs to prevent white spot lesions should not only induce healthy behavior, but also sustain the behavior change. Research has shown that behavior can be changed successfully, and the new behavior maintained, by programs that influence its determinants, i.e., the factors underlying it. Researchers have developed and tested various theories of health behaviors that identify behavioral determinants and specify the pathway whereby they influence behavior. Potentially, the effectiveness of a health promotion program can be increased by applying relevant behavioral theories.

According to motivational theories such as the Theory of Planned Behavior, an intention (or motivation) is the most important psychosocial determinant of a particular health behavior. While these theories describe determinants that are involved in forming an intention (pre-intentional factors), most do not address the factors involved in translating an intention into action. Theories that include psychosocial factors of the pre-intentional and post-intentional phase—such as the Health Action Process Approach (HAPA) and self-regulation theory—have been shown to explain a range of health behaviors and to be effective in changing these behaviors. But although their application has led to successful behavior change within healthcare, they have not been applied in orthodontic patients.

According to the HAPA theory, changing health behaviors involves two consecutive phases. The first is the motivational (or pre-intentional) phase, which corresponds largely with the theoretical framework of most motivational theories. The second is the volitional (or post-intentional) phase, which focuses on the cognitions involved in planning and initiating or controlling action post-intentionally. This phase emphasizes the role of self-efficacy regarding relapse prevention and the maintenance of a

behavioral change, the ability to regulate the action (action control), planning of the action (action planning) and planning of how to cope with barriers involved with the behavior and find solutions to them (coping planning). Self-regulation theory provides an understanding of the behavioral processes necessary for the self-management that will achieve a behavioral goal.

Due to their functionality and reach, smartphones provide opportunities for delivering preventive oral care. The provision of healthcare through mobile devices is known as mobile health (mHealth). Although mHealth programs have been shown to improve oral hygiene effectively, most studies have either not been designed on the basis of behavioral theories, or have not used theory for their program design. As a result, the studies evaluating these programs did not evaluate their effects on behavioral determinants, and the programs contained few behavior change techniques that targeted behavioral determinants. This means that the mechanisms underlying oral health behavior change are still not understood. As these evaluation studies were also poorly designed, or provided little or no details on program content, they limited the options for replicating programs or designing more effective ones.

Intervention Mapping is a protocol that offers evidence-based documents and guidelines for the stepwise planning, development and implementation of health programs. By guiding the systematic use of empirical data and behavioral theories, it helps researchers to identify and select determinants and then match them with appropriate behavior change techniques. By using intervention mapping to develop and evaluate a smartphone app for the promotion of oral health behavior, this dissertation aimed to contribute to the evidence base for the development of oral health programs.

The main objective of this dissertation was to develop and evaluate a smartphone app, the 'WhiteTeeth' app that would improve oral health behavior and oral hygiene in young people (age 12 to 16) with fixed orthodontic appliances. To design an app that would target oral health behavior and its determinants in people in this age group, three studies were conducted to increase our understanding of these behaviors and the factors underlying them: a systematic review with meta-analysis (chapter 2); a cross-sectional study (chapter 3); and a qualitative study (chapter 4).

Chapter 2 presents a systematic review with meta-analysis of the literature on the psychosocial factors underlying the oral hygiene behavior of people aged 9 to 19. In this review, data of 27 data sets presented in 22 publications were analyzed. A study was eligible for inclusion if it evaluated the association between the psychosocial factors and oral hygiene behavior. The measurements of this behavior varied from self-reports to clinical measurements, including plaque and bleeding scores. The results of the review showed that the psychosocial factors identified by the HAPA

theory (i.e., “self-efficacy,” “intention,” “attitude,” “social influences,” “coping planning,” and “action planning”) were positively associated with oral hygiene behavior.

The design of many of the included studies was based on commonly used theories, such as the Theory of Planned Behavior. Only rarely was it attempted to explain oral hygiene behavior on the basis of theories that include psychosocial factors in the post-intentional or volitional phase. As a result, very little study was devoted to psychosocial factors which turned out to be most important explaining oral health behavior (i.e. factors with the highest weighted correlation coefficient), e.g. post-intentional factors such as action planning and coping planning. On the basis of these findings, we concluded that oral health behaviors might be better explained through alternative theories that take account of such factors through a focus on the volitional aspect of the behavior process. The HAPA theory is one such theory.

As the systematic review applied to young people in general, and not specifically to those with fixed orthodontic appliances, we conducted a cross-sectional study to examine whether the findings of the literature review also apply to adolescents with fixed orthodontic appliances. **Chapter 3** presents this cross-sectional study, in which we used the HAPA theory to explore the extent to which psychosocial factors are associated with the presence of dental plaque and the frequency of oral hygiene behaviors in these adolescents. One hundred sixteen adolescents with fixed appliances at an orthodontic clinic in Almere, the Netherlands, completed on oral hygiene behaviors and their psychosocial HAPA factors. The results of the linear regression analyses showed that a decrease in dental plaque was associated mainly with increased use of a proxy brush ($R^2=45\%$) and that proxy brush use was subsequently associated with higher intention, action self-efficacy and maintenance self-efficacy ($R^2=45\%$). The results confirmed that the HAPA theory is useful in explaining oral hygiene behavior in adolescents with these appliances. For this reason, the WhiteTeeth app was based on this theory.

Chapter 4 describes the systematic development of the WhiteTeeth app according to Intervention Mapping. To gain additional insight into oral health behavior, 20 Dutch adolescents with fixed orthodontic appliances were interviewed about their oral health behavior. These interviews revealed that recommended dental aids, such as proxy brushes, were used only occasionally, as they believed the use of these aids was unnecessary. Although most respondents stated that they brushed their teeth twice a day as a matter of routine, they often failed to brush for as long as recommended. The respondents had little awareness of the benefit of fluoride, and fluoride mouth rinses were not a preventive measure they chose consciously.

The findings of these semi-structured interviews, the HAPA theory, and the self-regulation theory were all used to define specific program objectives. After defining

the objectives, we identified behavior change techniques that could be used to achieve them, such as providing oral health information and personalized feedback, prompting self-monitoring, coaching set action plans and coping plans, and sending reminders. Next, these techniques were translated into practical strategies, such as videos and a brushing timer. These strategies were then combined into a single program that resulted in the WhiteTeeth app.

The WhiteTeeth app is a self-steering program that is intended to improve the oral health behavior and oral hygiene of adolescents with fixed orthodontic appliances. It is intended for use at home. It focuses on two oral health behaviors and the psychosocial factors that HAPA showed to be related to them: (1) maintaining good oral hygiene (i.e. controlling dental plaque), and (2) using a sufficient amount of fluoride. After installing the app, adolescents are required to answer registration questions and provide personal information on their oral care. On the basis of this information, the app provides health risk information, personal advice and instructions in short videos.

Next, the app helps adolescents to set and customize personal oral health goals, create action plans and set reminders. Every day, it sends push notifications asking adolescents to monitor their daily oral-care-related activities by entering them into the app, and also to use the brushing timer, which helps support good tooth-brushing. When adolescents decide to brush, they have the option of turning on the timer. Afterwards, the app provides positive reinforcement.

Each week, the app asks adolescents to evaluate their dental plaque levels and to review their behavioral goals. For this purpose, they are asked to use a disclosing tablet to visualize the dental plaque, to take a selfie of the result, and to indicate the area of dental plaque this discloses. On the basis both of the information on the selfie and of the information on the activities submitted to it, the app concludes whether goals have been attained. It then compliments users for using the app, and, if necessary, guides them in setting goals or adapting existing ones, and also in creating coping plans. These plans, which use “if-then” formulations to specify how they would deal with difficult situations, are drawn up by anticipating possible barriers and devising possible solutions to them. Personalized text messages are sent as a reminder to use the app and to perform the oral health behavior desired.

To increase the success of implementation, the development process involved not only oral healthcare providers, but also adolescents with fixed orthodontic appliances. The pilot test showed that the app users appreciated and liked the app. It also showed an acceptable score for usability (SUS=77).

Chapter 5 presents the study protocol of the randomized controlled trial to determine the effectiveness of the WhiteTeeth app. To determine the effectiveness of the intervention, we investigated the effects on dental plaque and gingival bleeding, and

also on self-reported oral health behavior and its psychosocial factors. Measurements were performed during three orthodontic check-ups: a baseline measurement and follow-up measurements at six and twelve weeks.

Chapter 6 presents the results of the randomized controlled trial that compared the intervention group that used the WhiteTeeth app in addition to usual care with a group who received only usual care. Usual care included routine oral health education and instruction at orthodontic check-ups. Patients aged 12 to 16 with fixed orthodontic appliances were recruited from two orthodontic clinics situated in the western Netherlands. After baseline assessment, 132 patients were randomly assigned to the intervention condition (WhiteTeeth app; $n=67$) or the control condition (usual care; $n=65$). At 6 weeks, mixed model analyses showed that gingival bleeding had decreased significantly more in the intervention group ($p=0.031$) than in the control group. Although the intervention effects on the total amounts of dental plaque were not significant at 6-week follow-up ($p=0.143$), dental plaque accumulation at 12-week follow-up had been reduced significantly more in the intervention group. ($p=0.019$). Although tooth brushing frequency and duration had not changed significantly, the reduction in dental plaque reflected a change in brushing pattern, as the number of sites covered with plaque had decreased significantly at 12 weeks ($p=0.007$). At 6 weeks, fluoride mouth rinse use, intention towards fluoride mouth rinse use, and coping planning regarding tooth brushing improved significantly in the intervention group. At 12 weeks, only the effect on coping planning and intention remained statistically significant. These results show that offering an oral health promotion program through a smartphone app in addition to usual care is an effective means of supporting adolescents with fixed orthodontic appliances in improving their dental plaque control. However, the oral hygiene in the study population was still not optimal after the intervention period. This indicates the need for more research that can further develop mHealth's great potential for improving orthodontic care.

SAMENVATTING

Hoofdstuk 1 introduceert dit proefschrift en beschrijft het belang, het innovatieve en het doel ervan.

Een belangrijk doel van een orthodontische behandeling is het bereiken van een aangename, verbeterde esthetiek met een stabiele gebitsocclusie en kauwfunctie. Het orthodontisch behandelen van het gebit met een vaste beugel brengt ook een aantal risico's met zich mee, zoals het veroorzaken van plaatselijke plaqueaccumulatie en het belemmeren van de mondverzorging, waardoor het handhaven van een goede mondhygiëne vaak niet haalbaar is. Als gevolg van langdurige plaqueaccumulatie rondom de vaste beugel zijn plaquegerelateerde aandoeningen, zoals tandvleesontstekingen en ontkalkingen van het glazuur (wittefleklaesies), vaak aanwezig tijdens de orthodontische behandeling, met name bij jongeren van 12 tot 18 jaar. Wittefleklaesies kunnen permanent zichtbaar blijven en dit leidt bij veel patiënten tot een levenslang esthetisch probleem. Voor deze patiëntengroep zijn de huidige mondzorgprogramma's duidelijk niet effectief.

Mondzorgprogramma's ter preventie van wittefleklaesies moeten niet alleen gezond gedrag initiëren, maar ook duurzame gedragsverandering bewerkstelligen. Onderzoek heeft aangetoond dat programma's die zich richten op de causale factoren van het gedrag (gedragsdeterminanten) met succes gedrag veranderen en deze gedragsverandering bestendigen. Onderzoekers hebben verschillende gedragstheorieën ontwikkeld en getest. In deze theorieën worden gedragsdeterminanten geïdentificeerd en wordt aangegeven hoe de determinanten het gedrag beïnvloeden. Het toepassen van relevante gedragstheorieën kan mogelijk de effectiviteit van preventieprogramma's vergroten.

Volgens motivationele gedragstheorieën, zoals de Theorie van Gepland Gedrag, is een intentie (of motivatie) de belangrijkste psychosociale determinant van het gezondheidsgedrag. Veel van deze gedragstheorieën beschrijven determinanten die betrokken zijn bij het vormen van een intentie (pre-intentionele factoren), maar gaan niet in op de factoren die betrokken zijn bij de vertaling van een intentie naar actie (post-intentionele factoren). Theorieën die naast pre-intentionele factoren ook de post-intentionele factoren bevatten, zoals de 'Health Action Process Approach' (HAPA) theorie en de zelfregulatietheorie, blijken succesvol gedrag te verklaren en effectief te zijn bij het veranderen van een reeks gezondheidsgedragingen. Ondanks dat de toepassing van deze theorieën binnen de gezondheidszorg tot succesvolle gedragsverandering heeft geleid, zijn deze theorieën nog niet toegepast in de orthodontie.

Volgens de HAPA-theorie omvat het veranderen van het gezondheidsgedrag twee opeenvolgende fases; de eerste fase is de motivatiefase (pre-intentionele fase) en komt grotendeels overeen met het theoretische raamwerk van de meeste motivatio-

nele theorieën. De tweede fase is de actiefase (post-intentionele fase), die zich richt op de cognities die betrokken zijn bij het plannen, initiëren en zelfreguleren van acties nadat een intentie gevormd is. Deze fase legt nadruk op de rol van eigen-effectiviteit met betrekking tot terugvalpreventie en instandhouding van het gedrag, het vermogen om de actie te reguleren ('action control'), het beramen van het gedrag ('action planning') en het anticiperen op barrières en mogelijke oplossingen ('coping planning'). De zelfregulatietheorie verschaft inzicht in de gedragsprocessen die nodig zijn voor de zelfregulatie (of het zelfmanagement) om een gedragsdoel te bereiken.

'Smartphones' bieden vanwege de functionaliteit en het bereik de mogelijkheid om preventieve mondzorg te leveren. Het aanbieden van zorg via mobiele apparaten wordt 'Mobile Health' (mHealth) genoemd. Onderzoek dat de effecten van mHealth programma's evalueerde heeft aangetoond dat de mondhygiëne kan worden verbeterd door middel van preventieprogramma's via 'smartphones'. Dit onderzoek heeft echter geen theorie voor het programmaontwerp en de onderzoeksopzet gebruikt, met als gevolg dat het effect op de determinanten niet is gemeten en de programma's weinig gedragsmethodieken bevatten. Hierdoor is binnen de orthodontie onduidelijk welke specifieke factoren bijdragen aan de gedragsverandering. Bovendien is de opzet van deze evaluatiestudies van onvoldoende kwaliteit en/of verstrekken deze studies weinig tot geen details over de inhoud van het programma. Dit beperkt de mogelijkheid om programma's te reproduceren en/of effectievere programma's te ontwerpen.

'Intervention Mapping' is een beslissingsprotocol dat richtlijnen en werkdOCUMENTEN biedt om stapsgewijs, op basis van wetenschappelijk bewijs, gezondheidsprogramma's te ontwikkelen en te implementeren. Door het systematische gebruik van empirische gegevens en theoretische inzichten te begeleiden, helpt 'Intervention Mapping' onderzoekers bij het identificeren en selecteren van determinanten en deze te koppelen aan geschikte gedragsmethodieken. In dit proefschrift is 'Intervention Mapping' toegepast om op een planmatige wijze een mondzorg app voor jongeren met een vaste beugel te ontwikkelen en te evalueren. Hiermee beoogt het proefschrift een bijdrage te leveren aan de basis voor wetenschappelijk bewijs voor interventieontwikkeling binnen de mondzorg.

De hoofddoelstelling van dit proefschrift was het ontwikkelen en evalueren van een smartphone app, de WitGebit app, ter bevordering van de mondhygiëne en het mondgezondheidsgedrag bij beugeldragende jongeren in de leeftijd van 12 tot 16 jaar. Om de app te kunnen richten op het mondgezondheidsgedrag en de daaraan gerelateerde determinanten van jongeren in deze leeftijdsgroep, was het noodzakelijk om inzicht te verkrijgen in deze gedragingen en de onderliggende factoren door het uitvoeren van drie onderzoeken: een systematische review met meta-analyse (hoofdstuk 2), een cross-sectioneel onderzoek (hoofdstuk 3) en een kwalitatief onderzoek (hoofdstuk 4).

Hoofdstuk 2 presenteert een systematisch literatuuronderzoek met meta-analyse naar de psychosociale factoren van mondhygiënegedrag bij jongeren van 9 tot 19 jaar. In dit literatuuronderzoek werden de data van 27 afzonderlijke onderzoeken (gepresenteerd in 22 publicaties) geanalyseerd. Een onderzoek was geschikt voor inclusie wanneer het de associatie tussen de psychosociale factoren en het mondhygiënegedrag evalueerde. De metingen van het gedrag varieerden van zelfrapportages tot klinische metingen, waaronder plaque- en bloedingsscores. De resultaten van het literatuuronderzoek lieten zien dat de psychosociale factoren die deel uitmaken van de HAPA-theorie (met name: 'eigen-effectiviteit', 'intentie', 'houding', 'sociale invloeden', 'coping planning' en 'action planning') positief geassocieerd waren met het mondhygiënegedrag.

De onderzoeksopzet van de geïncludeerde studies was voornamelijk gebaseerd op de motivationele theorieën, zoals de Theorie van Gepland Gedrag. Slechts zelden is geprobeerd het gedrag te verklaren op basis van theorieën die de psychosociale factoren van de post-intentionele-fase bevatten. Hierdoor zijn de psychosociale factoren die het belangrijkst blijken te zijn bij het verklaren van het mondhygiënegedrag (de factoren die de hoogste gewogen correlatiecoëfficiënt hadden), zoals de post-intentionele factoren 'action planning' en 'coping planning', zelden bestudeerd. Op basis van deze bevindingen, concludeerden we dat het mondhygiënegedrag beter verklaard kan worden door gebruik van alternatieve theorieën die rekening houden met deze belangrijke factoren door zich focussen op post-intentionele fase van het gedragsproces, zoals de HAPA-theorie.

Omdat het literatuuronderzoek van toepassing was op jongeren in het algemeen, en niet specifiek op jongeren met een vaste beugel, voerden we een cross-sectioneel onderzoek uit om te onderzoeken of de bevindingen van het literatuuronderzoek eveneens van toepassing zijn op jongeren met een vaste beugel. **Hoofdstuk 3** presenteert dit cross-sectioneel onderzoek, waarin middels toepassing van de HAPA-theorie, is nagegaan in hoeverre psychosociale factoren geassocieerd zijn met de aanwezigheid van tandplaque en de frequentie van het mondhygiënegedrag van jongeren met een vaste beugel. Honderd zestien beugeldragende jongeren, die geworven zijn in een orthodontiepraktijk in Almere (Nederland), vulden een vragenlijst in ter evaluatie van hun mondhygiënegedrag en psychosociale HAPA-factoren. Uit de resultaten van de lineaire regressieanalyse bleek dat minder tandplaque voornamelijk verband hield met een frequenter gebruik van een rager ($R^2 = 45\%$). Het gebruik van een rager was vervolgens geassocieerd met een hogere intentie, eigen-effectiviteit over gedragscontrole en eigen-effectiviteit over gedragsonderhoud ($R^2 = 45\%$). De resultaten bevestigen dat de HAPA-theorie nuttig is in het verklaren van het mondhygiënegedrag van jongeren met een vaste beugel. Om deze reden is de Witgebit app op deze theorie gebaseerd.

Hoofdstuk 4 beschrijft de systematische ontwikkeling van de WitGebit app volgens ‘Intervention Mapping’. Om aanvullend inzicht te krijgen in het mondgezondheidsgedrag werden 20 Nederlandse jongeren met een vaste beugel geïnterviewd over hun mondgezondheidsgedrag. Uit de semigestructureerde interviews bleek dat aanbevolen mondhygiënehulpmiddelen, zoals de ragers, slechts af en toe gebruikt werden, omdat het gebruik van deze hulpmiddelen overbodig werd geacht. Hoewel de meeste respondenten in staat waren hun tanden twee keer per dag te poesten, slaagden zij er vaak niet in om zo lang te poetsen als aanbevolen. De respondenten waren zich niet bewust van het voordeel van fluoride, waardoor zij ook niet bewust kozen voor het gebruik van fluoridemondspoeling als preventief middel. De bevindingen van deze semigestructureerde interviews, de HAPA-theorie en de zelfregulatie theorie werden gebruikt om specifieke programmadoelstellingen te definiëren. Om deze programmadoelstellingen te bereiken identificeerden en selecteerden we gedragsmethodieken die verwerkt werden in de app, waaronder het verstrekken van mondgezondheidsinformatie en gepersonaliseerde feedback, het aanmoedigen van het zelfmonitoren van gedrag en het opstellen van actie- en copingplannen, en het versturen van herinneringen. Vervolgens werden deze technieken vertaald naar praktische strategieën, zoals video’s en een poetstimer. Deze strategieën werden daarna gecombineerd in een programma dat resulteerde in de WitGebit app.

De WitGebit app is een zelfsturend programma ter verbetering van het mondgezondheidsgedrag en de mondhygiëne van jongeren met vaste apparatuur en is te gebruiken in de thuissituatie. De app richt zich op de twee mondgezondheidsgedragingen (en de gerelateerde psychosociale factoren die zijn geïdentificeerd door de HAPA-theorie): (1) het onderhouden van een goede mondhygiëne (het beheersen van een goed tandplaqueniveau), en (2) het gebruik van een voldoende hoeveelheid fluoride. Na de installatie van de app dienen de jongeren een aantal registratievragen te beantwoorden en persoonlijke informatie omtrent hun mondverzorging te verstrekken. Op basis van deze informatie verstrekt de app gezondheidsrisico-informatie, persoonlijk advies en instructies in korte video’s.

Vervolgens helpt de app jongeren persoonlijke doelen voor het verbeteren van de mondgezondheid op te stellen, actieplannen te maken en herinneringen in te stellen. Dagelijks stuurt de app tekstberichten om de jongeren te herinneren hun dagelijkse mondverzorging in de app bij te houden en de poetstimer, die het tandpoetsen ondersteunt, te gebruiken. Wanneer jongeren besluiten hun tanden te poetsen, kunnen ze de poetstimer aanzetten. Na het gebruik van de poetstimer zal de app de gebruiker complimenteren.

Elke week vraagt de app de jongeren om hun tandplaqueniveaus en gedragsdoelen te evalueren. Voor de evaluatie worden de jongeren verzocht tabletten te gebruiken die

tandplaque zichtbaar maakt, vervolgens een selfie te maken van het resultaat, en aan te geven welk gebied bedekt is met tandplaque. Op basis van zowel de informatie die wordt verkregen via de selfie als de informatie over de uitgevoerde mondverzorging concludeert de app of de doelen behaald zijn. De app complimenteert gebruikers vervolgens met het gebruik van de app en begeleidt hen indien nodig bij het stellen van doelen of het aanpassen van bestaande doelen, en helpt bij het maken van copingplannen. Deze plannen gebruiken een alsdan formulering om aan te geven hoe om te gaan met moeilijke situaties. Deze copingplannen worden gevormd door de jongeren te laten anticiperen op mogelijke belemmeringen en door oplossingen te formuleren hoe met deze belemmeringen om kan worden gegaan. Gepersonaliseerde tekstberichten worden verzonden om de jongeren eraan te herinneren dat zij de app dienen te gebruiken en de mondverzorging uit te voeren.

Om het succes van de implementatie te vergroten, werden in het ontwikkelingsproces zowel tandheekkundige zorgverleners als jongeren met een vaste beugel betrokken. Uit het pilotonderzoek bleek dat de app-gebruikers de app waardeerden en leuk vonden. Het pilotonderzoek toonde ook een acceptabele score voor de gebruiksvriendelijkheid (SUS = 77).

Hoofdstuk 5 presenteert het onderzoeksprotocol van het gerandomiseerd gecontroleerd onderzoek om de effectiviteit van de WitGebit app te bepalen. Om de effectiviteit te bepalen, onderzochten we de effecten op tandplaque en gingivale bloedingen, evenals de effecten op zelfgerapporteerd mondgezondheidsgedrag en daaraan gerelateerde psychosociale factoren. Tijdens drie orthodontische controles werden metingen uitgevoerd, bestaand uit: een nulmeting, een meting na zes weken en na twaalf weken.

Hoofdstuk 6 presenteert de resultaten van het gerandomiseerd gecontroleerd onderzoek, waarbij de interventiegroep, die naast de gebruikelijke zorg de WitGebit app gebruikte, werd vergeleken met de controlegroep die alleen de gebruikelijke zorg ontving. De gebruikelijke zorg omvatte routinematige mondgezondheidsvoorlichting en -instructie tijdens de reguliere orthodontische afspraken. Patiënten in de leeftijdscategorie van 12 tot 16 jaar met een vaste beugel werden geworven in twee orthodontiepraktijken in het westen van Nederland. Na de baselinemetingen werden 132 jongeren willekeurig toegewezen aan de interventiegroep (WitGebit app; $n=67$) of de controlegroep (gebruikelijke zorg; $n=65$). Na 6 weken toonden de 'mixed model' analyses een grotere afname in de bloedingen in de interventiegroep ten opzichte van de controlegroep ($p=0,031$). Na 6 weken was het effect van de app op de totale hoeveelheid tandplaque niet statistisch significant ($p=0,143$), maar na 12 weken was de plaqueaccumulatie significant verminderd ten opzichte van de controlegroep

($p=0,019$). Hoewel de frequentie en duur van het tandenpoetsen niet significant veranderde gedurende de interventieperiode, blijkt na 12 weken uit de daling van het aantal vlakken dat bedekt was met plaque dat de poetsmethode veranderde ($p=0,007$). Na 6 weken toonde de interventiegroep significante verbeteringen in de intentie om fluoridemondspoeling te gebruiken, alsook het gebruik hiervan en de 'coping planning' met betrekking tot het tandenpoetsen. Na 12 weken was alleen het effect op 'coping planning' en intentie nog statistisch significant. Deze resultaten laten zien dat het aanbieden van een preventieprogramma, ter verbetering van de mondgezondheid, via een smartphone app, naast de gebruikelijke zorg, een effectief middel is om de hoeveelheid tandplaque te verminderen bij jongeren tussen 12 en 16 jaar met een vaste beugel. De mondhygiëne in de studiepopulatie was echter na de interventieperiode nog steeds niet optimaal. Dit geeft aan dat meer onderzoek vereist is om de huidige orthodontische zorg door het gebruik van mHealth te verbeteren.

Appendices



APPENDICES

OVERVIEW OF AUTHOR'S CONTRIBUTIONS

Author's contributions to manuscript 1: Scheerman JFM, van Loveren C, van Meijel B, Dusseldorp E, Wartewig E, Verrips GHW, Ket JCF, van Empelen P. Psychosocial correlates of oral hygiene behavior in people aged 9 to 19 – a systematic review with meta-analysis. *Community Dent Oral Epidemiol* 2016;44(4):331-41. PMID:26952723

JS and JK designed the comprehensive search strategy. JS and EW independently selected the studies and assessed the methodological quality of the selected studies. JS performed data extraction. PE checked the data extraction. JS wrote the first draft of the protocol. All authors contributed to the writing of the manuscript through its various amendments. All authors reviewed and approved its final version.

Author's contributions to manuscript 2: Scheerman JFM, van Empelen P, van Loveren C, Pakpour AH, van Meijel B, Gholami M, Mierzaie Z, van den Braak MCT, Verrips GH. An application of the Health Action Process Approach model to oral hygiene behavior and dental plaque in adolescents with fixed orthodontic appliances. *Int J Paediatr Dent* 2017;27(6):486-95. PMID:28176383

JS, PE and AP conceived the ideas. ZM and MB collected and entered the data. JS performed the analyses. PE and AP checked the analyses. JS wrote the first draft of the manuscript. EP, CvL, AP, BvM, MG supervised the writing. All authors reviewed and approved its final version.

Author's contributions to manuscript 3: Scheerman JFM, van Empelen P, van Loveren C, van Meijel B. Systematic development of WhiteTeeth, a smartphone application to promote good oral health behavior among Dutch adolescents with fixed orthodontic appliances. An Intervention Mapping Approach. *JMIR mHealth and uHealth*. 2018 (forthcoming/in press) DOI: 10.2196/mhealth.9626. URL: <http://preprints.jmir.org/preprint/9626>

JS designed and analysed the semi-structured interviews, collected data, and was responsible for obtaining ethical approval for these interviews. JS and PE formulated the performance and change objectives, and selected the theoretical methods and practical strategies. JS and CvL created the if-then algorithm. JS designed the WhiteTeeth app and pilot-tested the app. JS wrote the first draft of the manuscript. PE, BvM and CvL supervised the writing of the manuscript. All authors reviewed and approved its final version.

APPENDICES

Author's contributions to manuscript 4: Scheerman JFM, van Meijel B, van Empelen P, Kramer GJC, Verrips GHW, Pakpour AH, van Den Braak MCT, van Loveren C. 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. BMC Oral Health, 2018;18(1):19. PMID: 26952723.

JS designed the evaluation and was responsible for obtaining ethical approval for the trial. JS (principal researcher) wrote the first draft of the protocol. All authors contributed to the development of the protocol through its various amendments. BvM, PvE, GK, EV, AP and CvL supervised the writing of the manuscript. All authors reviewed and approved its final version.

Author's contributions to manuscript 5: Scheerman JFM, van Meijel B, van Empelen P, Verrips GHW, van Loveren C, Twisk JWR, van Den Braak MCT, Pakpour AH, Kramer GJC. The effectiveness of the WhiteTeeth app, a theory-based oral health promotion program for adolescent orthodontic patients – A Randomized Controlled Trial. To be submitted to the Journal of Medical Internet Research.

JS wrote the first draft of the protocol. JS, GK, and MvdB coordinated the data collection. JS and MvdB collected, managed and restructured the data. JS performed the analyses. PE, AP and JT were consulted for statistical guidance and checked the analyses. BvM, PE, EV, CvL, JT, AP and GK supervised the writing. All authors reviewed the manuscript and approved its final version.

APPENDICES

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Mijn lieve zus, Nicolien, psycholoog, communicatiewetenschapper (MSc²) en mijn grote voorbeeld. Wat lijken we op elkaar en zijn er veel overeenkomsten in onze interesses. Ik ben mij meer gaan verdiepen in de psychologie en jij bent gaan doceren. Je kent mij als geen ander. Na mijn master adviseerde je mij dat het onderwerp van mijn promotieonderzoek mij jarenlang zou moeten interesseren. Jij gaf mij de tip om meer met mijn creatieve kant te doen. Een combinatie leek mij daarom perfect, mijn creativiteit benutten om een app te ontwerpen en mijn wetenschappelijke kennis aanwenden om onderzoek uit te voeren. Fijn dat je altijd in mij gelooft. Dank voor het meedenken tijdens de ontwikkeling van de app. Als 'child-expert' kon je me goed adviseren over de "do's en don'ts" bij de doelgroep. Bedankt dat jij de rol als reserveparanimf geaccepteerd hebt. Rens, ik had mij geen betere zwager kunnen

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APPENDICES

ABOUT THE AUTHOR

Janneke Scheerman was born in Heemskerk, the Netherlands on 2 June 1986. With her older sister Nicolien and younger brother Kees, she was raised in a warm family environment in Bakkum.

After graduating from high school in Castricum in 2003, she studied at Inholland University of Applied Sciences in Amsterdam, where she received her Bachelor's degree in Oral Hygiene in 2007. In the same period, she spent several months attending additional dental courses at the University of Karlstad in Sweden. After graduation, she worked variously as a lecturer in Oral Hygiene at Inholland University, and as a freelance model and an oral hygienist.



In 2010, she received her Master's degree in Health Sciences (Prevention and Public Health) from the VU University Amsterdam. During her Master's program, she became interested in using Intervention Mapping to develop an app that would promote oral health in adolescent patients. To further pursue this interest alongside her full-time work as a university lecturer, she developed a PhD research proposal and was awarded a grant by Inholland to support her PhD research.

Janneke started her PhD research at the Academic Center for Dentistry Amsterdam (ACTA) in 2012, and worked as a guest researcher at the Department of Child Health in the Netherlands Organization for Applied Scientific Research (TNO) in Leiden. In addition to her PhD research, she continued working part-time as a university lecturer. As part of her PhD training, she also became a member of the Mental Health (GGZ) Nursing research group at Inholland.

Janneke currently lives in Amsterdam, where she continues her work as a lecturer in the Department of Oral Hygiene at Inholland. She is involved in various international research projects in mHealth, behavior change and health promotion. In her spare time she enjoys practicing yoga, traveling, painting and illustrating.

APPENDICES

PhD PORTFOLIO

Scientific Publications

Scheerman, J.F.M., van Empelen, P., van Loveren, van Meijel., B. (2018) A mobile app (White-teeth) to promote good oral health behavior among Dutch adolescents with fixed orthodontic appliances: Intervention Mapping approach. *JMIR mHealth and uHealth*, 6(8),e163. DOI:10.2196/mhealth.9626.

Scheerman, J.F.M., van Meijel., B., van Empelen, P., Kramer, G.J.C., Verrips, G.H.W., Pakpour, A.H., van den Braak, M.C.T., van Loveren, C. (2018) Study protocol for 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. *BMC Oral Health*, 18(1),19.

Scheerman, J.F.M., van Empelen, P., van Loveren, C., Pakpour, A.H., van Meijel, B., Gholami, M., van den Braak, M.T.C., Mierzaie, Z., Verrips, G.H.W. (2017). An application of the Health Action Process Approach model to oral hygiene behaviour and dental plaque in adolescents with fixed orthodontic appliances. *International Journal of Pediatric Dentistry*, 27(6), 486-495.

Lin, C. Y., Scheerman, J. F.M., Yaseri, M., Pakpour, A. H., Webb, T. L. (2017). A cluster randomised controlled trial of an intervention based on the Health Action Process Approach for increasing fruit and vegetable consumption in Iranian adolescents. *Psychology & Health*, 1-20.

Scheerman, J.F.M., van Loveren, C., van Meijel, B., Dusseldorp, E., Wartewig, E., Verrips, G.H.W., Ket, J.C.F., van Empelen P. (2016) Psychosocial correlates of oral hygiene behaviour in people aged 9 to 19 – a systematic review with meta-analysis. *Community Dentistry and Oral Epidemiology*, 44(4), 331-41.

Pakpour, A. H., Kumar, S., Scheerman, J. F.M., Lin, C. Y., Fridlund, B., Jansson, H. (2016). Oral health-related quality of life in Iranian patients with spinal cord injury: A case-control study. *Injury*, 47(6), 1345-1352.

Mey, L., Çömlekçi, C., Reuver, F., Waard, I., Gool, R., Scheerman, J. F.M., van Meijel, B. (2016). Oral Hygiene in Patients With Severe Mental Illness: A Pilot Study on the Collaboration Between Oral Hygienists and Mental Health Nurses. *Perspectives in psychiatric care*, 52(3),194-200.

Submitted Publications

Scheerman, J.F.M., van Meijel., B., van Empelen, P., Verrips, G.H.W., van Loveren, C., Twisk J.W.R., van den Braak, M.T.C., Pakpour, A.H., Kramer, G.J.C., (2018) The effectiveness of the WhiteTeeth app, a theory based oral health promotion program for adolescent orthodontic patients – A Randomized Controlled Trial. To be submitted to the Journal of Medical Internet Research.

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Scheerman, J.F.M, Hamilton, K., Sharif, O., Pakpour, A.H. (2018) The effectiveness of a social media-based oral health promotion program for Iranian adolescents – A Randomized Controlled Trial. To be submitted to the Journal of Dental Research. To be submitted to the Journal of Dental Research.

PhD Training

General courses - Year Workload (ECTS)

2017	Mixed Models/Multilevel Statistical Analysis (3 ECTS). <i>Epidm - VU University of Amsterdam; Amsterdam, the Netherlands.</i>
2017	English Writing and Presenting (4 ECTS). <i>Academic Centre for Dentistry Amsterdam; Amsterdam, the Netherlands.</i>
2017	Scientific Integrity (2 ECTS). <i>Epidm - VU University of Amsterdam; Amsterdam, the Netherlands.</i>
2016	Statistics and Methodology (3 ECTS). <i>Academic Centre for Dentistry Amsterdam; Amsterdam, the Netherlands.</i>
2015	Qualitative Analysis (3 ECTS) <i>Epidm - VU University of Amsterdam; Amsterdam, the Netherlands.</i>
2013	Behaviour Change and Complex Interventions: Design and Evaluation Multiphase Optimization Strategy (MOST) (1 ECT) <i>University College London (UCL); London, England.</i>
2012	Didactic Light (3 ECTS) <i>Inholland University; Amsterdam, the Netherlands.</i>

Poster presentations

2018	A Social Media-based Program Improved Oral Health Among Iranian Adolescents <i>International Association for Dental Research (IADR) Congress. London, England.</i>
2018	The effectiveness of the WhiteTeeth App on oral hygiene – a randomized controlled trial <i>European Organisation for Caries Research (ORCA) Congress. Copenhagen, Denmark.</i> Scheerman, J. F.M., van den Braak, M.C.T., Verrips, G.H.W., van Empelen, P., van Meijel, B., Somi, L., Boezewinkel, M., van Loveren, C., Kramer., G.J.C. (2018) Caries Res; 52: 468-547. DOI: 10.1159/000488302. (Conference paper)

2015	<p>Patients' evaluation of the content, appeal and usability of a dental smart-phone application–'GezondeMond app. <i>European Health Psychology Society (EHPS) Congress. Limassol, Cyprus.</i></p> <p>Scheerman, J. F.M., van Empelen, P., Parisius, K. G., Lelieveld, A. E., van der Veen, M. H. (2015). Patients' evaluation of the content, appeal and usability of a dental smart-phone application–'GezondeMond app.'. <i>European Health Psychologist</i>, 17(S), 834. (Conference paper)</p>
Oral presentations	
2018	<p>"The effectiveness of the WhiteTeeth app" (60 min) Department Preventive Dentistry; Academic Centre for Dentistry Amsterdam, Amsterdam, the Netherlands</p>
2016	<p>"Gedragmodellen toepassen in de praktijk" (Translating behaviour-change theories into practice) (75 min) <i>Nederlandse Vereniging voor Mondhygienisten (NVM) (A meeting of the Dutch Society for Dental Hygienists), Nieuwegein, the Netherlands</i></p>
2015	<p>"De WITGEBIT mondzorg app. – een planmatige aanpak" (The WhiteTeeth oral self-care app – a systematic approach) (60 min) <i>Department Orthodontics; Academic Centre for Dentistry Amsterdam, Amsterdam, the Netherlands.</i></p>
2015	<p>"Coaching for oral health care" (60 min) <i>Philips Design and Research, Philips Campus, Eindhoven, the Netherlands.</i></p>
2015	<p>"WitGebit, de mondzorg app." (WhiteTeeth, the oral self-care app) (30 min) <i>Seminar ICT in de zorg; Inholland University, Amsterdam, the Netherlands.</i></p>
2015	<p>"Oral health behaviour change" (45 min) <i>Department Oral Hygiene, University of Copenhagen, Copenhagen, Denmark.</i></p>
2015	<p>Hoe beïnvloed je het mondygiënegedrag? (How do you change oral health behaviour?) (90 min) <i>Department Orthodontics. Medical Centre of Alkmaar (Noordwest Ziekenhuis-groep) Alkmaar, the Netherlands.</i></p>
2014	<p>Behavioural determinants of dental health behaviour: a meta-analytic review (30 min) <i>European Health Psychology Society (EHPS) Congress; Innsbruck, Austria</i></p> <p>Scheerman, J. F. M., Dusseldorp, E., Wartewig, E., van Meijel, B., van Loveren, C., van Empelen, P. (2014). Behavioural Determinants of Dental Health Behaviour: a Meta-Analytical Review. <i>European Health Psychologist</i>, 16(S), 598. (Conference paper)</p>

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2014	Behavioural determinants of dental health behaviour: a meta-analytic review (30 min) <i>Department Child Health, TNO research group, Leiden, the Netherlands.</i>
2013	Behavioural smartphone application to improve dental compliance in orthodontics (20 min) <i>Department Social Dentistry; Academic Centre for Dentistry Amsterdam, Amsterdam, the Netherlands.</i>
2013	Behavioural smartphone application to improve dental compliance in orthodontics (20 min) <i>Department Preventive Dentistry; Academic Centre for Dentistry Amsterdam, Amsterdam, the Netherlands.</i>
Other	
From 2018	Editorial member of the journal Social Health and Behavior (http://www.shbonweb.com/)
From 2018	Member of the e-Oral Health Network (IADR)
From 2016	Reviewer for several scientific journals
From 2012	Member of the Mental Health (GGZ) Nursing research group

A stylized illustration of a hand holding a smartphone. The hand is rendered in a light pinkish-red color with simple, rounded shapes for the fingers and palm. The smartphone has a dark blue or black frame. The screen is a light pinkish-red color and displays a quote in black, sans-serif font. The quote is: "The new media are not ways of relating us to the 'real' world; they are the real world." Below the quote, the name "MARSHALL MCLUHAN" is written in a smaller, bold, black, sans-serif font. The background is a solid, light gray color.

**"The new media are not
ways of relating us to the
'real' world; they are the
real world."**

**MARSHALL
MCLUHAN**

The WhiteTeeth app

The development and evaluation of a smartphone app for promoting oral health behavior and oral hygiene in adolescent orthodontic patients

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. As the opacity or discoloration of these lesions can seriously compromise dental aesthetics, orthodontic treatment may not be entirely successful. It is therefore necessary to establish the extent to which innovative oral health promotion programs can further improve patients' oral health behaviors and outcomes. However, little is known about the effectiveness of continuous behavioral support via mobile phones (mHealth).

This thesis describes the development and evaluation of a mobile app—the WhiteTeeth app—that was designed to promote good oral health behavior among adolescent orthodontic patients. The app's development was guided by intervention mapping (IM). Development thus starts with an analysis of the health problem, which includes identification of the psychosocial factors related to the health behavior. To identify the psychosocial factors underlying oral health behavior in our target group, we conducted a systematic literature review with meta-analysis and a cross-sectional clinical study. Then, to target these psychosocial factors and facilitate continuous behavioral support, various behavior change techniques were incorporated into the app.

The app provides feedback on users' oral health behavior and allows users to evaluate and monitor their behavior. Finally, a randomized controlled trial was conducted. This showed that the app improved oral hygiene in adolescent orthodontic patients.

