# An exploratory study on the dynamic (microbiological, biochemical and immunological) interactions of the oral ecosystem during induction of mild gingival inflammation\*

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To explore the dynamic changes in the microbiological composition (of the separate niches) of the oral ecosystem upon refraining from oral hygiene for two weeks compared to baseline and after a one-week resolution phase assessed with or without the...

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

# Summary

### ID

NL-OMON42247

**Source** ToetsingOnline

**Brief title** Dynamics of the oral ecosystem

## Condition

Other condition

**Synonym** mild gingival inflammation

### Health condition

Milde gingivitis (milde tandvleesontsteking)

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#### **Research involving** Human

numan

### **Sponsors and support**

**Primary sponsor:** ACTA Dental research BV (ADR) **Source(s) of monetary or material Support:** Ministerie van OC&W,NWO,Cargill,TI Food and Nutrition,TIFN: Top Institute Food and Nutrition,TNO

### Intervention

Keyword: dynamic, microbial, mild gingival inflammation, oral ecosystem

### **Outcome measures**

#### **Primary outcome**

The primary outcome of this study will be the exploration of the dynamic biological process as assessed by changes in the microbiota of the different niches of the oral cavity, i.e. the microbiological composition of saliva, dental plaque (from the lingual aspect of the lower jaw, interproximal, sub gingival, supra gingival) and soft tissue (tongue dorsum (anterior and posterior) lateral border of the tongue, hard palate, attached gingival tissue). The secondary study parameters are the biochemical and immunological effects e.g. the level of bleeding on marginal probing (BOMP), oral PMN numbers and function, saliva and level of dental plaque, oral malodor, the extent of tongue coating, and Gingival Crevicular Fluid (GCF).

#### Secondary outcome

The secondary study parameters are the biochemical and immunological effects e.g. the level of bleeding on marginal probing (BOMP), oral PMN numbers and function, saliva and level of dental plaque, oral malodor, the extent of tongue coating, and Gingival Crevicular Fluid (GCF).

# **Study description**

#### **Background summary**

Individuals have been shown to differ in their vulnerability for oral disease. In experimental clinical setting, this has been demonstrated where individuals vary in the degree of gingival inflammation following overgrowth of dental plaque. We hypothesize this difference is due to differences in the mechanisms by which the individuals can withstand and/or adapt to the stress conditions applied in the clinical model and that these mechanisms are of key importance in our ability to maintain our oral health. We expect that - in analogy of other biological systems - the mouth has intrinsic mechanisms to maintain or restore homeostasis following a perturbance. These processes have up to date gained little attention in research. By examining in detail the dynamic biological responses of the oral ecosystem in individuals during experimental gingivitis induction and relating these responses to individual variation in the inflammatory outcome, it is expected that the biological processes that contribute to our ability to maintain oral health can be identified. Detailed insight in these processes may allow the development of novel strategies for dentists and dental hygienists to promote oral health and prevent of oral disease in the individual patient. This may include novel diagnostic tool to provide insight in the vulnerability of an individual for the development of disease but also may also include novel food and personal care products that stimulate resilience of the mouth.

### Study objective

To explore the dynamic changes in the microbiological composition (of the separate niches) of the oral ecosystem upon refraining from oral hygiene for two weeks compared to baseline and after a one-week resolution phase assessed with or without the use of erythritol in a systemically healthy adult population.

#### Study design

This is a single center, challenge intervention, randomized study in systemically healthy subjects.

#### Intervention

The challenge intervention is based on a full mouth experimental gingivitis protocol (Löe et al., 1965). For this, subjects will be requested to refrain from any form of oral hygiene for two weeks, resulting in plaque accumulation, temporarily leading to induction of (mild) gingival inflammation. To intervene in the composition (and activity) of the oral microbiota prior and during plaque accumulation, a subgroup (N=25) will receive a nutritional supplement called erythritol (a food additive known to be a possible stabilizer of the ecosystem) 6 times a day for 5 weeks, i.e. two weeks prior as well as two weeks during and one week after the challenge intervention (2 weeks wash-in, 2 weeks experimental gingivitis, 1 week recovery).

#### Study burden and risks

The risks and burden related to this study are judged to be very limited. The induction of mild (short term, temporarily/reversible) gingival inflammation is a well-established method without the occurrence of adverse events (Versteeg et al. 2008). Determination of the clinical parameters are part of standard dental clinical care. In addition, the collection of samples during the study do not require invasive procedures. As the outcomes of this study could support oral health and prevention of oral disease in the individual patient, the very limited burden and risks for the subjects are considered acceptable.

# Contacts

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

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

### **Inclusion criteria**

Adults, >= 18 years - 55 year Male and female Classified as systemically healthy, assessed by medical questionnaire Minimum of 20 natural teeth: first and second molars must be present Having visited the dentist for a regular check-up within the last year and having finished the necessary treatment. Willing and able to give written informed consent Willing to consent to use their collected anonymous and coded body materials for further research

### **Exclusion criteria**

Anyone presenting with a dental pocket probing depth >= 5mm with bleeding on probing and attachment loss >= 2 mm, Dutch Periodontal Screening Index score 3+/ 4 >40% BOP Overt dental caries Smokers, definition non-smoker: <1 cigarette every day for at least one year Removable partial dentures Removable night guard Oral and/or peri-oral piercings Apparent oral lesions (aphthous ulcers excluded) Presence of orthodontic banding (except for lingual retention wire) Abuse of drugs/ alcohol ACTA dental student or ACTA professional Participation in a clinical study within the previous 30 days

# Study design

### Design

Study type: Interventional	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

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### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-02-2015
Enrollment:	80
Туре:	Actual

# **Ethics review**

Approved WMO Date:	30-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	04-03-2016
Application type:	Amendment
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** CCMO Other ID NL51111.029.14 tbd