The effect of manual toothbrushing on dental plaque in healthy subjects: using a pre- rinse and regarding brushing order -RCT-

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Primary Objective exp. 1:What is the effect of manual toothbrushing after pre-rinsing for 1 minute with water compared with toothbrushing without pre-rinsing on the level of post-brushing dental plaque in healthy subjects?Primary Objective exp. 2:…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41142

Source
ToetsingOnline

Brief title
Effect pre-rinsing and brushing order on dental plaque

Condition

- Other condition

Synonym
Pre- rinse and brushing order

Health condition

Tandplaque

Research involving

Human

Sponsors and support

Primary sponsor: ACTA Dental Research B.V. (ADR)
Source(s) of monetary or material Support: ACTA Dental Research B.V. ,The Procter & Gamble Company

Intervention

Keyword: Brushing order, Dental plaque, Manual toothbrushing, Pre- rinse

Outcome measures

Primary outcome

The main study parameter is the level of dental plaque measured by the modified

Silness & Löe Plaque Index.

Secondary outcome

Questionnaire regarding to oral hygiene and perception of the clinical study.

Assessment of plaque and oral health by use of a novel intra-oral camera.

Study description

Background summary

The clinical concepts established in the 1950s remain valid. Namely, that the maintenance of an effective plaque control is the cornerstone of any attempt to prevent and control periodontal diseases (Weijden van der & Hioe 2005). Toothbrushing is today the most widespread mechanical means of controlling plaque at home (Lang & Karring 1994). The efficacy of brushing with regard to plaque removal is dictated by three main factors: the design of the brush, the skill of the individual using the brush and the frequency and duration of use (Frandsen 1985). Toothbrushing techniques and procedures are thoroughly investigated to reach high quality of mechanical plaque-control, based on individual needs, which can efficiently prevent initiation (primary prevention) as well as recurrence (secondary prevention) of gingivitis and periodontitis.

Supragingival plaque is exposed to saliva and to the natural self-cleansing mechanisms existing in the oral cavity. However, although such mechanisms may

eliminate food debris, they do not adequately remove dental plaque (Weijden van der & Hioe 2005). Dawes et al. (1963) described plaque as the soft tenacious material found on tooth surfaces which is not readily removed by rinsing with water. However the high-speed camera videos as presented in Kronberg, Germany showed that pre-wetted plaque might be easier to remove.

Mandibular lingual surfaces demonstrate greater accumulations of both hard and soft deposits and more bleeding on probing than other areas of the mouth. Despite these findings, standard toothbrushing focuses little or no attention on this area. Suggested by Axelsson (Lang & Karring 1994) the toothbrush should first be applied to the lingual of the mandibular posterior teeth, on the right side, where most right-handed people do not use the toothbrush efficiently. Lingual plaque reaccumulates rapidly in this region, and is most adhesive: toothbrushing should commence there, while most toothpaste is on the brush and the bristles are most rigid. The mandibular buccal and occlusal surfaces should then be cleaned (Lang & Karring 1994). Dentists and hygienists have dealt with this problem by simply telling patients to brush the inside of the bottom teeth first (O*Hehir 1998).

Study objective

Primary Objective exp. 1:
What is the effect of manual toothbrushing after pre-rinsing for 1 minute with water compared with toothbrushing without pre-rinsing on the level of post-brushing dental plaque in healthy subjects?

Primary Objective exp. 2:
What is the effect of manual toothbrushing starting from the lingual aspect of the lower jaw compared with toothbrushing starting from the buccal aspect of the upper jaw on the level of post-brushing dental plaque in healthy subjects?

Secondary Objectives:
What is the opinion of the participants of the 48-hours non brushing protocol, the used toothbrush, the use of a dry/wet toothbrush and rinsing 1 minute of water?

Additional post-trial objective:
What is the difference between the plaque and gingivitis scores assessed orally and from an intra-oral photo taken with the SOPROCARE?

Study design

This study is a randomized, single-blind (examiner), two visits, split-mouth design.

Intervention

Intervention= 1 minute rinsing wil 15ml of Christaline SAINTE-SOPHIE bottled Spring water

Study burden and risks

Not applicable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- * 18 years - Classified as systemically healthy, assessed by the medical questionnaire - At least five evaluable teeth in each of the four quadrants excluding teeth with porcelain crowns - Presence of the *Ramfjord teeth* (Ramfjord 1959) or replacement teeth as proposed by

Wolf et al (2004) - Regular manual brushers - Right handed (right hand brushers) Participated and/or undergo screening for previous clinical research of the ACTA Department of Periodontology - Willing and able to give written informed consent - Agree to use throughout the study period the distributed products - Agree to brush only manually during the course of the study - Agree not to participate in any other clinical study for the duration of this study - Agree to delay any elective dentistry, including dental prophylaxis (except that provided in this study) until study completion - Agree to refrain from using any other oral care products (f.i. interdental cleaning aids) during the course of the study - Agree to refrain from brushing their teeth and from performing any other oral hygiene procedures for 48 hours prior to each visit.

Exclusion criteria

- Use of medication possibly influencing normal gingival health; use of antibiotics within 2 weeks before the first visit or anticipation of taking antibiotics during the course of the study; chronic use of non-steroidal anti-inflammatory drugs (NSAID*s) - Self-reported pregnancy or nursing
- Anyone presenting a probing depth * 5mm with bleeding on probing and attachment loss * 2 mm (Dutch Periodontal Screening Index (DPSI) * 3+)- Overt caries lesions - Presence of orthodontic banding (except for lingual retention wire), (removable) partial dentures or removable night guard
- Show evidence of any disease or conditions that could be expected to interfere with examination or outcomes of the study.- Dental student or dental professional.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	05-06-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	15-05-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL48620.018.14