Can a low-threshold check-up motivate older people to schedule a dental visit?

A Randomized Controlled Trial

NCT:

GERODENT PLUS

Protocol

Administrative information

The numbers in brackets [ ] are referring to the items on the SPIRIT 2013 Checklist.

Titel [1]	**Can a low-threshold check-up motivate older people to schedule a dental visit? A Randomized Controlled Trial** - Superiority trial - Parallel study
Trial registration [2a, 2b]	
Protocol version	Version 1.0, 25/03/2024
Funding	Funded by the Flemish Agency for Care and Health (project-number VLA.DIV.2021.0090.01) Elke Ghyllebert T 02 553 29 85 E elke.ghyllebert@vlaanderen.be Koning Albert II-laan 35 bus 33, 1030 Brussel
Roles and responsibilities [5a en 31b]	Aster De Vleeschauwer[1] Ellen Baele[1] Natalie Hoste[2] Louise Poppe[2] Roos Colman[3] Peter Pype[2] Fien Mertens[2] Barbara Janssens[1] [1]Department of Oral Health Sciences, Ghent University, Belgium [2]Department of Public Health and Primary Care, Ghent University, Belgium [3]Biostatistics Unit, Faculty of Medicine and Health Sciences, Ghent University, Belgium - BJ conceived of the study. - ADV, LP en BJ initiated the study design and EB, NH, PP and FM contributed to refinement of the study protocol. - ADV will perform collection, management, analysis and interpretation of the data. - BJ is grant holder. - RC and LP provided statistical expertise in clinical trial design and analysis. - ADV, EB, NH, LP, PP, FM and BJ will approve the final manuscript.
Name and contact information for the trial sponsor [5b]	There was no sponsor. The funder had no role in the study design; collection, management, analysis and interpretation of the data; the writing of the report or the decision to submit the results.

Role of study sponsor and funders, if any, in study design [5c]	
Composition, roles and responsibilities of the coordinating center, steering committee, endpoint adjudication committee, data management team and other individuals or groups overseeing the trial, if applicable [5d]	The members of the Gerodent PLUS-research project (ADV, EB, NH, LP, PP, FM and BJ) and RC will advise on study design, interpretation of the data, writing of the report and the decision to submit the report for publication. A stakeholder group was formed. They will oversee the project and provide advice according to their expertise. Members of this group are: - Vlaams Instituut Mondgezondheid (Gezonde Mond) - Logo Limburg on behalf of all Flemish Logo's - Expertisecentrum Dementie Paradox - Vlaams Instituut Gezond Leven - VZW Zorg-Saam ZKJ - Woonzorggroep GVO - Vivel - ELZ Scheldekracht vzw - ELZ RITS - Logo Midden West-Vlaanderen - Zorgband Leie en Schelde

Introduction

[6a] Background and rationale

People are living longer, therefore the population is aging. By 2061, the number of people older than 55 years in Belgium will increase by a third to 35.4% of the total population. The number of people older than 85 is expected to double (1). Thus, healthy ageing is more crucial than ever to avoid straining the health care system.

The World Health Organization (WHO) defines healthy ageing as "the process of developing and maintaining the functional ability that enables wellbeing in older age". (2) Chan's study from 2023 provides a good summary of the impact of oral health on healthy aging (3). Poor oral hygiene causes caries and periodontitis, resulting in a high level of tooth loss in older generations. Older people are also more susceptible to xerostomia or oral cancer (4). The effects of poor oral health extend beyond the mouth and have an impact on overall health e.g. the risk of aspiratory pneumonia-related death (4). Poor oral health is also associated with cardiovascular disease and diabetes (5). Additionally, tooth loss, xerostomia and oral cancer can cause chewing and swallowing problems, which can lead to reduced nutritional uptake (6). Furthermore, the psychological impact of oral health should not be ignored. Poor oral health can lead to pain, feelings of shame and reduced social contact. All of these have an impact on the quality of life of older adults (7).

Despite the fact that oral health is an important part of overall health, oral diseases are the most prevalent condition worldwide (8). Chan's 2021 systematic review reports a median untreated caries prevalence of 46% in Europe in older adults aged 60 years or above (9). Research from 2016 reported poor oral health among frail elderly people in Belgium. There was a high treatment need, and oral health was distressing (10).

Most oral diseases are preventable by maintaining good daily oral hygiene and periodic professional care (11-13). However, dental attendance is low in older adults. Research in Belgium from the period 2019-2021 showed that only 34% of the population received preventive oral care and 26% of the population did not go to the dentist at all (14). Likewise, a recent oral health consumption analysis indicated that 41.7% of adults over 65 years in Flanders in the period 2020-2022 had no contact with the dentist at all and only 32.2% of them went for regular dental checkups. Once more, it was confirmed in our own interview studies with older people that the majority did not have a regular dental check-up. The main reasons for not seeking dental care are bad previous experiences, not knowing its importance, edentulousness, fear of the dentist, perceived costs and practical issues in reaching a dental office (15-17).

There is little research on the effect of oral screening campaigns for improving oral health in older people. Therefore, the aim of this study is to investigate the effect of a low-threshold contact with an oral health professional, including an oral health examination, on dental attendance of older people (65 years of age or older).

[6b] Explanation for choice of comparators

Our interview studies and a review of literature showed that older people are not aware of the importance of regular dental attendance and don't always have enough skills to schedule a dental visit and find a new dentist after retirement of their previous one. (16, 18)

The intervention group will be provided with tools to facilitate dental contact and will be informed about the importance of regular dental visits. Participants are given the opportunity to receive an oral examination. Afterwards, each participant will receive brochures with oral hygiene instructions to take home. Participants will receive information about any identified oral pathology. A referral letter for the dentist and a report for the general practitioner will also be prepared to increase social influence. If the participant doesn't have a dentist, the participant will receive a list of contact information for dentists in the area.

In the control group, no oral examination will be performed. However, participants will be given a list of nearby dentists and flyers with oral hygiene instructions.

In this way, we want to find out whether the presence of a dental professional with tailored advice is crucial to motivate an elderly person to good oral care.

[7] Objectives

The objective is to determine whether offering a low-threshold oral check-up to older adults, including oral health counselling, referral and report letters and a list of nearby dentists, results in a higher likelihood of contacting a dentist in the following 4 months compared to a control group that only received general oral health promotion leaflets and a list of nearby dentists.

Research hypothesis

We expect that elders who had a low-threshold oral check-up and received information about their oral situation will be more likely to contact a dentist.

[8]Trial design

This trial is designed as a randomized, controlled, non-blinded, superiority trial with two parallel groups. Randomization will be performed as block randomization with a 1:1 allocation. For practical reasons, each block will consist of 8 to 12 people.

Methods: Participants, interventions and outcomes

[9] Study setting

The study will be conducted within two specific regions in Flanders, Belgium. All service centers within the primary care zones RITS and Scheldekracht will be invited to participate in the study. Organizations focusing on older people will also be contacted to spread our call for participation in the study.

[10] Eligibility criteria

Older people are included when they meet the following criteria: they are 65 years of age or older, home-dwelling within the selected regions, they are Dutch speaking, and they did not have a dental check-up in the last 12 months. (19) By home-dwelling, we mean anyone who does not reside 24/7 in a residential care facility. If it concerns a couple, only one person can participate. Participants should have sufficient cognitive ability to answer the questions. If we ask the questions and find that the older person is unable to answer them adequately due to cognitive impairment, he or she will not be included in the study.

[11a] Interventions

After filling out the interview based questionnaire (see Appendix), the participants will be randomized between the control group and the intervention group. This will ensure that there are equal numbers of frail people in both groups.

The participants in the intervention group will receive an oral examination. Subsequently, information about any identified problem will be given. Lastly, participants will receive a referral letter for their dentist and a report for the general practitioner. If the participants don't have a regular dentist, they will also be given a list with contact information of dentists in the area.

Both the intervention and the control group will receive a flyer with oral hygiene instructions adapted to their needs and if necessary a list with contact information of dentist in the area. These flyers are evidence-based brochures compiled by the Flemish institute of oral health ("Gezonde Mond") on performing good oral hygiene.

[11b] Interventions - modifications

If an elderly person is randomized into the intervention group but refuses to have on oral examination, this will be noted.

If an elderly person in the control group asks for an oral examination because of a particular problem, the elderly person will be given the advice to contact a dentist.

[11c] Interventions – adherence

At the end of the initial contact, participants will be reminded that they will receive a phone call after 4 months. All participants will receive a pen with the logo of Gerodent PLUS as a gift.

[11d] Interventions – concomitant care

No concomitant care is prohibited to the participants. The intent of the study is to examine whether older people find access to regular care due to our intervention.

[12] Outcomes

Primary Outcome Measures

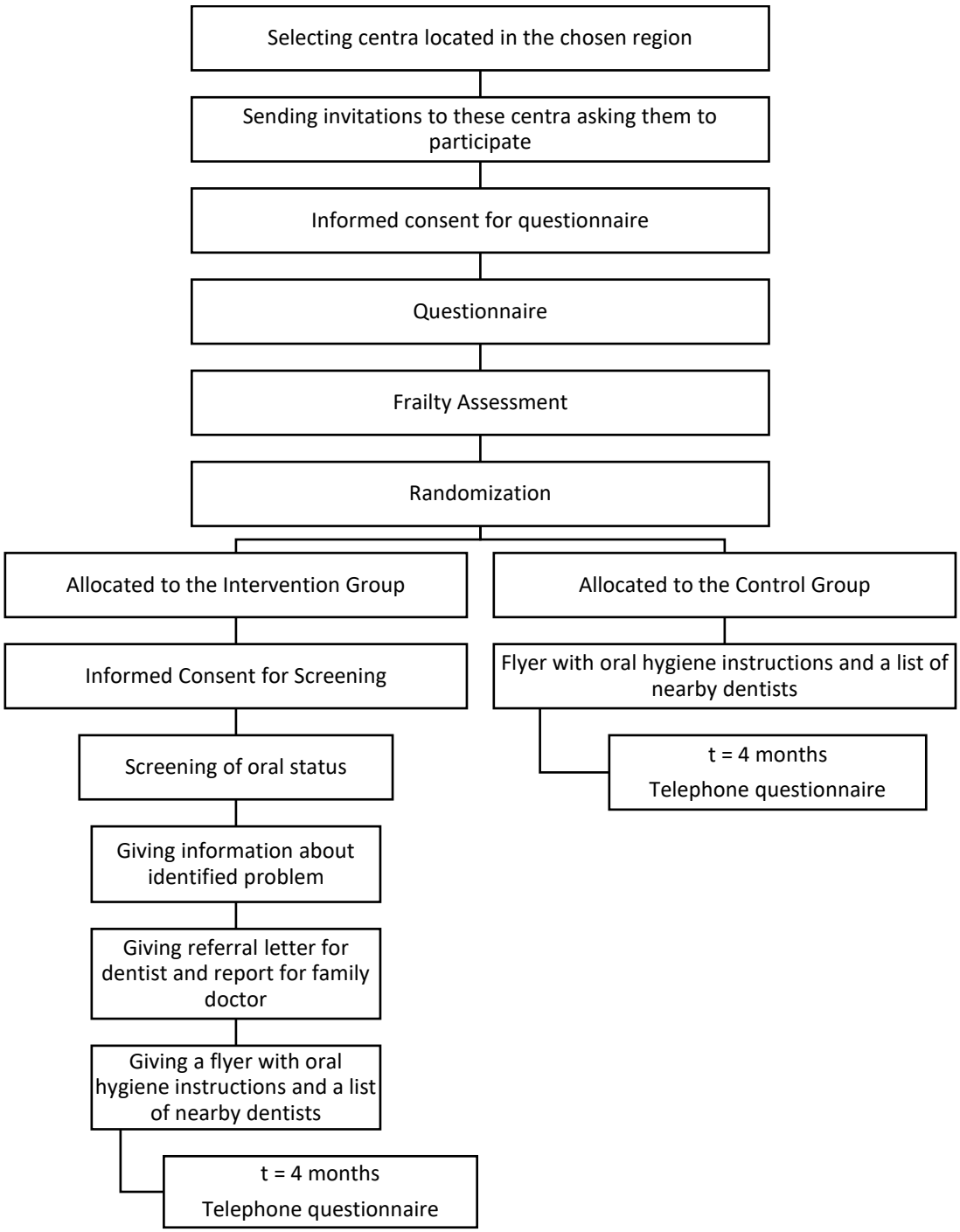
Participants will be contacted 4 months after the initial contact by telephone to ask if they contacted a dental professional since the first contact. We will make four attempts to contact them, two in the

morning and two in the afternoon. Contact information of partner or caregiver will also be included, in case the participant cannot be reached.

If the older person has contacted a dental professional within 4 months of our initial contact, then this is considered a success. Due to a shortage of dental professionals in Flanders, there is often a fairly long waiting period before a patient can get an appointment. In addition, many professionals have implemented a patient stop. So we want to give the elders enough time to find a dental professional. Differences in proportions will be reported.

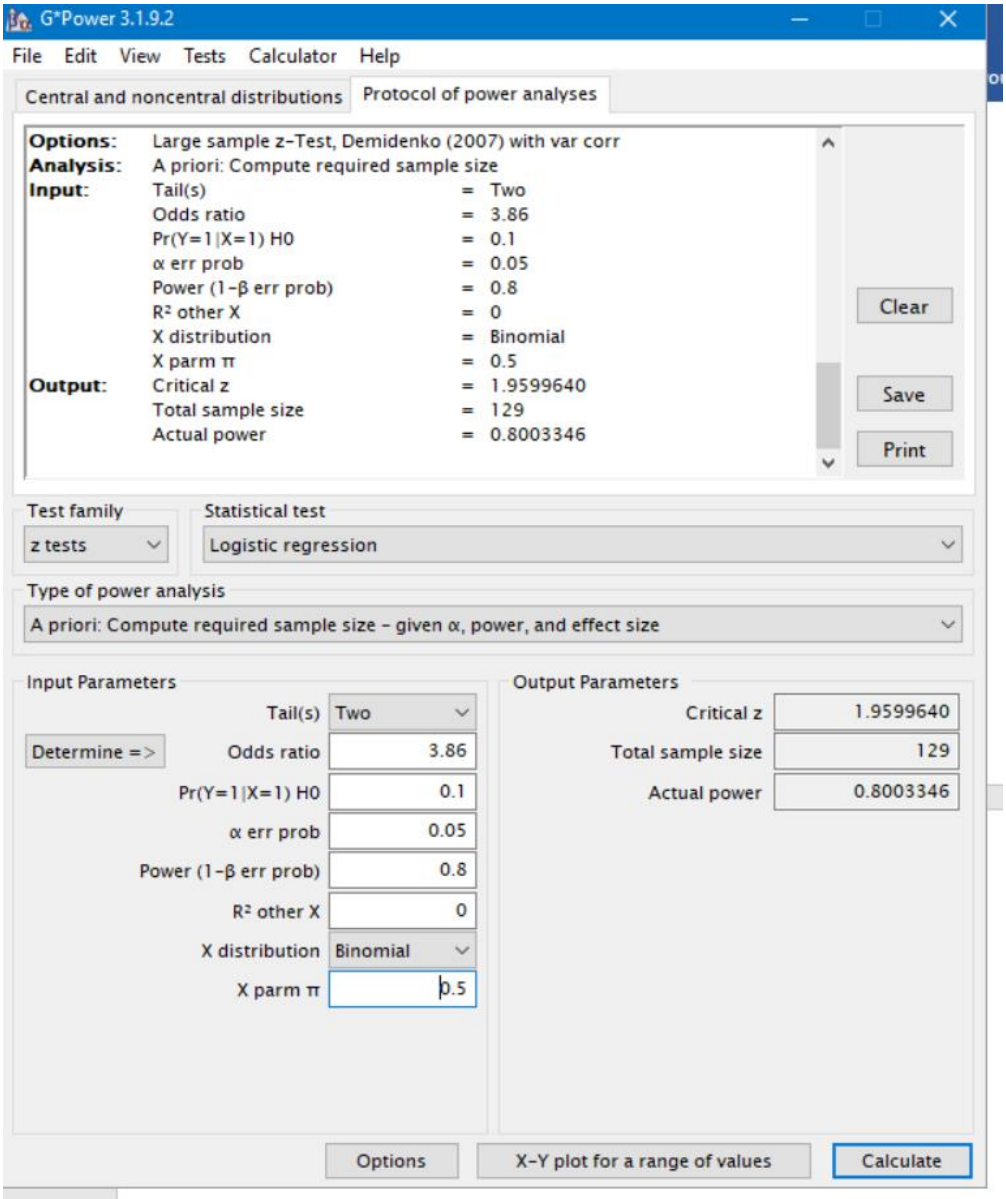
	Intervention group	Control group
Contacted a dentist within 4 months		
Not contacted a dentist within 4 months		

[13] Participant timeline



[14] Sample size

We expect to activate 30% of the participants in the intervention group; in the control group, we expect a maximum of 10%. To detect a mean difference of 20% with equal allocation to both groups would require 129 persons in total. To allow for 33% drop-out, 194 persons will be recruited.



[15] Recruitment

Service centers within the RITS and Scheldekracht primary care zones will be asked if they are willing to participate in the study. A date will be arranged with the interested centers when the study can take place in their facilities.

Organizations and other local initiatives will also be contacted to spread our call for participation in the study. Older people will be able to sign up at a participating service center to participate in the study.

Furthermore, home nursing and home care service organizations in the region have agreed to assist with participant recruitment.

Methods: Assignment of interventions

Allocation

[16a] Sequence generation

Participants will be randomly assigned to either control or intervention group with a 1:1 allocation. Randomization will be stratified by frailty. Random permuted blocks will be created using SAS v9.4 with variable sizes to avoid that the treatment allocation can be predicted. For practical reasons block size will vary between 8 and 12.

[16b] Allocation concealment mechanism and [16c] Implementation

A randomization list (prepared by RC) will be processed in REDCap by a HIRUZ staff member. Screeners will not have access to this list. Allocation concealment will be ensured as the REDCap-program will not release the randomization code until the questionnaire was completed.

[17] Blinding (masking)

This study is an open trial. The researchers at timepoint 1 are not blind to allocations. Participants in the control group will not be informed by the researchers that other participants might receive an oral examination. Participants in the intervention group will be told that due to an excess of time, they will also receive an oral examination. There is no procedure for unblinding needed.

At timepoint 2 the person will be contacted again by a different researcher than the researcher of the first contact, that way the researcher does not know in which group the participant was assigned.

Methods: Data collection, management and analysis

Data collection methods

[18a] Plans for assessment and collection of outcomes

The study will be piloted outside the region where the study takes place. Researchers PM and TC will be trained for screening of the oral status by researcher ADV. Interrater reliability will be calculated (20). Piloting will not be terminated until sufficient agreement is established.

No x-rays will be taken due to ethical concerns. Examiners will use a head lamp, a mouth mirror and periodontal probe for the oral examination. Denture plaque will be evaluated using methylene blue staining.

A script was integrated into the questionnaire on REDCap. It will not only display the questions, but will also display reminders so that no part of the survey can be forgotten (see Appendix). For example, researchers will have to check off that the informed consent form was signed or whether referral letters were completed and given to the participants. After each section of the questionnaire, the researcher will need to confirm that all questions in this section were completed.

Using REDCap, a calendar will be created automatically showing when the participants should be called for the questionnaire at timepoint 2.

[18b] Plans to promote participant retention and complete follow-up

- At the end of the initial contact, participants will be reminded that they will be called again 4 months later. Contact information for a partner, child or caregiver will also be noted. If a participant indicates they prefer to receive a letter, the home address will be noted.
- All participants will receive a pen with the logo of Gerodent PLUS as a gift.
- A 33% drop-out rate was taken into account when calculating the sample size.

- Refusal of the oral examination will be noted. However, since we are working from the intention to treat principle, the participant will remain in the intervention group.

[19] Data management

Data will be collected exclusively electronically through REDCap. REDCap is a secure web application for building and managing online surveys and databases. The type of activity that an individual user may undertake is regulated by the privileges associated with his/her account.

Once all data are collected, a copy of REDCap will be kept on the secure servers of Ghent University. Only members of the research team will have access to the data. If needed, data will be transferred using a Secure File Transfer platform, Belnet Filesender.

Statistical methods

[20a] Statistical methods for primary and secondary outcomes

Two weeks after the last telephone questionnaire was scheduled, we will end the data collection and the statistical analysis will be executed. The intervention group will be compared against the control group for having consulted a dentist within 4 months after the initial contact. Differences in proportions will be reported, logistic regression models will be used.

[20b] Methods for additional analyses (e.g. subgroup analyses)

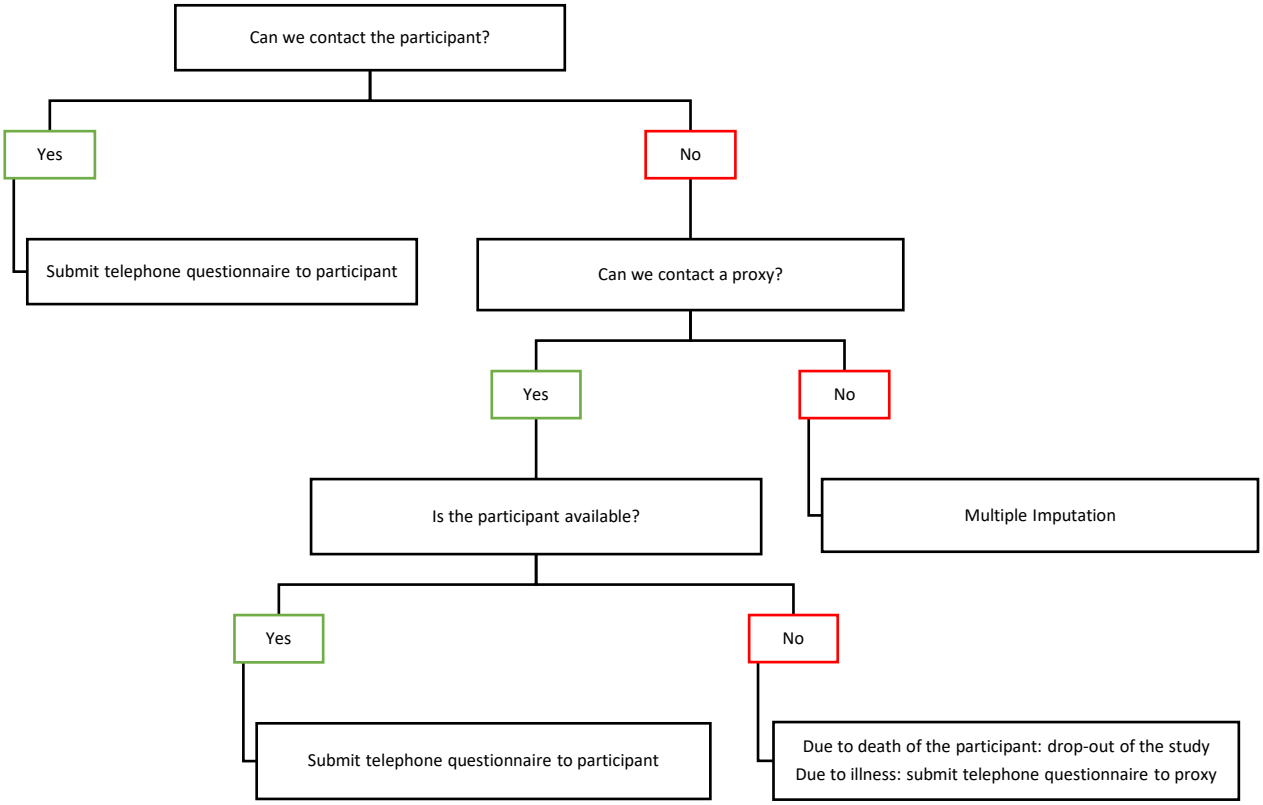
Subgroup analyses will be purely exploratory:

- Impact of age on outcome
- Impact of gender on outcome
- Impact of education on outcome
- Impact of financial situation on outcome
- Impact of frailty on outcome.
- Impact of whether participant is dentate or edentulous on outcome.
- Impact of whether participant experienced oral problems the previous 6 months on outcome.

[20c] Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data

All randomized participants will be included in the “intention to treat”-analysis. This means that a participant allocated to the intervention group, who refuses an oral examination will remain in the intervention group.

If we cannot reach a participant at timepoint 2, the specified proxy will be contacted. If it appears that the participant has since died, they will be considered as drop-out. If it appears that the participant is not available (e.g., due to hospitalization), we will submit the questionnaire to the proxy. When we cannot reach an individual at all, we will address this missing data by applying multiple imputation per randomization arm. We will check for having natural teeth and when the last dental visit occurred, but this is not an exhaustive list.



Methods: monitoring

[21] Data monitoring

Since this study has no major safety concerns, no data monitoring committee will be composed. No interim analysis will be conducted.

[22] Harms

An adverse event refers to an unwanted side-effect during the study, which may or may not be causally related to the intervention or other aspects of participation in the study. We expect no such events to happen because of the design of the intervention. However, participants are informed that when an injury does occur, they may contact the investigator or a member of the research team. Contact information is included in the informed consent form.

[23] Auditing

There will be no auditing.

Ethics and dissemination

[24] Research ethics approval

This study was approved by an independent Medical Ethics Committee affiliated with Ghent University Hospital and Ghent University. The study is conducted according to the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki established to protect people participating in clinical studies. (Reference number ONZ-2023-0350). Written informed consent will be obtained from all the participants.

[25] Protocol amendments

Any modification to the protocol of the study will need a new approval by the Medical Ethics Committee, an amendment will be requested. The decision to amend the protocol will be discussed within the research team.

[26] Consent or assent

The informed consent forms [32] were approved by the Medical Ethics Committee affiliated with the Ghent University Hospital and Ghent University. The forms are addressed to the elderly person living at home. The participants should read the informed consent forms thoroughly and discuss them with the researcher. After all questions have been answered and upon agreement, the participant should sign the forms in the space provided.

The informed consent form requests the participant's permission to use his pseudonymized data for future scientific research in the same/similar research domain.

[27] Confidentiality

All the data will be collected pseudonymized. Each participant will be given a coded identification number. The key will be kept on a secured server of UGent to which only researchers of the Gerodent PLUS project will have access. The informed consent forms will be stored separately from study participants records identified by code number.

The informed consent form requests the participants permission to share the results of the oral examination with the family doctor or dentist. A referral and report letter will be given to the participant for these professionals.

Raw data will not be shared with members outside of the Gerodent PLUS-research team.

[28] Declaration of interests

The researchers declare that they have no competing interests.

[29] Access to data

Only members of the Gerodent PLUS-research team will have full access to the data. Raw data will not be shared with the sponsor or with journals.

[30] Ancillary and post-trial care

No disadvantages are expected for elderly people participating in this study; therefore no arrangements are made for ancillary care and post-trial care.

[31] Dissemination policy

Results of this study will be published and will be communicated to the Flemish Government. No professional writers will be used.

No later than 3 years after the collection of the final results, a description of the trial methods (including the protocol), deidentified data and all analyses will be shared upon request.

Appendices

[32] Informed consent materials

ICF – questionnaire

Information letter for participants

Study title: Gerodent PLUS: oral status of elderly people living at home

Dear,

You are invited to participate in a study. Before you decide to participate in this study, please take sufficient time to read this information letter carefully and discuss it with the investigator or his/her representative. Also, take the time to ask questions if there are ambiguities or if you would like additional information. This process is called "informed consent" to participate in a study. Once you have decided to participate in the study, you will be asked to sign the consent form on the back.

1. **DESCRIPTION AND PURPOSE OF THE STUDY**

Gerodent PLUS is a project of Ghent University. The aim of this project is to improve oral health in frail elderly people living at home. We want to improve oral health by improving cooperation between health care providers (e.g. dentist, general practitioner and pharmacist) and access to care.

We kindly ask you if you would take the time to answer some questions. This will take a maximum of 1 hour of your time.

We would also like to ask you if we may contact you by phone 4 months later to answer another short questionnaire. This will take approximately 10 minutes of your time.

This study was pre-approved by an independent Committee on Medical Ethics affiliated with Ghent University Hospital and Ghent University. The study is conducted according to the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki established to protect people participating in clinical studies.

The sponsor of this study is Ghent University. This data collection is conducted under the supervision of Prof. Dr. Barbara Janssens. Students of the Department of Oral Health Sciences will be part of the research team.
This study is made possible by the Flemish Agency for Care & Health.

2. **CONSENT AND REFUSAL**

Participation in this study is completely voluntary. You may refuse to have the oral examination performed without having to give a reason and without in any way affecting the further relationship with the researcher.

3. **BENEFITS**

By participating in this study, the results obtained may lead to new and more effective methods for the prevention, identification and treatment of oral health problems in elderly people living at home.

4. **COST**

Participation in this study entails no additional cost to you, but it also offers no financial benefit.

5. **PROCESSING OF PERSONAL DATA**

In accordance with the Belgian law of August 22, 2002 on patient's rights, the General Data Protection Regulation (AVG or GDPR) (EU) 2016/679 of April 27, 2016, and the Belgian law of July 30, 2018, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, your privacy will be respected and you may access the data collected about you. Any incorrect data can be corrected at your request. Your other rights (including the right to restrict the processing of your (personal) data, the right to have your (already collected) data erased in certain circumstances, and the right to lodge a complaint) will also be safeguarded.
For more information on the rights you have and how to exercise them, please visit the UGent website (https://www.ugent.be/nl/univgent/privacy/privacyverklaring.htm).

Your participation in the study means that your data will be processed for the purpose of the clinical study. This processing of data is necessary for the performance of a task carried out in the public interest according to Article 6, paragraph 1 (e) and is necessary for the purpose of scientific research according to Article 9, paragraph 2 (j) of the General Data Protection Regulation.

All information collected during this study will be pseudonymized (in doing so, your data can still be linked back to your personal file by means of a code). The key to the codes will only be accessible to the researchers. The collected pseudonymized data can be shared with other (future) researchers. This may lead to reuse of your pseudonymized data for future academic research projects and studies exclusively in the context of the same or similar disease/pathology or treatment. Such new study and data reuse must always be submitted and approved by the ethics committee. If you wish your data not to be used for future research, you can contact the DPO for this purpose (see contact details under chapter 5).

Only the pseudonymized data will be used for data analysis and in any documentation, reports or publications (in medical journals or congresses) about the study. Confidentiality of your data is thus guaranteed at all times.

Both personal data and data concerning your health will be processed and kept for at least 10 years after the end of the study and for security reasons regarding the study conducted and its (possible) follow-up.

The data controller is the institution of the study's principal investigator, Prof. Dr. Barbara Janssens (Ghent University). Her research team will have access to your personal data. For data protection purposes, the data will be processed by persons belonging to the research team and designated by and under the responsibility of the principal investigator, including internal employees with non-health care professions.

Representatives of the sponsor, auditors, the Medical Ethics Committee and the competent authorities, all bound by professional secrecy, have direct access to your medical records to check the procedures of the study and/or the data, without

violating confidentiality. This can only be done within the limits permitted by the relevant laws. By signing the consent form, after prior explanation, you consent to this access.

To obtain more substantive information about the study and to exercise your rights, please contact the study team.
The Data Protection Officer can also provide you with more information on the protection of your personal data if you wish. Contact details: Hanne Elsen, privacy@ugent.be.

The Belgian supervisory authority responsible for enforcing data protection legislation can be reached at the contact details below:

Gegevensbeschermingsautoriteit (GBA)
Drukpersstraat 35 – 1000 Brussel
Tel. +32 2 274 48 00
e-mail: contact@apd-gba.be
Website: www.gegevensbeschermingsautoriteit.be

6. **INSURANCE**

The sponsor provides compensation and/or medical treatment in the event of damage and/or injury resulting from participation in this clinical trial. For this purpose, an insurance policy with faultless liability has been taken out in accordance with the Law on Experiments on the Human Person of May 7, 2004, the Belgian Law of May 7, 2017 on clinical trials on medicinal products for human use and the Belgian Law of December 22, 2020 on medical devices (Allianz Global Corporate & Specialty; Uitbreidingstraat 86, 2600 Berchem; Tel: +32 33 04 16 00; policy number for UZ Gent BEL001889 - policy number for UGent BEL000862).

7. **CONTACT**

If an injury occurs as a result of the study, or if you require additional information about the study or about your rights and obligations, you may contact the investigator or a member of his or her team:

Responsible researcher: Prof. Dr. Barbara Janssens (barbarae.janssens@ugent.be)

Executive researcher: Aster De Vleeschauwer (aster.devleeschauwer@ugent.be)

Adres: C. Heymanslaan 10 (1P8), 9000 Gent

Phone number: +32 9 332 02 81

Email address: gerodentplus@ugent.be

CONSENT FORM FOR PARTICIPANTS

I have read and understood the document "Information Letter for Participants" pages 1 through 3 and have been given a copy of it. I have been explained the nature, purpose and duration of the study and what is expected of me.
I understand that participation in the study is voluntary and that I may withdraw from the study at any time without giving a reason for this decision and without affecting my continued treatment.
I am aware that this study was approved by an independent Committee on Medical Ethics attached to Ghent University Hospital and the University of Ghent and that this study will be conducted according to the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki, established to protect people participating in experiments. This approval was in no way the impetus for deciding to participate in this study.
I have been informed that both personal data and data concerning my health will be processed and kept for at least 10 years after the end of the study. I am informed that I have the right to access and correct this data. Since this data is processed for medical scientific purposes, I understand that access to my data may be delayed until after the study has ended. If I want access to my data, I will contact the researcher responsible for its processing.
I am aware that my pseudonymized data will be used for **current** scientific research.
I am aware that my pseudonymized data may be used for **future** academic scientific research within the framework of the same/similar research field. Such new study should always be submitted and approved by the ethics committee. If I wish my data not to be used for future research, I will contact the DPO (see contact details under section 5).
I understand that my primary care physician and dentist will be informed of my participation in this study and any problems present in my mouth.

Check box by participant if agreed

I agree to participate in this study consisting of the following **mandatory aspects** as explained under section 1 of the information letter:
- I agree to answer a questionnaire.
- I agree to be contacted after 4 months for a short telephone questionnaire.

Name of participant	Signature	Date
Name of researcher*	Signature	Date

2 copies should be completed. The original will be kept by the researcher in the hospital for at least 10 years, the copy will be given to the participant.

*Check box by researcher if agreed

I certify that I have orally provided the necessary information regarding this study (the nature, purpose, and foreseeable effects) as well as a copy of the information document to the participant.	
I confirm that no pressure has been exerted on the participant to get him/her to agree to participate in the study and I am willing to answer any additional questions.	

ICF – oral examination

Information letter for participants

Study title: Gerodent PLUS: oral status of elderly people living at home

Dear,

You are invited to participate in a study. Before you decide to participate in this study, please take sufficient time to read this information letter carefully and discuss it with the investigator or his/her representative. Also, take the time to ask questions if there are ambiguities or if you would like additional information. This process is called "informed consent" to participate in a study. Once you have decided to participate in the study, you will be asked to sign the consent form on the back.

1. **DESCRIPTION AND PURPOSE OF THE STUDY**

Gerodent PLUS is a project of Ghent University. The aim of this project is to improve oral health in frail elderly people living at home. We want to improve oral health by improving the cooperation between health care providers (e.g. dentist, general practitioner and pharmacist) and access to care.

To this end, on the one hand we want to map the oral health of 65+ people living at home. On the other hand, we also want to find out whether a low-threshold initial oral examination is sufficient to make the elderly visit a dentist again, when this would not be the case now.

We kindly ask you if you would take the time to have an examination of your mouth by a dentist (in training). This will take about 40 minutes of your time. Afterwards, we will update you on your oral health and what you can do about it if any problems are identified.

This study was pre-approved by an independent Medical Ethics Committee affiliated with Ghent University Hospital and Ghent University. The study is conducted according to the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki established to protect people participating in clinical studies.

The sponsor of this study is Ghent University. This data collection is conducted under the supervision of Prof. Dr. Barbara Janssens. Students from the Department of Oral Health Sciences will participate

2. **CONSENT AND REFUSAL**

Participation in this study is completely voluntary. You may refuse to have the oral examination performed without having to give a reason and without in any way affecting the further relationship with the researcher.

3. **BENEFITS**

By participating in this study, you will receive an oral examination and will be explained about any identified problems in your mouth. In addition, you will receive information on how to improve your oral health.

Furthermore, the results obtained may lead to new and more efficient methods for the prevention, identification and treatment of oral health problems in elderly people living at home.

4. **COST**

Participation in this study entails no additional cost to you, but it also offers no financial benefit.

5. **PROCESSING OF PERSONAL DATA**

In accordance with the Belgian law of August 22, 2002 on patient's rights, the General Data Protection Regulation (AVG or GDPR) (EU) 2016/679 of April 27, 2016, and the Belgian law of July 30, 2018, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, your privacy will be respected and you may access the data collected about you. Any incorrect data can be corrected at your request. Your other rights (including the right to restrict the processing of your (personal) data, the right to have your (already collected) data erased in certain circumstances, and the right to lodge a complaint) will also be safeguarded.
For more information on the rights you have and how to exercise them, please visit the UGent website (https://www.ugent.be/nl/univgent/privacy/privacyverklaring.htm).

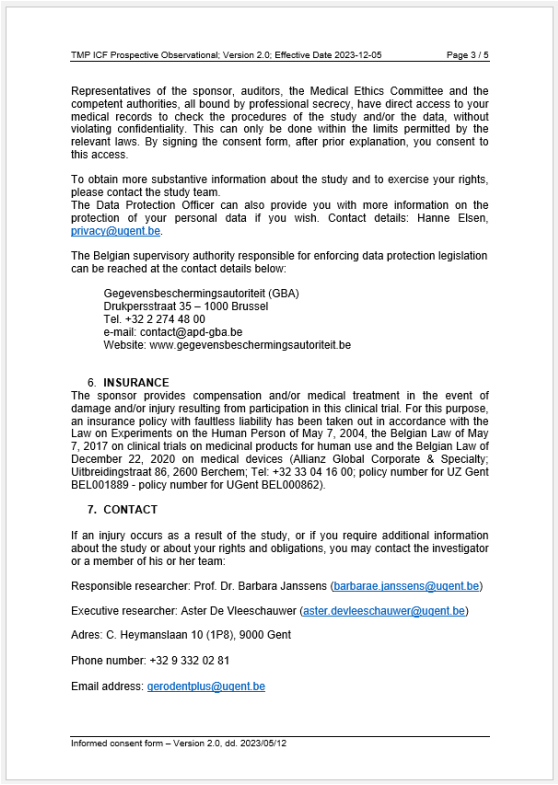
Your participation in the study means that your data will be processed for the purpose of the clinical study. This processing of data is necessary for the performance of a task carried out in the public interest according to Article 6, paragraph 1 (e) and is necessary for the purpose of scientific research according to Article 9, paragraph 2 (j) of the General Data Protection Regulation.

All information collected during this study will be pseudonymized (in doing so, your data can still be linked back to your personal file by means of a code). The key to the codes will only be accessible to the researchers. The collected pseudonymized data can be shared with other (future) researchers. This may lead to reuse of your pseudonymized data for future academic research projects and studies exclusively in the context of the same or similar disease/pathology or treatment. Such new study and data reuse must always be submitted and approved by the ethics committee. If you wish your data not to be used for future research, you can contact the DPO for this purpose (see contact details under chapter 5).

Only the pseudonymized data will be used for data analysis and in any documentation, reports or publications (in medical journals or congresses) about the study. Confidentiality of your data is thus guaranteed at all times.

Both personal data and data concerning your health will be processed and kept for at least 10 years after the end of the study and for security reasons regarding the study conducted and its (possible) follow-up.

The data controller is the institution of the study's principal investigator, Prof. Dr. Barbara Janssens (Ghent University). Her research team will have access to your personal data. For data protection purposes, the data will be processed by persons belonging to the research team and designated by and under the responsibility of the principal investigator, including internal employees with non-health care professions.



Representatives of the sponsor, auditors, the Medical Ethics Committee and the competent authorities, all bound by professional secrecy, have direct access to your medical records to check the procedures of the study and/or the data, without violating confidentiality. This can only be done within the limits permitted by the relevant laws. By signing the consent form, after prior explanation, you consent to this access.

To obtain more substantive information about the study and to exercise your rights, please contact the study team.
The Data Protection Officer can also provide you with more information on the protection of your personal data if you wish. Contact details: Hanne Elsen, privacy@ugent.be.

The Belgian supervisory authority responsible for enforcing data protection legislation can be reached at the contact details below:

Gegevensbeschermingsautoriteit (GBA)
Drukpersstraat 35 – 1000 Brussel
Tel. +32 2 274 48 00
e-mail: contact@apd-gba.be
Website: www.gegevensbeschermingsautoriteit.be

6. **INSURANCE**

The sponsor provides compensation and/or medical treatment in the event of damage and/or injury resulting from participation in this clinical trial. For this purpose, an insurance policy with faultless liability has been taken out in accordance with the Law on Experiments on the Human Person of May 7, 2004, the Belgian Law of May 7, 2017 on clinical trials on medicinal products for human use and the Belgian Law of December 22, 2020 on medical devices (Allianz Global Corporate & Specialty; Uitbreidingstraat 86, 2600 Berchem; Tel: +32 33 04 16 00; policy number for UZ Gent BEL001889 - policy number for UGent BEL000862).

7. **CONTACT**

If an injury occurs as a result of the study, or if you require additional information about the study or about your rights and obligations, you may contact the investigator or a member of his or her team:

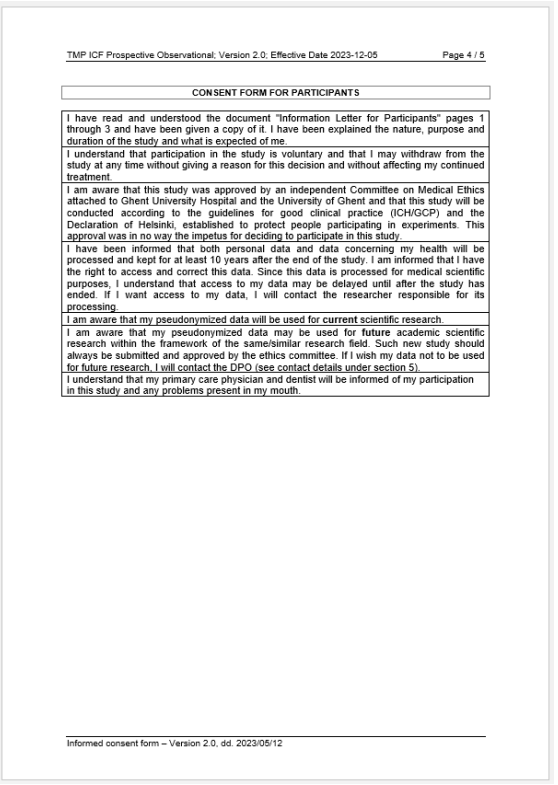
Responsible researcher: Prof. Dr. Barbara Janssens (barbarae.janssens@ugent.be)

Executive researcher: Aster De Vleeschauwer (aster.devleeschauwer@ugent.be)

Adres: C. Heymanslaan 10 (1P8), 9000 Gent

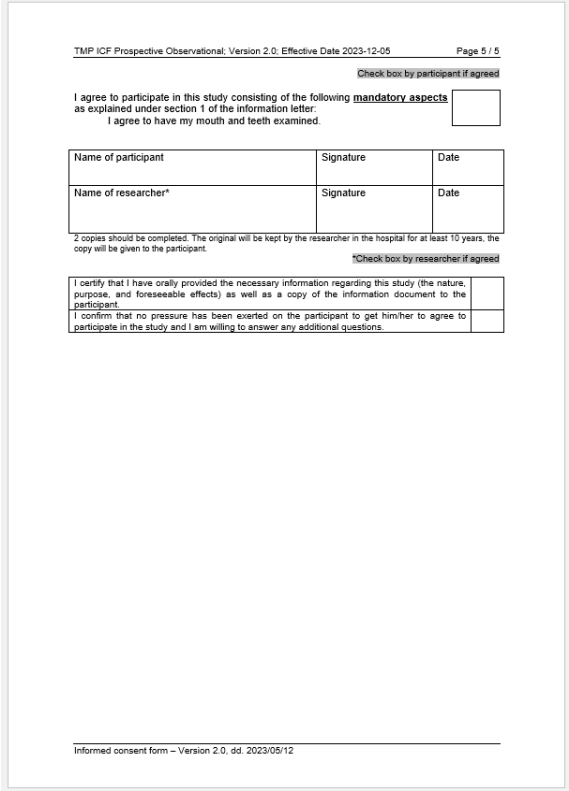
Phone number: +32 9 332 02 81

Email address: gerodentplus@ugent.be



CONSENT FORM FOR PARTICIPANTS

I have read and understood the document "Information Letter for Participants" pages 1 through 3 and have been given a copy of it. I have been explained the nature, purpose and duration of the study and what is expected of me.
I understand that participation in the study is voluntary and that I may withdraw from the study at any time without giving a reason for this decision and without affecting my continued treatment.
I am aware that this study was approved by an independent Committee on Medical Ethics attached to Ghent University Hospital and the University of Ghent and that this study will be conducted according to the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki, established to protect people participating in experiments. This approval was in no way the impetus for deciding to participate in this study.
I have been informed that both personal data and data concerning my health will be processed and kept for at least 10 years after the end of the study. I am informed that I have the right to access and correct this data. Since this data is processed for medical scientific purposes, I understand that access to my data may be delayed until after the study has ended. If I want access to my data, I will contact the researcher responsible for its processing.
I am aware that my pseudonymized data will be used for **current** scientific research.
I am aware that my pseudonymized data may be used for **future** academic scientific research within the framework of the same/similar research field. Such new study should always be submitted and approved by the ethics committee. If I wish my data not to be used for future research, I will contact the DPO (see contact details under section 5).
I understand that my primary care physician and dentist will be informed of my participation in this study and any problems present in my mouth.



Check box by participant if agreed

I agree to participate in this study consisting of the following **mandatory aspects** as explained under section 1 of the information letter:
I agree to have my mouth and teeth examined. ☐

Name of participant	Signature	Date
Name of researcher*	Signature	Date

2 copies should be completed. The original will be kept by the researcher in the hospital for at least 10 years, the copy will be given to the participant.

*Check box by researcher if agreed

I certify that I have orally provided the necessary information regarding this study (the nature, purpose, and foreseeable effects) as well as a copy of the information document to the participant.	☐
I confirm that no pressure has been exerted on the participant to get him/her to agree to participate in the study and I am willing to answer any additional questions.	☐

[33] Biological specimens

No biological specimens will be collected.

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