

# Evaluating child and maternal oral microbiota sampling methods for at home usage

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Defining which sampling site in the mouth in infants and their mothers is most reproducible as determined by the differences in microbiota composition of samples collected by a trained researcher and those collected by the mother

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON46070

### Source

ToetsingOnline

### Brief title

Oral microbiota sampling at home

### Condition

- Other condition

### Synonym

oral microbiota

### Health condition

er wordt geen aandoening onderzocht

### Research involving

Human

## Sponsors and support

**Primary sponsor:** ACTA

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** infant, microbiota, oral, reproducibility

## Outcome measures

### Primary outcome

Primary endpoint will be reproducibility of sampling oral sites as determined by the differences in microbiota composition of samples collected by a trained researcher and those collected by the mother.

### Secondary outcome

Information about the feasibility such as comprehensibility of the instruction video and sampling site will be collected.

## Study description

### Background summary

It is becoming more and more apparent that human microbiota influences health and disease. The oral microbiota develops during the first three years after birth, but it remains unclear what factors drive this development. Studying the oral microbiota can provide us with valuable insights in its influence on human health. Especially large scale longitudinal studies are needed to gain knowledge on this subject. Home sampling would make studying of the oral microbiota less costly and more convenient for the study subjects in these kind of studies. Although several oral sites can be used for home sampling, information on reproducibility is lacking. Besides, little is known about feasibility of oral sampling in infants. This study aims to evaluate reproducibility and feasibility of several oral sampling sites.

### Study objective

Defining which sampling site in the mouth in infants and their mothers is most

reproducible as determined by the differences in microbiota composition of samples collected by a trained researcher and those collected by the mother

## **Study design**

Observational study design

## **Study burden and risks**

Development of oral microbiota can only be studied in infants, since oral microbiota develops in the first 3 years after birth. This study is therefore group-related. The burden of taking oral microbiota samples is very low and the methods are non-invasive, so the risk of participating in the study is limited for the infants and their mothers. By participating in this study, mothers gain information on oral care for their infants, and receive a free toothbrush. We expect no adverse or serious adverse events of this non-invasive data collection. 7-9 samples will be collected per infant and mother.

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

### Inclusion criteria

For mothers: Having an infant aged 2-4; 6-8 or 12-14 months

For infants: Being an infant aged 2-4; 6-8 or 12-14 months

### Exclusion criteria

Not mastering the Dutch language

Mothers younger than 18 years old

Serious congenital abnormalities

Guardian not available for consent

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 10-09-2018

Enrollment: 60

Type: Actual

## Ethics review

Approved WMO

Date: 16-08-2018

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	NL66102.018.18

## Study results

Date completed: 22-01-2019

Actual enrolment: 60

### Summary results

Trial is ongoing in other countries