

# Verification of a questionnaire for screening of gum disease in a medical setting

<b>Submission date</b> 13/01/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 31/01/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/02/2022	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Periodontitis is often known as 'Gum Disease' and is a very common condition in which the gums and deeper periodontal structures become inflamed.

In a previous project from our research group, a self-reported oral health questionnaire to screen for periodontitis was validated a rapid and non-invasive screening tool for periodontitis was developed. The tool is eventually to be used in medical settings where oral examinations for periodontitis are not feasible. Before this screening tool can be implemented on a large scale, it also requires external validation. In other words, we need to assess its performance in a medical patient population other than the one used for the development. Once externally validated against a routine clinical periodontitis screening, our screening tool could support, for example, diabetes care providers to screen for periodontitis and with that to adhere to the medical guidelines and recommendations without the need of an oral examination.

The main objective of this study is to externally validate a screening tool for periodontitis, based on a self-reported oral health questionnaire and patient demographics (sex, age, smoking, ethnicity, education level, number of yearly dental visits).

### Who can participate?

Patients aged 18 – 80 years, with at least one of their own teeth

### What does the study involve?

Patients will be examined using the new screening tool and the standard method when they attend clinic.

### What are the possible benefits and risks of participating?

It is likely that there will be no noticeable advantages for the patients. However, it is possible that the routine oral examination (the screening for periodontitis) reveals periodontal problems that had been unnoticed until that point. If so, the patient is immediately notified, and it is recommended to visit his/her dentist. If this results in early diagnosis and treatment of periodontitis by the dentist, this will have positive effects on oral health and possibly also systemic health of the patient.

All oral examinations and measurements are non-invasive and fast (The Dutch Periodontal Screening index, 5 minutes); there are no risks for the patient, except perhaps in some situations there will be a short-lived discomfort. The DPSI measurements take place during the already planned appointment at the outpatient internal medicine policlinic (UMC, location AMC). Other than the additional time that is required for this study (approximately 3 minutes for filling in the questionnaire and 5 mins for the DPSI), there are no disadvantages for participating in the study.

Where is the study run from?

UMC, location AMC Amsterdam, The Netherlands

When is the study starting and how long is it expected to run for?

September 2019 to March 2020

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Prof B.G. Loos

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## Contact information

**Type(s)**

Scientific

**Contact name**

Prof B.G. Loos

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**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

## Secondary identifying numbers

2019.267

# Study information

## Scientific Title

Validation of a questionnaire for rapid, non-invasive screening of periodontitis in a medical care setting

## Acronym

PERIOSCREEN

## Study objectives

The primary purpose of this present study was to perform an external validation of the rapid non-invasive screening tool for periodontitis as developed by Verhulst et al. (2019). It will be investigated whether this screening tool model is valid outside the ACTA clinics.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 12/07/2019, Medical Ethical Committee of the UMC, location VU Medical Center (VUmc) (BS7, room H-443, Postbus 7057, 1007 MB Amsterdam; +31 20 44 45585; metc@vumc.nl), ref: 2019.267

## Study design

Observational cross-sectional study

## Primary study design

Observational

## Secondary study design

Cross sectional study

## Study setting(s)

Hospital

## Study type(s)

Screening

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Periodontitis

## Interventions

Within one week before a clinical visit to a medical doctor (internist, outpatient internal medicine clinics UMC (University Medical Center), location AMC (Academic Medical Center)

Amsterdam), all planned patients will receive an information letter about the current ongoing study. When waiting in the waiting room, researcher 1 will ask the patient to participate. If the patient approves to participate, he/she is taken into the research room.

First researcher 1, the SROH (Self-Reported Oral Health) questionnaire is conducted, which will take about 3 minutes.

Second, researcher 2 performs the periodontal examination (periodontitis screening by the Dutch Periodontal Screening Index [DPSI]) and informs the patient about whether he/she is suspected to have periodontitis (DPSI category C); the periodontal examination will take about 5 minutes. Therefore the research will take 8 minutes total.

Finally, the remaining data of the GH questionnaire such as BMI, blood pressure, HbA1c, LDL-, HDL- and total cholesterol level, triglycerides, eGFR, albumin and creatinine concentration, medication and diseases are obtained through EPIC, the electronic health record of the UMC.

## **Intervention Type**

Other

## **Primary outcome measure**

1. DPSI (measured by one of the researchers): periodontitis yes/no
2. SROH questionnaire (done by one of the researchers and calculated by a formula): suspected to have periodontitis yes/no'
3. Model performance parameters: sensitivity, specificity, NPV, PPV and AURROC

## **Secondary outcome measures**

Obtained through EPIC, the electronic health record of the UMC:

1. BMI (kg/m<sup>2</sup>)
2. Blood pressure (mmHg)
3. HbA1c, LDL-, HDL- and total cholesterol level
4. Triglycerides
5. eGFR
6. Albumin and creatinine concentration
7. Demographic factors (age, ethnicity and education level)

## **Overall study start date**

01/01/2019

## **Completion date**

01/07/2020

# **Eligibility**

## **Key inclusion criteria**

1. Patients from 18 - 80 years of age
2. All ethnicities
3. All sexes
4. All education levels
5. At least one of their own teeth
6. Patients under control to an internist at the internal medicine clinic (UMC, location AMC)

**Participant type(s)**

Patient

**Age group**

Mixed

**Sex**

Both

**Target number of participants**

200

**Total final enrolment**

159

**Key exclusion criteria**

1. Edentulous (with or without full dentures (regardless of dental implant support)
2. Do not speak Dutch or English
3. Patients who were not present in EPIC (the electronic health record of the UMC)

**Date of first enrolment**

01/09/2019

**Date of final enrolment**

01/04/2020

**Locations****Countries of recruitment**

Netherlands

**Study participating centre****UMC location AMC Amsterdam**

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

**Sponsor information****Organisation**

Academic Center for Dentistry Amsterdam

**Sponsor details**

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info@acta.nl

**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.acta.nl/nl/>

**ROR**

<https://ror.org/04x5wnb75>

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

01/09/2020

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a publically available repository (Figshare). The data will be offered upon request to Prof. dr. B.G. Loos. Email: b.loos@acta.nl. Type of data: SPSS data file. Data is available from: after successful publication in a peer-reviewed journal for 10 years. Access criteria: academic researchers and joined publications. Patients did sign informed consent. Data is anonymous and can only be connected to the participant by the main investigators.

**IPD sharing plan summary**

Stored in repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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<a href="#">Protocol file</a>	version v4.0	11/06/2019	05/02/2020	No	No
<a href="#">Results article</a>		01/12/2021	11/02/2022	Yes	No