Trials

STUDY PROTOCOL

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Can a low-threshold check-up motivate older adults to schedule a dental visit? Study protocol for a randomized controlled trial

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Abstract

Background Most oral diseases benefit from early detection by dental professionals. However, in the older population, regular dental attendance is low. This trial investigates whether a low-threshold check-up by a dental professional in a non-dental setting can motivate older persons to seek professional oral care.

Methods A total of 194 community-dwelling persons aged 65 years and older, without a dental check-up over the last 12 months, will be recruited for this randomized, controlled, two-arm, single-blinded, superiority trial with a 1:1 allocation ratio. The intervention group will receive an oral examination including tailored oral health information. They will also be informed about the importance of regular dental visits and will be provided with referral letters for the dental professional and the family physician and a list of nearby dentists. In the control group, the oral examination including tailored information will not be performed. This group will only receive flyers with general oral hygiene information and a list of nearby dentists. The primary outcome is whether or not the participants will contact a dental professional within four months after the intervention.

Discussion This study examines the efficacy of a low-threshold dental check-up intervention to motivate older adults to contact a dental professional and reactivate them into primary oral care, addressing barriers to oral care such as low health literacy, subjective treatment need, and dental anxiety. Key strategies include enhancing oral health knowledge, identifying existing oral issues, and involving family physicians. The study, set to run from April 2024 to March 2025, aims to inform future evidence-based oral health promotion strategies for community-dwelling older adults.

Trial registration ClinicalTrials.gov NCT06341959. Registered on 25 April 2024.

Keywords Older adults, Oral examination, Dental attendance, Dental care, Oral health promotion, Oral health

Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

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Title {1}	Can a low-threshold check-up motivate older adults to schedule a dental visit? Study protocol for a Randomized Controlled Trial
Trial registration {2a and 2b}	Protocol ID: GerodentPLUS1 ClinicalTrials.gov ID: NCT06341959 All relevant items from the WHO Trial Registration Data Set can be found within the body of this protocol.
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Name and contact information for the trial sponsor {5b}	N/A, there was no sponsor.
Role of sponsor {5c}	The funder has 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.

Introduction

Background and rationale {6a}

Globally the population is aging. In 2022, almost 10% of the global population was aged 65 or older. Europe and Northern America accounted for the largest proportion of older individuals in 2022 and projections indicate a rise to 22.0% in 2030 and 26.9% in 2050 in these regions. Belgium ranks in the top European countries with the highest proportion of individuals aged 85 and older within its population [1, 2].

Oral disorders are among the main disability drivers in people aged 70 and above [3]. Given the cumulative nature of oral conditions, older adults experience higher levels of tooth loss than their younger counterparts. Furthermore, they present with high levels of untreated oral diseases [4]. This not only contributes to poor overall health but also negatively impacts their quality of life and general well-being [5–7].

Regular dental attendance plays a pivotal role in the early diagnosis and effective treatment of oral diseases [8–10]. Nevertheless, regular dental attendance is lower in older than in younger age groups [11, 12]. Moreover, the frequency of attending a family doctor is negatively associated with dental attendance [13]. The main reported reasons among older adults for not seeking dental care are lack of awareness on its importance, edentulousness, perceived costs, logistical challenges associated with accessing dental services, dental anxiety, and negative prior experiences [14–16]. To improve dental attendance in older adults, health services research to reduce these barriers is needed and aligns with the expressed needs of the target group themselves [17].

To our knowledge, the impact of a dental screening in a setting belonging to their familiar environment on future contact with a dental professional among older adults has not yet been examined.

Objectives {7}

The objective of this study is to examine the effect of a low-threshold dental check-up in a non-dental setting among community-dwelling older adults (≥65 years of age) on contacting a dentist.

The intervention will include an oral examination including tailored information on oral health issues. Participants will be informed about the importance of regular dental visits and will be given referral letters for the dental professional and the family physician. Participants will also receive informational flyers about oral hygiene and a list of nearby dentists, in case they do not have a regular dentist. This will be compared to a control group, which will only receive informational flyers and a list of nearby dentists.

Trial design {8}

A randomized, controlled, single-blinded, superiority trial with two groups will be conducted using a 1:1 allocation ratio. To avoid imbalance between groups, blocked randomization with blocks consisting of 8 to 12 people will be conducted. The protocol was written following the SPIRIT guidelines [18].

Methods: participants, interventions, and outcomes

Study setting {9}

The study will be conducted in a non-dental setting at a location familiar for older adults within two primary care regions (ELZ RITS and ELZ Scheldekracht) in Flanders, Belgium.

Eligibility criteria {10}

Interested individuals will be included if they (a) are 65 years of age or older, (b) are community-dwelling within the two selected primary care zones in Flanders (Belgium), (c) are Dutch speaking, (d) did not have a dental check-up in the last 12 months, and (e) have sufficient cognitive ability to answer the questionnaires. Older

adults of whom the partner is already enrolled in the study will be excluded. Community-dwelling refers to anyone who does not reside 24/7 in a residential care facility.

Who will take informed consent? {26a}

The informed consent forms {32} were approved by the Medical Ethics Committee affiliated with Ghent University Hospital. The participants will be encouraged to read the informed consent forms thoroughly and discuss them with the researcher. After all questions have been answered and upon agreement, the participants will be asked to sign the forms.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

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

Interventions

Explanation for the choice of comparators {6b}

The intervention will be compared to non-specific oral health information. Upon completion of the questionnaire, which is identical to that of the intervention group (as discussed later in Sect. 18a), the control group will be provided with basic guidance on oral hygiene via flyers and, in case they do not have a regular dentist, a list of local dentists. This comparator is chosen as this information, which is readily available online, can be provided to older adults without the involvement of a dental professional.

Intervention description {11a}

The participants allocated to the intervention group will receive an oral examination performed by the project-affiliated dental researchers. This will involve an assessment of oral hygiene, including the presence of plaque on teeth, tongue, and dentures, as well as the presence of food debris in the oral cavity. Participants will be inspected for mucosal lesions. For dentate participants, the number of teeth and the presence of caries, fillings, or crowns will be recorded. The severity of caries will be evaluated using the PUFA score [19]. Periodontal status will be assessed by examining the mobility of natural teeth and the Dutch Periodontal Screening Index (DPSI) [20]. Additionally, the presence of removable and fixed dentures and the number of occlusal contacts (with dentures present) will be noted. Examiners will use a head lamp, a mouth mirror (Henry Schein 900,748 and 9,009,470), and a periodontal probe (CyberTech C900-3456) for the oral examination. No x-rays will be taken because this will not be feasible if this intervention should be upscaled. Next, verbal information about any identified oral problem will be given. Finally, participants in the intervention group will receive a referral letter for a dental professional and a report for their family doctor (Appendix 1).

All participants will receive a flyer with oral hygiene instructions adapted to their needs (natural teeth and/or dentures). These flyers are evidence-based brochures compiled by the Flemish Institute of Oral Health ("Gezonde Mond") on performing good oral hygiene (Appendix 2). Participants without a regular dentist will receive a list with contact information of dentists in the area.

Criteria for discontinuing or modifying allocated interventions {11b}

If a participant is randomized into the intervention group but refuses to have an oral examination, this will be noted. Participants allocated to the control group requesting an oral examination will be advised to contact a dental professional, this will also be noted.

Strategies to improve adherence to interventions {11c}

Participants are not required to perform any actions independently; all procedures will be conducted in collaboration with the researcher. This approach ensures that participants do not need to initiate actions on their own. Consequently, no strategies to improve adherence are pre-established.

Relevant concomitant care permitted or prohibited during the trial {11d}

All concomitant care is permitted during the trial.

Provisions for post-trial care {30}

N/A, no disadvantages are expected for the participants. However, they are informed of possibilities to contact the researchers if ancillary care or post-trial care is needed.

Outcomes {12}

The primary outcome is whether or not the participant will contact a dental professional within four months after the intervention (yes/no). In Flanders (Belgium), there is an increasing shortage of dental professionals. As a consequence, many dental practices do not accept any new patients or have long waiting lists. Therefore, the outcome is not an actual dental appointment. Differences in proportions between the intervention and control group at timepoint 1 will be reported.

The secondary outcomes are self-reported brushing frequency in comparison to the norm and changes in self-reported use of brushing materials.

Self-reported brushing frequency in comparison to the norm

The number of brushing episodes achieved by participants will be analyzed relative to the expected norm, which represents the recommended weekly brushing frequency outlined in the flyer provided to all participants. For individuals with natural teeth and no removable dentures, the norm is twice daily (14 times per week) [21]. For those without natural teeth but with removable dentures, the norm is once daily (7 times per week) [22]. For participants with both natural teeth and removable dentures, the combined norm is 21 brushing episodes per week. Brushing frequency will be calculated separately for natural teeth and dentures, based on questionnaire responses categorized as follows: (1) Once per week or less: 1 brushing episode per week, (2) Less than once per day: 3.5 brushing episodes per week (midpoint centering), (3) Once per day: 7 brushing episodes per week. (4) Twice per day: 14 brushing episodes per week. For example, a participant with both natural teeth and removable dentures who brushes their natural teeth once daily (7/14) and their dentures once daily (7/7) will achieve a brushing ratio of 0.67 (14/21). If a participant exceeds the expected brushing norm, the maximum score of 1.0 will be assigned.

Changes in self-reported use of brushing materials

Among participants with removable dentures, the self-reported use of a denture brush will be evaluated. This variable will be categorized as follows: "no change" for participants whose self-reported denture brush usage remained consistent between T0 and T1; "improvement" for participants who did not report using a denture brush at T0 but reported its use at T1; and "deterioration" for participants who reported using a denture brush at T0 but not at T1.

Similarly, the self-reported use of hand soap or denture cleanser will be evaluated among participants with removable dentures. This variable will be categorized as follows: "no change" for participants whose self-reported use of these materials remained consistent between T0 and T1; "improvement" for participants who did not report using hand soap or a denture cleaner at T0 but reported using hand soap or a denture cleaner at T1; and "deterioration" for participants who reported using hand soap or a denture cleaner at T0 but not at T1.

Participant timeline {13}

The participant timeline is shown in Fig. 1.

Sample size {14}

G*Power (version 3.1.9.2) was used to calculate the sample size. To the best of our knowledge, this type of

	Study period			
	Enrollment	Allocation	Post-allocation	Close-out
Timepoint	T0	T0	T0	T1*
ENROLLMENT:				
Eligibility screening	X			
Informed consent	X			
Questionnaire including frailty assessment	X			
Allocation		X		
INTERVENTION:				
Informed consent			X	
Screening of oral status			X	
Giving tailored information about oral status and oral hygiene instructions			X	
Referral letter for dental professional and report for family physician			X	
List of dental professionals			X	
ASSESSMENT:				
Telephone questionnaire				X

* Four months after T0.

Fig. 1 Participant timeline. *Four months after T0

intervention has not yet been conducted within the target population. Therefore, expert opinions were utilized to estimate that the intervention would activate 30% of participants in the intervention group. In the control group, a maximum of 10% is expected to contact a dentist. Using logistic regression, with $\alpha = 0.05$ and $1 - \beta = 80\%$, to detect a mean difference of 20% with equal allocation to both groups, a sample size of 129 persons is required. To allow for 33% drop-out (due to advanced age and potential frailty of the participants or due to an incorrect phone number or not answering calls), 194 persons will be recruited.

Recruitment {15}

All service centers and Social Welfare Offices within the selected primary care regions will be contacted to participate in the study. Together with the interested centers, different dates will be selected to perform the study in their facilities. Organizations within these primary care regions and other local initiatives focusing on social activities or care for older people will also be contacted to spread the call for participation in the study. Furthermore, residents of assisted living facilities will be contacted. Home care service organizations in the region have agreed to assist with participant recruitment.

Assignment of interventions: allocation

Sequence generation {16a}

A randomization list (computer-generated by RC) will be processed in REDCap by a HIRUZ staff member. HIRUZ is the Clinical Research Centre of Ghent University Hospital and Ghent University. Randomization will be stratified by frailty status, based on the outcome of the Groningen Frailty Indicator included in the initial questionnaire. Random permuted blocks will be created using SAS v9.4 with variable sizes to avoid that the treatment allocation can be predicted.

Concealment mechanism {16b}

Participants will be randomly assigned to either control or intervention group with a 1:1 allocation by the REDCap program. 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 is completed.

Implementation {16c}

A randomization list (prepared by RC) will be processed in REDCap by a HIRUZ staff member. Screeners will enroll participants, but they will not have access to this list.

Assignment of interventions: blinding

Who will be blinded {17a}

This study is a single-blinded trial. At timepoint 0, after completion of the questionnaire, allocation will be revealed to the researcher. No information will be given to the participants in the control group about oral examinations in the intervention group. Participants in the intervention group will be told that due to an excess of time, they will also receive an oral examination. At timepoint 1 the participants will be contacted again by a different researcher, blinded to the actual allocation of the participants.

Procedure for unblinding if needed {17b}

N/A, there is no procedure for unblinding needed, participants remain blinded to their allocation.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Following the provision of informed consent, all participants will receive a questionnaire. This questionnaire will be administered through a structured interview. The questionnaire consists of five sections. The first section addresses general participant information, including date of birth, gender, education, income, place of residence, living arrangements (alone or with others), and whether the participant receives assistance from a home care nurse. Part 2 assesses the participant's frailty utilizing the Groningen Frailty Indicator, a validated and multidimensional screening tool [23, 24]. The tool consists of 15 questions addressing physical, cognitive, social, and psychological domains. The score, ranging from 0 to 15, reflects increasing limitations, with a score of ≥ 4 serving as the threshold for identifying frailty. The third section inquires about the participant's family physician and whether the participant has a regular dentist. The fourth section focuses on the dental history, oral status, current issues related to their mouth, teeth or dentures, and oral hygiene practices including the frequency of care and the tools utilized (toothpaste, electric toothbrush, tongue scraper, etc.). They will be asked whether they currently perceive a need for dental treatment and what the reasons behind this perception is. A xerostomia questionnaire is administered in the final Sect. (25).

Next, participants will be allocated to either an intervention or control group. The intervention will be executed as described in Sect. 11a. Four months after T0, the participants will be contacted by phone. Information on any communication on oral health with a dental professional since the intervention and the reasons for this interaction will be gathered. Furthermore, it will be determined whether the participant

has discussed this study with their family physician. In addition, they will be asked once more about self-care practices concerning teeth or dentures, the frequency of care, and used brushing materials, as well as whether the participant has reviewed the oral hygiene flyers at home.

Study data will be collected and managed using REDCap electronic data capture tools hosted at Ghent University. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for data integration and interoperability with external sources [26, 27].

Several validated questionnaires and screening tools will be used. The Groningen Frailty Indicator will be used to determine the level of frailty. The feasibility, reliability, and validity of this tool have been confirmed in previous research [23, 24]. The Dutch version of the Summated Xerostomia Inventory will be used, this is a valid tool for measuring xerostomia symptoms in clinical and epidemiological research [25]. Dental plaque will be evaluated by the Quigley-Hein plaque index, denture plaque will be evaluated according to the method of Augsburger and Elahi, and tongue plaque will be assessed through the Winkel tongue coating index. These tools are widely used methods for measuring dental plaque in clinical research and dental practices [28–30]. To evaluate the severity of untreated dental caries, the PUFA index will be used. The reliability of this index has been proven [19]. The periodontal condition will be screened by using the Miller index for tooth mobility and the validated Dutch Periodontal Screening Index [20, 31].

The study was piloted to examine the duration and feasibility of the intervention, software usability and to iron out mistakes. Following a brief training and calibration sessions provided by ADV, the intraclass correlation coefficient was calculated for all data screeners for the oral examination. These coefficients ranged from 0.833 to 0.967, indicating a strong to almost perfect level of agreement [32].

Researchers will be guided by an integrated script on REDCap, questions will be displayed and reminders will pop up in case of missing data. This will be further reinforced by mandatory selection per section that all questions are completed. REDCap will automatically generate a calendar for the telephonic questionnaire at timepoint 1.

Plans to promote participant retention and complete follow-up {18b}

At the end of the intervention, participants will be reminded that they will receive a phone call (or e-mail if requested by the participant) four months later. Contact information of a partner or caregiver will also be registered in case the participant does not answer the telephone call. Four attempts will be made on two different days to contact the participant or caregiver: two calls in the morning and two calls in the afternoon. If the participant prefers to be contacted back by e-mail, one reminder will be sent one week after the first e-mail.

During the piloting phase, it was observed that recruiting participants during social activities and game afternoons is not advisable. This approach leads to early drop-out, as individuals prefer to participate in the ongoing activities rather than to commit to the study. Hence, it was decided to minimize the recruitment of participants during this type of event.

All participants will receive a pen with the logo of Gerodent PLUS (i.e., the name of the study project) as a gift. This pen might serve as an additional reminder about the upcoming phone call by the researchers.

Data management {19}

The data will exclusively be entered electronically within the REDCap system. Data quality is ensured within the REDCap platform through an integrated script and multiple measures to guarantee data completeness. The extent of actions that each user can undertake is restricted by the rights associated with their respective accounts.

Data collection will end two weeks after the last planned telephone questionnaire. Upon completion of data collection, data will be exported out of the REDCap platform for subsequent analysis. These files will be securely stored on servers maintained by Ghent University, only accessible by the members of the research team. For data transference, a Secure File Transfer platform, namely Belnet Filesender will be used.

Confidentiality {27}

Each participant will receive a unique identification number to pseudonymize the data. The corresponding key will be kept on a secured server of Ghent University, exclusively accessible by the members of the research team. The hard copy informed consent forms will be scanned for electronic storage separately from the study participants' records. Both collected data and informed consent forms will be kept for 10 years, as stipulated in the informed consent form. Following

the publication of the research findings, raw pseudonymized data can be made available upon request.

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

N/A, no biological specimens will be collected.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Primary outcome

Our primary estimand is the difference between the two conditions in the proportion of participants who had dental contact in the period between baseline to month 4, regardless of whether they refused to have an oral examination (i.e., treatment-policy strategy).

A logistic regression analysis will be performed with self-reported dental contact as the outcome. Group allocation (two levels: intervention group and control group) and frailty (two levels: frail and non-frail) will be added as predictors to the model. The exponentiated regression coefficient for group allocation will be interpreted as the intervention effect, expressed as the odds ratio for dental contact, conditional on frailty. To improve interpretability, predicted probabilities will be calculated to estimate the risk difference.

Secondary outcomes

A linear regression analysis will be performed with the percentage of self-reported brushing frequency at T1 relative to the norm as the outcome. Group allocation (two levels: intervention group and control group), frailty (two levels: frail and non-frail), and percentage of self-reported brushing episodes relative to the norm at T0 will be added as predictors to the model.

Multinomial logistic regression analysis will be performed with a change in self-reported brushing materials (i.e., denture brush usage and use of hand soap/denture cleanser) as the outcome, with "no change" as the reference group [33]. Group allocation (two levels: intervention group and control group) and frailty (two levels: frail and non-frail) will be added as predictors to the model.

Interim analyses {21b}

N/A, no interim analyses will be performed.

Methods for additional analyses (e.g., subgroup analyses) {20b}

Exploratory subgroup analyses will be conducted to examine interaction between group allocation and the following baseline characteristics of interest: age, gender (male vs. female), education (low vs. high), living arrangements (alone vs. with others), receiving assistance from a home care nurse (yes vs. no), frailty status (frail vs. not frail), time since last dental visit, having a regular dentist (yes vs. no), perceived need for dental visit by the participant, and dental status (dentate vs. edentulous) in order to ascertain the beneficiaries of the intervention. For each baseline characteristic of interest, a logistic regression model with the predictor, group allocation, and their interaction will be applied. To improve interpretability, predicted probabilities will be calculated to estimate the risk differences.

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

If the participant refuses the oral examination, this will be noted and participants will be further analyzed in the intervention group following the treatment policy strategy (under the intention-to-treat principle).

All participants will be contacted at the stipulated timepoint 1. If direct participant contact can't be established, the recorded proxy (partner, child, or caregiver) will be approached in an attempt to communicate with the participant. Should direct communication with the participant be infeasible (e.g., due to hospitalization), the questionnaire will be submitted to the proxy. Participants deceased during the trial period will be analyzed according to the "while alive strategy." If a participant remains unreachable, missing data will be addressed by applying multiple imputation per randomization arm. In addition, the imputation model will be improved by including variables related to the missingness and variables correlated with variables of interest. Predictors of the multiple imputation model will be group allocation, age, gender, education, living arrangements (alone or with others), whether the participant receives assistance from a home care nurse, frailty status, time since last dental visit, whether the participant has a regular dentist, perceived need for dental visit by the participant, and dentate or edentulous status. See Fig. 2 for an overview of our process for handling missing data.

Plans to give access to the full protocol, participant-level data, and statistical code {31c}

Raw pseudonymized data and statistical code will be shared after the publication of the research data.

Oversight and monitoring

Composition of the coordinating center and trial steering committee {5d}

Conceptualization, methodology, investigation, formal analysis of the data, writing of initial draft, review and editing, and decision to submit for publication will be performed by the research team (ADV, LP, BJ, and RC).

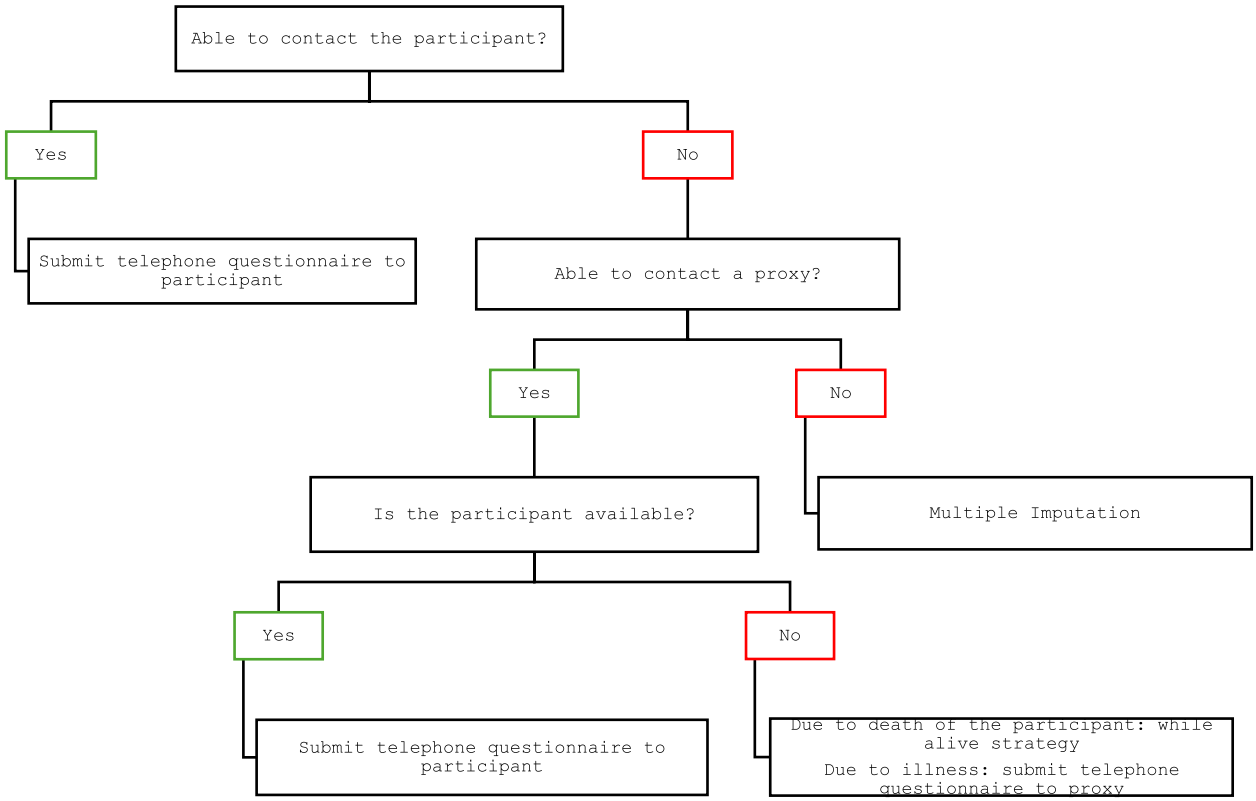

Fig. 2 Flowchart for handling missing data

There will be two dental students and two dentists collecting data. The steering committee, consisting of the members of the Gerodent PLUS team, will meet monthly to provide oversight. The REDCap-Team of Ghent University handles data management. Daily coordination of the trial will be performed by ADV.

Stakeholders in the Gerodent PLUS research project are met twice a year to provide advice and support in the implementation of the project and dissemination of the results. 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
- ELZ RITS
- Logo Midden West-Vlaanderen
- Zorgband Leie en Schelde

Composition of the data monitoring committee, its role and reporting structure {21a}

Since this study has a low risk for harm, no data monitoring committee was composed.

Adverse event reporting and harms {22}

The risk for adverse events is low. However, participants will be informed and encouraged to contact the research team in case of an adverse event. Contact information is included in the informed consent form. Unexpected harms will be documented based on participants' spontaneous reports. These harms will not be classified or codified using standardized terminology. Should any harms occur, they will be reported in the publication of the study results.

Frequency and plans for auditing trial conduct {23}

N/A, there will be no auditing.

Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethical committees) {25}

If modifications to the study protocol are needed, an amendment to the original application will be submitted

for approval to the Medical Ethics Committee of the University Hospital Ghent. Approved modifications will also be made public on ClinicalTrials.gov (ID: NCT06341959) and corrections will be sent to this journal. If necessary, a modified informed consent form will be drafted. Decisions to amend will be thoroughly discussed within the study steering committee.

Dissemination plans {31a}

Trial results will be made public to the scientific community and healthcare professionals via conferences, scientific publications, and on the university research platform https://research.ugent.be search term "Gerodent PLUS". The findings will also be communicated to the general public and policy makers through the Flemish Government, social media, and the different organizations in the stakeholders group (including the Flemish agency for Oral Health that includes the different health professional associations).

Discussion

Regular dental attendance among older adults is low, therefore interventions to reactivate this target group into primary care are necessary. This study aims to address this issue by investigating the efficacy of a low-threshold check-up to motivate older adults to schedule a dental visit. In practice, this involves conducting the check-up at a familiar location, without the use of dental chairs or X-rays.

The results of this trial have the potential to significantly contribute to the knowledge about how to promote dental attendance among community-dwelling older people. If a low-threshold check-up motivates them to schedule a dental visit, it could be an effective tool to reactivate older adults into primary care, potentially resulting in improved oral health.

Existing literature highlights barriers for older adults' access to oral care of which several will be addressed by the intervention. Firstly, oral health literacy will be enhanced by providing information about their oral health status and on the importance of regular dental attendance. Secondly, low subjective treatment needs will be addressed by highlighting any existing issues in their oral cavity after oral screening. Thirdly, an attempt will be made to overcome possible dental anxiety by performing the screening in a non-dental setting without a dental chair and white coats. Finally, lack of awareness of oral health among healthcare professionals will be addressed by involving the family physician as a trusted healthcare professional to provide additional motivation for older adults to visit the dentist.

This study has a number of limitations that should be acknowledged. First, our intervention will not tackle the barrier of experiencing logistics challenges for dental attendance. Second, administering the questionnaire by telephone at timepoint 1 might be challenging for participants. Therefore, we deliberately will keep these questions very short and straightforward. Third, we will provide referral letters to participants for their general practitioners and dentists. However, we will not have any means to verify whether the participants will have actually delivered these letters to the intended recipients.

A pilot study was conducted. Subsequently, the wording of some questions was simplified. It was also observed that approaching individuals during social events, such as game afternoons, yielded minimal engagement. Older adults prefer participating in the event itself and lack the time and interest for our study. However, engaging older adults in their assisted living residences proved to be effective. They feel comfortable in their own homes and take the time to participate in our study. The next step will involve organizing and conducting the screening followed by administering the subsequent telephone questionnaire, scheduled from April 2024 to March 2025. To date, a total of 147 participants have been included in the study. Additionally, 60 participants have been contacted four months after enrollment. Of these 60 participants, nine individuals could not be reached.

In conclusion, the results from this study could help in designing and implementing an evidence-based intervention for community-dwelling older adults, who are currently often neglected in oral health promotion programs. This intervention might consist of simply distributing informational brochures or it might involve a more personalized approach with one-on-one conversations and oral examinations. It is also possible that the results of this study will indicate that these approaches are insufficient and that it will be necessary to focus on the pre-intentional phase and place greater emphasis on determinants beyond knowledge, namely self-efficacy and outcome expectations.

Trial status

Recruitment began in April 2024 and will continue until the required sample size is achieved, this is estimated to be in March 2025. Version 1.3, 22/12/2024.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-08728-7.

Additional file 1.

Additional file 2. Letter for dentist. Letter for family physician. Flyers with oral hygiene instructions(Future use of the materials of Gezonde Mond by others is permitted, provided that the logo of Gezonde Mond is included.)

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Authors' contributions {31b}
Conceptualization: ADV, BJ, and LP. Methodology: ADV, LP, BJ, and RC. Software: ADV. Investigation: ADV. Formal analysis: ADV, LP, BJ, and RC. Writing—original draft preparation: ADV. Writing—review and editing: ADV, LP, B,J and RC. Visualization: ADV. Supervision: LP and BJ. Authorship for future publications will be determined based on substantial contributions to the data collection, data interpretation and critically revising the paper presenting the results.

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The funder has 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.

Data availability {29}
The members of the research team will have full access to the data. Data will be available upon reasonable request after the trial.

Declarations

Ethics approval and consent to participate {24}
This study was approved (reference number ONZ-2023-0350) by an independent Medical Ethics Committee affiliated with Ghent University Hospital. The 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 clinical studies. Written informed consent will be obtained from all participants.

Consent for publication {32}
Please refer additional file 1.

Competing interests {28}
The authors declare that they have no competing interests.

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References

1. European Commission: Eurostat, Corselli-Nordblad L, Strandell H. Ageing Europe: looking at the lives of older people in the EU: 2020 edition. Publications Office; 2020. Available from: https://doi.org/10.2785/628105.
2. United Nations Department of Economic and Social Affairs PD. World population prospects 2022: summary of results. 2022.
3. GBD 2019 Ageing Collaborators, Kusuma D. Global, regional, and national burden of diseases and injuries for adults 70 years and older: systematic analysis for the global burden of disease 2019 study. Br Med J. 2022;376:e068208. https://doi.org/10.1136/bmj-2021-068208.
4. De Visschere L, Janssens B, De Reu G, Duyck J, Vanobbergen J. An oral health survey of vulnerable older people in Belgium. Clin Oral Investig. 2016;20(8):1903–12.
5. Block C, König HH, Hajek A. Oral health and quality of life: findings from the survey of health, ageing and retirement in Europe. BMC Oral Health. 2022;22(1):606.
6. Nguyen ATM, Akhter R, Garde S, Scott C, Twigg SM, Colagiuri S, et al. The association of periodontal disease with the complications of diabetes mellitus. A systematic review. Diabetes Res Clin Pract. 2020;165: 108244.
7. Ritchie CS, Joshipura K, Silliman RA, Miller B, Douglas CW. Oral health problems and significant weight loss among community-dwelling older adults. J Gerontol A Biol Sci Med Sci. 2000;55(7):M366–71.
8. Lee Y. Diagnosis and prevention strategies for dental caries. J Lifestyle Med. 2013;3(2):107–9.
9. Janto M, Iurcov R, Daina CM, Venter AC, Suteu CL, Sabau M, et al. The importance of periodic dental control in the oral health status of elderly patients. Clin Pract. 2023;13(2):537–52.
10. Sälzer S, Graetz C, Dörfer CE, Slot DE, Van der Weijden FA. Contemporary practices for mechanical oral hygiene to prevent periodontal disease. Periodontol 2000. 2020;84(1):35–44.
11. Nitschke I, Stillhart A, Kunze J. Utilization of dental services in old age. Swiss Dent J. 2015;125(4):433–47.
12. Janssens B, Tsakos G, De Visschere L, Verté D, De Witte N. Frailty as a determinant of dental attendance among community-dwelling older adults. Gerodontology. 2022;40(3):363-371.
13. Terraneo M. Inequities in health care utilization by people aged 50+: Evidence from 12 European countries. Soc Sci Med. 2015;126:154–63.
14. Hassan BH, Abd El Moniem MM, Dawood SS, Alsultan AA, Abdelhafez AI, Elsakhy NM. Dental Anxiety and Oral-Health-Related Quality of Life among Rural Community-Dwelling Older Adults. Int J Environ Res Public Health. 2022;19(13):7643.
15. Kiyak HA, Reichmuth M. Barriers to and enablers of older adults' use of dental services. J Dent Educ. 2005;69(9):975–86.
16. Legge AR, Latour JM, Nasser M. Older patients' views of oral health care and factors which facilitate or obstruct regular access to dental care-services: a qualitative systematic review. Community Dent Health. 2021;38(3):165–71.
17. Graham L, Brundle C, Harrison N, Andre D, Clegg A, Forster A, et al. What are the priorities for research of older people living in their own home, including those living with frailty? A systematic review and content analysis of studies reporting older people's priorities and unmet needs. Age Ageing. 2024;53(1):1–21.
18. Chan AW, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013;346: e7586.
19. Monse B, Heinrich-Weltzien R, Benzian H, Holmgren C, van Palenstein HW. PUFA–an index of clinical consequences of untreated dental caries. Community Dent Oral Epidemiol. 2010;38(1):77–82.
20. Van der Velden U. The Dutch periodontal screening index validation and its application in The Netherlands. J Clin Periodontol. 2009;36(12):1018–24.
21. Attin T, Hornecker E. Tooth brushing and oral health: how frequently and when should tooth brushing be performed? Oral Health Prev Dent. 2005;3(3):135–40.
22. Galvan R, McBride M, Korioth TV, Garcia-Godoy F. Denture hygiene as it relates to denture stomatitis: a review. Compend Contin Educ Dent. 2021;42(4):e1–4.
23. Peters LL, Boter H, Buskens E, Slaets JP. Measurement properties of the Groningen Frailty Indicator in home-dwelling and institutionalized elderly people. J Am Med Dir Assoc. 2012;13(6):546–51.
24. Peters LL, Boter H, Burgerhof JG, Slaets JP, Buskens E. Construct validity of the Groningen Frailty Indicator established in a large sample of home-dwelling elderly persons: evidence of stability across age and gender. Exp Gerontol. 2015;69:129–41.
25. Thomson WM, van der Putten GJ, de Baat C, Ikebe K, Matsuda K, Enoki K, et al. Shortening the xerostomia inventory. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2011;112(3):322–7.
26. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)–a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009;42(2):377–81.
27. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, et al. The REDCap consortium: building an international community of software platform partners. J Biomed Inform. 2019;95:103208.
28. Quigley GA, Hein JW. Comparative cleansing efficiency of manual and power brushing. J Am Dent Assoc. 1962;65:26–9.
29. Augsburger RH, Elahi JM. Evaluation of seven proprietary denture cleansers. J Prosthet Dent. 1982;47(4):356–9.
30. Winkel EG, Roldán S, Van Winkelhoff AJ, Herrera D, Sanz M. Clinical effects of a new mouthrinse containing chlorhexidine, cetylpyridinium chloride

and zinc-lactate on oral halitosis. A dual-center, double-blind placebo-controlled study. J Clin Periodontol. 2003;30(4):300–6.
31. Miller SC. Textbook of periodontia-oral medicine. By S.C. Miller ... and Members of the Periodontia Staff of New York University College of Dentistry. With ... a chapter on "the endocrine system in periodontal disease" by Felix Boenheim, Etc: London; York, Pa. printed; 1938.
32. McHugh ML. Interrater reliability: the kappa statistic. Biochem Med (Zagreb). 2012;22(3):276–82.
33. Twisk J, Proper K. Evaluation of the results of a randomized controlled trial: how to define changes between baseline and follow-up. J Clin Epidemiol. 2004;57(3):223–8.

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