

Interdental brush and waterflosser on gingival bleeding and gingival abrasions. A 4 weeks randomized clinical trial.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24237

Source

NTR

Brief title

WATER

Health condition

Gingivitis

Gingival abrasion

Sponsors and support

Primary sponsor: ACTA-ADR B.V.

Source(s) of monetary or material Support: Water Pik, inc.

Intervention

Outcome measures

Primary outcome

Bleeding upon Pocket probing (BOPP)

Secondary outcome

- Bleeding On Marginal Probing (BOMP)
- Modified gingival abrasion index
- Subjects' attitude towards the study protocol and study products according to a questionnaire
- Clinical photos taken of the buccal aspect of teeth from cuspid to cuspid

Study description

Background summary

The toothbrush does not adequately reach the interproximal surfaces of the teeth. As gingivitis and periodontitis are usually more pronounced in the interdental areas than on the oral or facial surfaces in susceptible patients. The rationale is to determine the effectiveness of product Water Flosser with water and interdental brush on gingival bleeding and gingival abrasion and to evaluate subjects' attitudes towards the used products in this study.

Study objective

To assess the effect of the commercially available Water Flosser compared to interdental brushes evaluating gingival bleeding and gingival abrasions in a group of systemically healthy participants with gingivitis but without periodontitis.

Study design

Screening

Visit 1: baseline

Visit 2: week 2

Visit 3: week 4

Intervention

Test groep: Waterpik® with a classic standard jet tip (with water) + manual toothbrush with the use of a regular toothpaste

Control groep: Interdental brush Interprox+ manual toothbrush with the use of a regular toothpaste

Contacts

Public

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Eligibility criteria

Inclusion criteria

- Male and female
- Age 18-65 years
- Right handed brusher and writer
- Classified as systemically healthy
- Non-smokers (Lie et al. 1998) definition non-smoker: <1 cigarette every day for at least one year

- Moderate gingivitis (level of gingival bleeding assessed BOPP ; 50%)
- Minimum of 20 natural teeth, at least 5 evaluable in each quadrant available
- Buccal accessible interdental spaces to apply the interdental brush
- The interdental brushes must fit between at least 4 spaces per quadrant when approached buccally, of these 2 should be interdental spaces involving at least two spaces of the molar area.
- The other 2 spaces can be between the pre-molars, cuspid and incisors.

The participant is willing during the study:

- able to give written informed consent
- to brush with a manual toothbrush for the duration of the study.

Exclusion criteria

- Pockets deeper than 5mm (excluding distal of the last molars)
- Overt dental caries
- Oral lesions
- Usage of any interdental device as part of regular daily oral care
- Removable (partial) dentures
- Crowns, bridges and implant supported restorations
- Removable night guard
- Orthodontic banding (except for lingual retention wire)
- Oral and/or peri-oral piercings
- Dental student or dental professional
- Participation in a clinical study within the previous 30 days

General health:

- Medication, except for birth control pills
- Self-reported pregnancy or breastfeeding
- Use of antibiotics during the last 3 months
- Need of antibiotic prophylaxis prior to dental treatment
- Use of anti-inflammatory drugs on a regular basis

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	13-09-2016
Enrollment:	80
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 43014

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5893
NTR-old	NTR6081
CCMO	NL58265.018.16
OMON	NL-OMON43014

Study results

Summary results

N/A