The WhiteTeeth app to promote oral hygiene

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27130

Source
Nationaal Trial Register

Health condition

Oral hygiene, prevention of dental caries, WhiteTeeth app, smartphone intervention, psychosocial factors, oral health behavior; Witgebit app.

Sponsors and support

Primary sponsor: no sponsors.
Source(s) of monetary or material Support: no funding sources.

Intervention

Outcome measures

Primary outcome

The primary outcomes of the study are the presence of dental plaque (measured with a modified Silness and Loë Plaque Index), gingival bleeding (measured with the Bleeding on Marginal Probing Index), and self-reported oral health behaviors. The plaque index will be used to describe the amount of plaque on the buccal surfaces of the first premolars, canines and incisors using a mouth mirror and a probe. The buccal surface of each tooth is divided into four zones according the position of the orthodontic bracket: mesial, distal, gingival and incisal to the bracket. Each of the four sites of the buccal tooth surface is given a score from

0 (absence) to 3. For the bleeding score, three sections (mesio-vestibular, vestibular, disto-vestibular) of the vestibular surfaces of the first premolar, canines and incisors will be assessed to determine whether probing elicited marginal bleeding (score 1) or not (score 0). Data are collected at baseline, and 6 and 12 weeks follow-up.

Secondary outcome

Secondary outcomes include changes in psychosocial factors of the HAPA model, such as outcome-expectancies, intention, action-self-efficacy, coping planning and action control. A self-administered digital questionnaire contains questions with both single and multiple response items concerning oral health behaviors and their psychosocial factors. Data are collected at baseline, and 6 and 12 weeks follow-up.

Study description

Background summary

This study is a parallel randomized controlled trial with two conditions: the experimental group, which receives the WhiteTeeth app in addition to care as usual, and the control group receiving only care as usual. The WhiteTeeth app is a smartphone app which targets oral health behavior of adolescents with fixed orthodontic appliances. The primary outcomes are the presence of dental plaque, bleeding index and self-reported oral health behaviors. Data will be collected during three orthodontic check-ups: baseline (T0), 6 weeks (T1) and 12 weeks of follow up (T2).

Study objective

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

Study design

Data will be collected during three orthodontic check-ups: baseline (T0), 6 weeks (T1) and 12 weeks of follow up (T2).

Intervention

This study is a parallel randomized controlled trial with two conditions: the experimental group, which receives the WhiteTeeth app in addition to care as usual, and the control group receiving only care as usual. The WhiteTeeth app is a smartphone app which targets oral health behavior of adolescents with fixed orthodontic appliances. The ‘White-teeth’ app integrates several behavior change techniques including information on health consequences, demonstration of the desired behavior, self-monitoring, implementation intentions or planning, volitional sheets, and reminders. Participants in the intervention group receive twelve disclosing tablets (Gum® Red-Cote®) to visualize dental plaque. During the intervention period the participants will monitor their dental plaque levels by taking a selfie of their teeth, and designate the visualized plaque on the selfie.

Contacts

Public
Hogeschool Inholland Amsterdam

Janneke F.M. Scheerman
De Boelelaan 1109

Amsterdam 1081HV
The Netherlands
Mob: +31 630 9887 01
Scientific
Hogeschool Inholland Amsterdam

Janneke F.M. Scheerman
De Boelelaan 1109

Amsterdam 1081HV
The Netherlands
Mob: +31 630 9887 01

Eligibility criteria

Inclusion criteria

Patients are eligible for the study if they meet the following criteria:

- Boys and girls aged 12 to 16

- For at least 1,5 month maxillary and mandibular fixed orthodontic appliance therapy, which consists of bonding of at least premolar-to-premolar with edgewise appliances and their modifications.

- Not scheduled to remove fixed orthodontic treatment before the end of the study.

- Able to perform their own oral hygiene activities, without physical and/or mental disabilities.

- Not engaged in other oral health education or research program.

- No enamel and dentine dysplasia and/or craniofacial malformation (e.g. cleft).

- Sufficient command of the Dutch language.

- In the possession of smart-phone with the software IOS >7 or Android > 4.1.

- Patients and their parents are able or willing to give informed consent.

- Patients that have not use medication that may affect plaque accumulation, for example antibiotics and antibacterial mouth rinses.

- All patients in the study receive upper and lower fixed orthodontic treatment.

Exclusion criteria

See the inclusion/eligibility criteria.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	02-12-2016
Enrollment:	144
Type:	Unknown

Ethics review

Positive opinion Date:	20-02-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6059
NTR-old	NTR6206
Other	The Medical Ethics Committee of VU Medical Centre of Amsterdam : protocol. nr. 2016.162

Study results