The WhiteTeeth app to promote oral hygiene

Gepubliceerd: 20-02-2017 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27130

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: no sponsors.
Overige ondersteuning: no funding sources.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

See the inclusion/eligibility criteria.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	02-12-2016
Aantal proefpersonen:	144
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	20-02-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten