

Preventive strategies in order to obtain healthy teeth for life

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Objective: The objective of the study is to evaluate the long-term effect of a short preventive intervention on oral health.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32996

Source

ToetsingOnline

Brief title

Healthy teeth 4life

Condition

- Other condition

Synonym

inflammation of the gingiva

Health condition

gingivitis

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Chlorhexidine, Gingivitis, Prevention

Outcome measures

Primary outcome

Primary parameters: Bleeding on Marginal Probing- Index.

Secondary outcome

Secondary parameters: Plaque Index and Staining-Index.

Study description

Background summary

Background: It is generally accepted that bacterial plaque is an important etiological factor of periodontal disease. Mechanical plaque removal is the primary method for controlling supra-gingival plaque. Patients' efforts are however often compromised by the presence of hard-to-reach areas as well as inadequate skill, poor motivation and lack of compliance. Consequently above the age of 35 almost everybody has inflamed periodontal tissues. Antimicrobial mouthrinses as adjuncts to mechanical oral hygiene regimens have been introduced as a means to enhance plaque removal. In 2 recent studies a stringent protocol of 1 oral hygiene instruction, 1 session of professional and 3 weeks of rinsing with chlorhexidine and sodiumperoxyborate significantly improved the level of gingival health which was maintained up to a subsequent period of 9 months. The design of the present study is based on a model as previously published by Svatun et al. (Svatun et al. 1987, Svatun et al. 1989) and will test the concept that good gingival health can be maintained by the use of a prophylactic aid.

Study objective

Objective: The objective of the study is to evaluate the long-term effect of a short preventive intervention on oral health.

Study design

Study design: 240 subjects will be divided *at random* among 6 groups. All 6 groups will perform a basic regime of 2x daily brushing with a standard toothbrush and toothpaste. Group 1 and 2 will brush only, group 3 will receive

additionally 1 oral hygiene instruction, group 4 will receive 1 professional prophylaxis, group 5 will rinse for 3 weeks with chlorhexidine and sodiumperoxyborate and group 6 will receive all 3 supplementary preventive interventions. Group 1 will be seen at baseline 3 weeks and 12 months while the other 5 groups will be seen at baseline, 3 weeks, 3, 6, 9 and 12 months.

Intervention

A basic regime of 2x daily brushing with a standard toothbrush and toothpaste.

- with no additional regimen OR
- with additionally 1 oral hygiene instruction OR
- with additional 1 professional prophylaxis OR
- with additional rinsing for 3 weeks with chlorhexidine and sodiumperoxyborate OR
- with additional a combination of 1 oral hygiene instruction, 1 professional prophylaxis and for 3 weeks rinsing with chlorhexidine and sodiumperoxyborate

Study burden and risks

n/a

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 of age, -a minimum of 5 evaluable teeth in each quadrant (with no partial dentures, orthodontic banding or wires) * 40% bleeding on marginal probing.

Exclusion criteria

-oral lesions and/or periodontal pockets >5 mm - pregnancy or systemic diseases such as diabetes

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	03-11-2009
Enrollment:	240
Type:	Anticipated

Ethics review

Approved WMO

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	NL28783.018.09