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Update of a questionnaire for periodontitis screening

Submission date	Recruitment status	[ ] Prospectively registered
27/02/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/03/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/03/2023	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Medical professionals should advise their patients to visit a dentist if necessary. Due to the lack of time and knowledge, screening for periodontitis (gum disease) is often not done. To alleviate this problem, a screening model for total and severe periodontitis in a medical care setting was developed at the Academic Center of Dentistry Amsterdam (ACTA). These models were externally validated in a medical care setting. The aim of this study is to find out whether it is possible to update the models for periodontitis screening in a medical care setting for better performance.

Who can participate?
Patients between 18 and 80 years of age who have at least one of their own teeth

What does the study involve?
Participants complete an oral health questionnaire, demographic data are collected, and a periodontal examination is performed.

What are the possible benefits and risks of participating?
The benefit of participation is to get a free periodontal screening. There are no risks involved.

Where is the study run from?
Amsterdam University Medical Centers (location Academic Medical Center) (Netherlands)

When is the study starting and how long is it expected to run for?
October 2021 to May 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Nina Nijland, ninanijland@hotmail.com

Contact information

Type(s)
Principal Investigator

Contact name
Miss Nina Nijland

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Update of a rapid, non-invasive tool for periodontitis screening in a medical care setting: a cross-sectional study

Acronym
UPSIMS

Study objectives
It is possible to update the models (previously made by Verhulst et al. [2019]) for periodontitis screening in a medical care setting for better performance.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 08/11/2021, Ethical Committee of the Academic Center for Dentistry Amsterdam (Gustav Mahlerlaan 3004, 1081 LA Amsterdam, Netherlands; +31 (0)20 59 8080888; etc@acta.nl), ref: 2021-59159

Study design
Single-centre 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 to request a participant information sheet

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

Interventions
Patients were required in an outpatient medical setting from the internal medicine policlinic in the Amsterdam UMC (University Medical Center) as the update cohort. The two prediction models (Verhulst et al [2019]) will be updated based on the update cohort. First, the self-reported oral health (SROH) questionnaire was conducted. Second, demographic and systemic health data (age, sex, education level, smoking, BMI and diabetes status) were collected. Finally, the periodontal examination took place. Participants from the prior study (Nijland, Overtoom et al. 2021) served as the validation cohort.

Intervention Type
Other

Primary outcome measure
Performance of the models measured with the area under the receiver-operating characteristic curves (AUC) at baseline

Secondary outcome measures
Calibration of the updated models assessed based on calibration plots and the overall observed: expected ratios (O: E ratios) at baseline

Overall study start date
01/10/2021

Completion date

01/05/2023

Eligibility

Key inclusion criteria
1. 18 and 80 years of age
2. Have at least one of their own teeth

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
90 individuals per group for two groups (non-periodontitis and total periodontitis)

Key exclusion criteria
1. <18 and >80 years of age
2. Complete edentulism with or without full dentures (regardless of dental implant support)
3. Need for antibiotic prophylaxis before probing
4. Not speaking Dutch or English

Date of first enrolment
01/11/2021

Date of final enrolment
08/07/2022

Locations

Countries of recruitment
Netherlands

Study participating centre
Amsterdam UMC, location AMC
Meibergdreef 9

Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Center for Dentistry Amsterdam

Sponsor details
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Sponsor type
University/education

Website
http://www.acta.nl/en/

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
01/05/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Nina Nijland (ninanijland@hotmail.com). Data is available after the study publication. The data consists of: medical data of the participants (diabetes state, BMI), oral status in Community Periodontal Index of Treatment Needs (CPITN) score, and answers to the SROH questions. Participants were asked to participate, if so, they got an information letter and signed informed consent. A key document connected the research numbers to the AMC patient numbers. This document was stored together with the completed questionnaires in separate folders in a closed closet at the Department of Periodontology at ACTA.

IPD sharing plan summary

Available on request