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

Submission date	Recruitment status	[_] Prospectively registered
13/01/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/01/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/02/2022	Oral Health	

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 fort 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 possible 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

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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/m²)
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

Gustav Mahlerlaan 3004
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Netherlands
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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?

Protocol file	version v4.0	11/06/2019	05/02/2020	No	No
Results article		01/12/2021	11/02/2022	Yes	No