

# MANUAL TOOTHBRUSHES AND REVERSAL OF EXPERIMENTAL GINGIVITIS

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The aim of this study is to assess the effect of the CrossAction ProHealth toothbrush and the Advantage 123 toothbrush on gingival bleeding in a group of subjects who have been allowed to develop gingivitis by abstaining from oral hygiene for 21...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON32086

### Source

ToetsingOnline

### Brief title

Manual toothbrushing and reversal of experimental gingivitis

### Condition

- Other condition

### Synonym

inflammation of the gingiva

### Health condition

gingivitis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** The Procter & Gamble Company

**Source(s) of monetary or material Support:** Industrie

## Intervention

**Keyword:** bleeding, experimental gingivitis, manual toothbrush

## Outcome measures

### Primary outcome

Bleeding on Marginal Probing (BOMP) \* Angular Bleeding Index

### Secondary outcome

Quigley & Hein Plaque index

## Study description

### Background summary

The important relationship between the presence of plaque and the development of gingivitis was first proven in an experimental gingivitis study published in 1965 by Loe, Theilade and Jensen. In their study, subjects were allowed to neglect their oral hygiene and develop gingivitis, but once thorough toothbrushing was reinstated there was a rapid return to a plaque free condition that was followed within 5 days by a return to a gingival condition that was classified as healthy. Thus the importance of plaque control in the overall maintenance of good oral hygiene was established.

### Study objective

The aim of this study is to assess the effect of the CrossAction ProHealth toothbrush and the Advantage 123 toothbrush on gingival bleeding in a group of subjects who have been allowed to develop gingivitis by abstaining from oral hygiene for 21 days.

### Study design

The study is designed as a two treatment, examiner-blind, randomized, experimental gingivitis, split-mouth design study. A 3-week non-brushing period (experimental gingivitis) will be introduced to standardize the level of

gingivitis inflammation at the start of the actual experiment. This model will assess the reduction of gingivitis after this 3-week experimental gingivitis (EG) period comparing 2 manual brushes in a split-mouth design.

## **Intervention**

Brushing with 2 different manual toothbrushes in a experimental gingivitis model.

## **Study burden and risks**

none

## **Contacts**

### **Public**

The Procter & Gamble Company

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U.S.A.

### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

- \*Be between the ages of 18 and 70,
- \*Be in good general health as determined by the investigator/designee based on a review of the medical history/update,
- \*Possess at least 5 evaluable teeth in each quadrant in the lower jaw,
- \*Be a non-smoker,
- \*Have a > 25% level of bleeding,
- \*Be right handed.

## Exclusion criteria

- \*Orthodontic banding or wires or partial dentures,
- \*Severe periodontal disease (no sites with PPD > 5mm), including but not limited to purulent exudate, generalized mobility, and or severe recession,
- \*Any disease or conditions that could be expected to interfere with examination procedures or the subject safely completing the trial.

## Study design

### Design

**Study type:** Interventional

Masking: Single blinded (masking used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 19-02-2008

Enrollment: 40

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	NL20496.018.07