# The effect of maltitol sweetened chewing gum on the oral microbiology.

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What is the effect of the use of a maltitol sweetened chewing gum compared to a gum base and no gum in during a 28 days on the composition of the supragingival plaque microbiome in healthy non dental students *18 years old?

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

## Summary

### ID

NL-OMON38887

**Source**
ToetsingOnline

**Brief title**
Effect of maltitol sweetened chewing gum on the oral microbiology.

### Condition

- Other condition

**Synonym**
Oral microbiology and supragingival dental plaque

**Health condition**

Microbiologie van de supragingivale 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. ,TNO- Earth Environment and Life Sciences (EELS)

## Intervention

**Keyword:** Gum base, Maltitol sweetened chewing gum, Oral microbiology

## Outcome measures

### Primary outcome

2 Supra gingival plaque samples

### Secondary outcome

Food questionnaire

# Study description

### Background summary

This metgenomic study is based on the Marsh*s theory ( Marsh et al 2006, BMC oral health). This theory consist in considering that the bacteria of dental plaque belong to a dynamic equilibrium where various factors can be deleterious. Indeed environment( diet health status) can let or not some pathogenic bacteria colonizing dental plaque. The equilibrium can move form a **healthy state** to a **sick state**.
Sugar alcohols, a class of polyols, are commonly added to foods because of their lower calorific content compared to sugars. Maltitol, sorbitol, xylitol, erythritol are often used as sweetner in chewing gum because they are not broken down by bacteria in the mouth or metabolized to acids, and thus do not contribute to tooth decay. Importantly, polyol sugars promote tooth mineralization by increasing the flow of saliva. Xylitol and sorbitol have been demonstrated in vivo and in vitro to inhibit growth of a number of cariogenic bacterial species, including mutans streptococci, most prominently Streptococcus mutans and Streptococcus sobrinus. The exact mechanism of action of xylitol on mutans streptococci (MS) is not fully known but habitual xylitol consumption, at high enough doses reduces counts of MS, apparently making plaque and mutans streptococci less adhesive to teeth. Loesche et al showed that consumption of 5*7 g of xylitol in chewing gum reduced MS in both plaque and saliva but not counts of S. sanguis. Very little is actually known about

the effects of the polyole sugars on the oral microbiota. This study aims to establish the effects of frequent consumption of chewing gum (sweetened with maltitol or the use of gum base) during 28 days on the oral microbiome composition, and to relate to effects to microbial risk factors for gingivitis and caries. Also, the prolonged effects of chewing gum (sweetened with maltitol or the use of gum base) consumtion are examined after 2 weeks. The study can contribute to effective dosage of gum consumption and improve our understanding on the level of the dental plaque ecosystem.

### Study objective

What is the effect of the use of a maltitol sweetened chewing gum compared to a gum base and no gum in during a 28 days on the composition of the supragingival plaque microbiome in healthy non dental students *18 years old?

### Study design

This is a parallel single- blind (examiner), randomized clinical trial.

### Intervention

Intervention= maltitol sweetened chewing gum. 3x daily 2 maltitol gums

Placebo= gum base. 3 x daily 1 gum
Control= no gum

### Study burden and risks

Neither immediate nor long- range physical risks are involved.

## Contacts

**Public**
ACTA Dental Research B.V. (ADR)

Gustav Maherlaan 3004
Amsterdam 1081 LA
NL
**Scientific**
ACTA Dental Research B.V. (ADR)

Gustav Maherlaan 3004
Amsterdam 1081 LA
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

- Male and female - Age *18 years - Classified as systemically healthy, assessed by medical questionnaire - Non-smokers - Minimum of 20 natural teeth: at least 5 evaluable teeth in each quadrant - DPSI 0-3- - With moderate gingivitis (30-60% BOMP) - No partial dentures - No orthodontic banding - No oral lesions - Subjects who do not use a interdental device at home. - No use of antibiotics 60 days before baseline - No pregnancy/breast feeding - No participation in clinical trials 30 days before baseline - No consumer of > 3 sugar free chewing gums a day - Willing and able to give written informed consent - No medication except for birth control pills

## Exclusion criteria

- Anyone presenting with a probing depth * 5mm with bleeding on probing and attachment loss * 2 mm - Overt dental caries - Usage of any interdental device as part of regular daily oral care - Smokers - DPSI 3+-4 - Removable (partial) dentures - Crowns, bridges and implant supported restorations - Removable night guard - Oral and/or peri-oral piercings - Apparent oral lesions (aphthous ulcers excluded) - Presence of orthodontic banding (except for lingual retention wire) - Dental student or dental professional - Participation in a clinical study within the previous 30 days ;General health and use of medication:
- Self-reported pregnancy or breastfeeding - Use of antibiotics during the last 2 months - Need of antibiotic prophylaxis prior to dental treatment - Use of anti-inflammatory drugs on a regular basis - Evidence of any systemic disease or compromised health condition - Adverse medical history or long-term medication - Prescribed medication (except for birthcontrol pills)

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 12-09-2013 |
| Enrollment: | 150 |
| Type: | Actual |

# Ethics review

Approved WMO

| | |
|---|---|
| Date: | 06-09-2013 |
| 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

ID: 27321
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL45518.018.13 |
| OMON | NL-OMON27321 |
| OMON | NL-OMON28925 |