# The effect of maltitol and xylitol sweetened chewing gum on caries risk factors of dental plaque and saliva, and on the development of gingivitis in a 21 day non-brushing study model

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The main objective of this study is to compare the effect of chewing gum sweetened with maltitol or xylitol to the use of gum base on (the development of) gingivitis and on some plaque and salivary caries risk factors.

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

# Summary

### ID

NL-OMON36248

**Source** ToetsingOnline

Brief title Maltitol and oral health

### Condition

Other condition

**Synonym** caries, cavities and gum disease

### Health condition

mondgezondheid

### Research involving

Human

### **Sponsors and support**

Primary sponsor: Roquette Freres Source(s) of monetary or material Support: bedrijf: Roquette Freres

### Intervention

Keyword: chewing gum, maltitol, oral health, xylitol

### **Outcome measures**

#### **Primary outcome**

The effect of chewing gum sweetened with various polyols in a 21-days non

brushing model on the pH and the amount of dental plaque, and on selected oral

pathogens in dental plaque, being:

Total bacterial numbers

Streptococcus sanguinis

Streptococcus mutans

Actinomyces naeslundii

Lactobacillus casei

Veillonella dispar

Fusobacterium nucleatum.

Prevotella intermedia

Porphyromonas gingivalis

Aggregatibacter actinomycetencomitans

#### Secondary outcome

The effect of chewing gum sweetened with various polyols in a 21-days non

brushing model on various markers of oral health in dental plaque and saliva

being gingivitis, salivary flow rate, salivary pH, sucrase activity, sialidase

activity, acid production upon sucrose challenge and insoluble glucan.

# **Study description**

#### **Background summary**

Saliva has many properties to promote oral health. It clears off food remnants and cleans (washes) the mouth resulting in a reduced time that oral health is at risk after the intake of food. Furthermore saliva contains natural antimicrobials which will reduce the growth of dental plague. The use of chewing gum stimulates the salivary flow. An active antimicrobial role of sugar substitutes is claimed. Xyltiol chewing gum is acknowledged by EFSA: \*Chewing gum sweetened with 100% xylitol has been shown to reduce dental plague. High content/level of dental plague is a risk factor in the development of caries in children.\* There are, however, important guestions that remain to be answered: 1. is this claim specific for xylitol or may also other sugar substitutes exert these effects, 2. does the reduction of dental plague also result in a more healthy gingiva (less gingivitis) and 3. Is the reduction of dental plague generic or are with diseased associated species more affected than others. The first question is important because it would increase the number of (\*functional\*) foods available to the public. The second question is important, while gingivitis is a prevalent oral disorder. The third answer will give us more insight in the mechanisms involved.

#### **Study objective**

The main objective of this study is to compare the effect of chewing gum sweetened with maltitol or xylitol to the use of gum base on (the development of) gingivitis and on some plaque and salivary caries risk factors.

### Study design

The design of the study is a four group double-blind placebo controlled intervention study lasting for 3 weeks. Within each group a split mouth design will be used, participants will not to brush the teeth in the lower jaw for 3 weeks while maintaining normal oral hygiene in the upper jaw.

#### Intervention

There are four treatments:

- 1. chewing gum base containing maltitol
- 2. chewing gum base containing xylitol
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- 3. positive control: chewing gum base
- 4. negative control: no gum group

The participants will use 2 pieces of gum 5 times a day for 10 minutes after breakfast, lunch, snack in the afternoon or in the middle of the afternoon, after diner and before sleeping

There is a 21-days non brushing model in which the participants do not brush the lower jaw for 3 weeks.

#### Study burden and risks

none

# Contacts

**Public** Roquette Freres

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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

### **Inclusion criteria**

- Male and female between18 and 30 years
- Self classified as healthy
- At least 5 evaluable teeth in each quadrant
- With moderate gingivitis (30-60% bleeding on marginal probing)
- Non-smokers

### **Exclusion criteria**

- Any known allergy to any of the ingredients (xylitol or maltitol) of the study products
- Current periodontitis with periodontal pocketing over 5mm
- Any pathological change of the oral mucosa
- Wearing of an (intra-)oral piercing
- Use of antibiotics in 30 days prior to the experiment
- Participation in professional dental cleaning during the study period
- Abuse of drugs, alcohol, etc.
- Systemic disease such as diabetes or HIV
- Pregnancy or breastfeeding
- Participation in a clinical study within the previous 30 days
- Orthodontic appliances and banding
- Removable prosthesis
- Usually consumer of more than 3 sugar-free chewing gums a day

# Study design

### Design

Study type:InterventionalIntervention model:ParallelAllocation:Randomized controlled trialMasking:Double blinded (masking used)Control:PlaceboPrimary purpose:Prevention

### Recruitment

NL Recruitment status:

Recruitment stopped

Start date (anticipated):	13-09-2011
Enrollment:	220
Туре:	Actual

# **Ethics review**

Approved WMO Date: Application type: Review commission:

25-08-2011 First submission 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 CCMO

**ID** NL35214.029.11