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Interaction of Systemic Morbidity and Oral Health in Ambulatory Patients in Need of Home Care (InSEMaP): an observational study at the sector boundary between dental and general practice care in Germany

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ABSTRACT

Introduction Older people in need of home care are at risk of declining oral health as their visits to dentists are becoming less frequent due to restricted mobility. There is increasing evidence that poor oral health and systemic diseases are closely associated, for example, in cardiological, metabolic or neurodegenerative conditions. Thus, Interaction of Systemic Morbidity and Oral Health in Ambulatory Patients in Need of Home Care (InSEMaP) is investigating the need, provision and utilisation of oral healthcare, systemic morbidity and clinical status of the oral cavity in older people.

Methods and analysis InSEMaP consists of four subprojects (SP), all involving the target population of older people in need of home care. In SP1 part a, a sample is surveyed using a self-report questionnaire. In SP1 part b, stakeholders (general practitioners, dentists, medical assistants, family and professional caregivers) are interviewed regarding barriers and facilitators using focus groups and personal interviews. In SP2, a retrospective cohort study, health insurance claims data are examined to investigate the utilisation of oral healthcare, its association with systemic morbidity and healthcare costs. In SP3, a clinical observational study will assess the oral health of participants by a dentist's visit at home. SP4 synthesises the results of SP1, SP2 and SP3 to develop integrated clinical pathways, identifying strategies to uphold oral healthcare in older people. In assessing and evaluating the process of oral healthcare, and its associated systemic morbidity, InSEMaP aims to improve general healthcare across the sector boundary of dental and general practitioner care.

Ethics and dissemination Ethics approval was obtained from the Institutional Review Board of the Hamburg Medical Chamber (approval number: 2021-100715-BO-ff). The results of this study will be disseminated through conference presentations and publications in peer-reviewed journals. An expert advisory board to support the InSEMaP study group will be established.

Trial registration number German Clinical Trials Register: DRKS00027020.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Complex observational study on oral healthcare and systemic morbidity in older persons in need of home care.
⇒ Sequential, quantitative and qualitative (mixed) methodology using questionnaires, focus groups, retrospective analyses of health insurance claims data on oral healthcare and systemic morbidity, and a dental examination visiting patients at home—all to inform expert workshops in SP4.
⇒ Observation and recruitment bias may jeopardise the interpretation and generalisability of results.
⇒ The study comprises assessment and evaluation of oral health in older people only, not a planned intervention.

INTRODUCTION

As early as the end of the 19th century, bacterial infestation of the oral cavity was held specifically responsible for a large number of somatic diseases (focal infection theory[1]). However, its influence faded because evidence of a robust association could not be established. It was not until the 1990s that improved detection methods brought the relationship between oral health and systemic disease back into the focus of scientific interest and especially health services research.

Associations of oral health and systemic diseases

Numerous reviews now support the association of oral health with non-communicable systemic diseases such as cardiovascular diseases,[2] type 2 diabetes mellitus,[3] respiratory disorders,[4 5] rheumatoid arthritis[6] and

neurodegenerative diseases.[7 8] A recent review[9] showed evidence that prostate cancer is associated with periodontitis. Chronic oral inflammation promotes the progression of neurodegenerative diseases and the occurrence of pneumonia, which is already a common cause of death in long-term care patients.[10] Besides single conditions, all-cause mortality is increased in patients with periodontitis.[11]

Support for older people in need of home care

It has been show that reducing the microbial in the oral cavity of older people decreased the likelihood to develop nosocomial-acquired pneumonia.[12] Adequate oral hygiene could prevent 1 in 10 of pneumonia-associated deaths.[13] Intervention studies have demonstrated that improving oral hygiene helps to prevent the recurrence of an atherosclerotic complication, that is, myocardial infarction or apoplexy.[14] Epidemiological reviews clearly demonstrate a higher mortality rate for patients with poor oral health after adjusting for other contributing factors.[15]

In the light of a growing proportion of old and very old people in the German population, review findings suggest that people in need of home care due to multimorbidity require special dental attention.[16] They are less able to access preventive dental services and treatments due to potentially restricted mobility. Moreover, it is more difficult for them to adequately carry out the necessary dental care themselves because visual and motor skills decrease with age.[17]

A report by Rothgang *et al*[18] has shown that dental treatment rate decreased with a higher level of care. In another study, inadequate oral hygiene facilitated the accumulation of a pathogenic biofilm in the mouth within days.[19] Consequences for older people are documented by the 'Fifth German Oral Health Study'.[20] This survey brought to light that utilisation of dental care in older people in home care decreased significantly compared with independently living older people. Besides maintaining their own teeth into old age, the risk for caries is increasing due to reduced salivary flow, and among other things, due to medication side effects. The same applies for periodontitis due to poorer immune responses and systemic diseases as cofactors. Thus, even for spry older people, it is more difficult to maintain oral and dental health.

Psychosocial factors and oral health of older people in need of care

Oral health can generally contribute to a better quality of life through better nutritional intake and increased well-being, therefore having a positive influence on the course of an existing systemic disease.

Since oral health in persons in need of home care is associated with social status, underutilisation could be seen particularly among socioeconomically deprived groups.[20] Patients in need of care often depend on nurses or family caregivers for their oral hygiene. Thus, oral health of these patients relies on the availability, the level of knowledge and the handling of those taking responsibility as well as the patients' own adherence.[21 22]

Oral healthcare in Germany

Ninety per cent of the German population is insured with a statutory health insurance. This part of the population is therefore entitled to use most medical and dental services provided. Supplementary private insurances can be contracted in order to receive additional benefits.[23] The remaining part (10% of the population) is privately insured.

German legislators have responded to the lack of oral care by implementing a series of changes in social law.[24] In 2011, additional dental reimbursements were established for ambulatory care of patients in home care based on Section 87 (2i) of the German Social Code, Fifth Book (SGB V). In 2012, these benefits were extended to people with special needs (eg, people with cognitive impairment). Taking effect in July 2018, the supreme decision-making body in the German statutory health insurance system, the Federal Joint Committee, issued a guideline regulating the entitlements of patients in home care for the prevention of dental diseases. Benefits include oral health status assessment, education on the importance of oral hygiene instruction, care planning and hard plaque removal. Nurses should be included in the provision. Since 2014, it is possible to initiate cooperation contracts between nursing homes and dentists to improve the dental care of residents. In 2017, almost every third nursing home in Germany cooperated with dentists.[25] However, as of now, only a few dentists arrange home visits for persons in need of home care in Germany.

Lack of cooperation between dentists and general practitioners

Healthcare in Germany is fragmented into different administrative and healthcare sectors,[26] lacking intersectoral clinical pathways, and a continuous flow of clinical information. All sectors providing care manage their own budgets, provisional scope, reimbursement schemes and accounting procedures. There is no regular exchange between dental and general practitioner (GP) care. Vulnerable groups like patients in need of home care are particularly affected, as they have an increased burden of both systemic and oral diseases. There are no reciprocal referral opportunities, even though dentists and GPs need to rely on each other's information to coordinate their respective treatments. Individual attempts to contact each other by phone are often unsuccessful due to practice structures and heavy workload.[27]

These circumstances have received more attention in recent years—both from a dental[27–29] and from a general practice perspective.[30–32]

Göstemeyer *et al*[33] identified impeding and facilitating factors of oral healthcare (OHC) and dental treatment of older people in need of care. The authors recommended further research of the effects of improved professional collaboration across sectors on oral health. It should be a

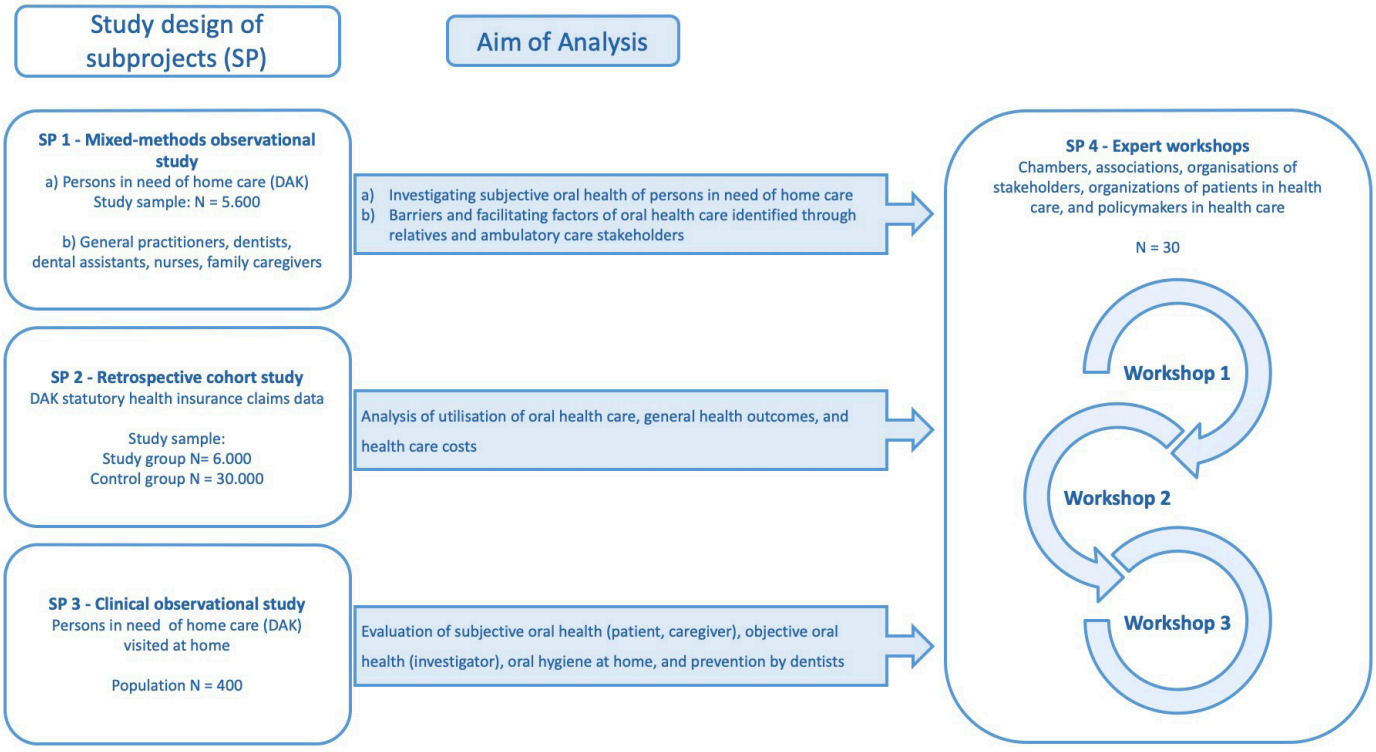

Figure 1 Structure of InSEMaP research project

goal to reduce hindering factors (lack of knowledge, technical skills to improve oral health). Moreover, the inconvenience of a dentist's visit of a patient in need of home care or the transport of the patients should be addressed.

Aim and objectives

Funded by the Innovation Fund of the Federal Joint Committee, the project Interaction of Systemic Morbidity and Oral Health in Ambulatory Patients in Need of Home Care (InSEMaP) addresses intersectoral communication between GPs and dentists, examines the oral condition in a sample of persons using ambulatory home care and maps the procedures and processes that promote or prevent participation in OHC of these persons. Different ways of cooperation between dental and general practice as well as nursing care services will be explored, aiming to improve health status of persons in need of home care.

We have planned and designed a complex observational study using questionnaire data, health insurance claims data and clinical data to record the subjective, clinical and objective oral health as well as the utilisation of OHC, and its association with systemic diseases of persons in need of home care.

METHODS AND ANALYSIS

Study design

InSEMaP consists of four subprojects (SP) (see figure 1 for structure of the InSEMaP study).

SP1: An observational study will be conducted using a sequential, mixed (quantitative and qualitative)-methods design. SP1 aims to identify barriers and facilitating factors as well as opportunities and options of oral care from the perspective of older persons in need of home care, family caregivers and other stakeholders of care such as dentists, GPs, medical assistants and nurses. SP1 is split into two parts: (a) a quantitative, anonymous study of older persons ≥60 years, insured with the Deutsche Angestellten-Krankenkasse (DAK), and (b) focus groups (FG) and personal interviews with stakeholders of oral and general healthcare.

SP2: Retrospective cohort study analysing health insurance claims data of DAK (see figure 2 for the research design of SP2). The aim is to examine the utilisation of OHC by persons with incident need of home care, its associations with systemic diseases and its healthcare costs. In SP2, we want to learn how often regular dental visits are discontinued due to the onset of ambulatory care needs and to determine the costs associated with discontinued OHC.

SP3: Observational study on the subjective, clinical and objective radiological assessment of the oral health status of patients ≥60 years old in need of home care (a) with dental service provision in the last 12 months and (b) without dental service provision in the last 12 months. Additionally, clinical data are supplemented with health insurance claims data on general health, systemic diseases and healthcare utilisation (see figure 3 for examination procedures).

SP4: Conducting expert workshops to aggregate, analyse and synthesise the results from SP1 to SP3.

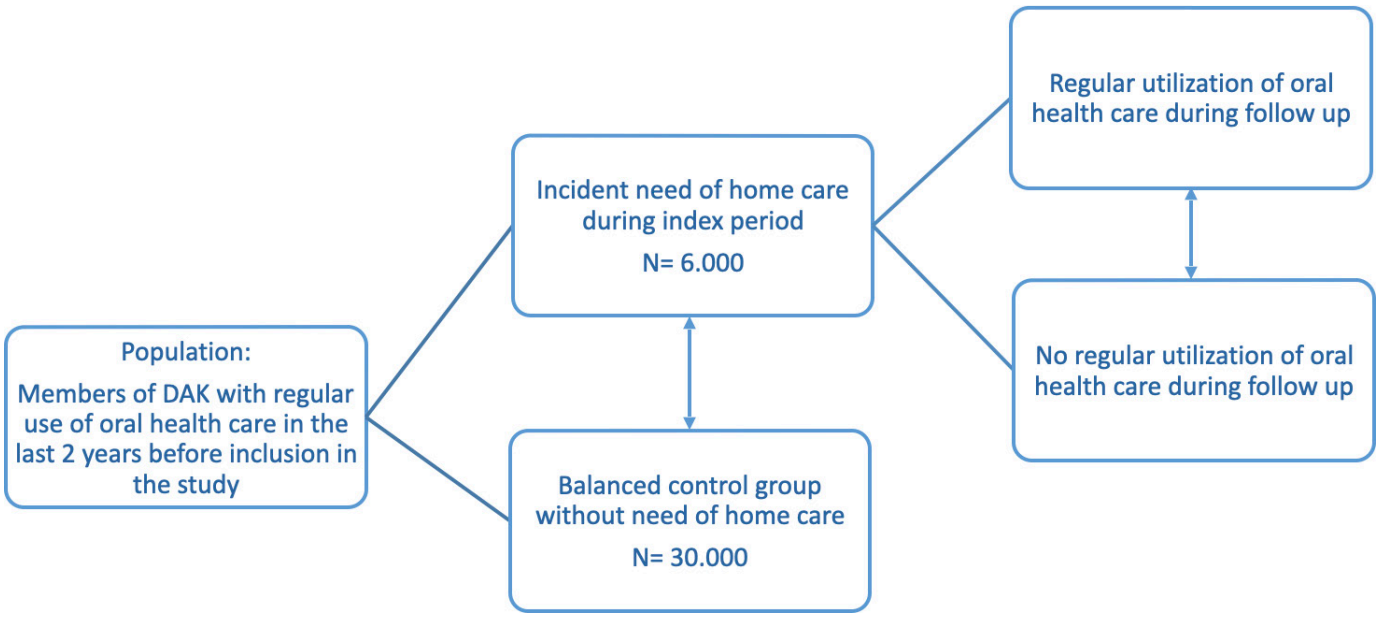

Figure 2 Research design subproject 2

Research findings will be integrated to identify indicators for intervention and to outline pathways for clinical care to improve oral health in older people in need of home care.

This research project has started in July 2021 with setting up structures, elaborating plans and designing procedures. Depending on circumstances and general regulations in the COVID-19 pandemic situation, we intend to have conducted and evaluated the study until June 2024, recruiting the first participants in February 2022 (SP1) and the last participant in December 2023 (SP3, SP4).

Study population and setting

Study samples are selected cohorts of older persons insured with the DAK statutory health insurance. In SP1, persons are selected according to one of the five care levels as assessed by the Medical Service, a statutory body commissioned to evaluate levels of care. Populations in SP1, SP3 and SP4 are further defined by their residence in the metropolitan region of Hamburg. In SP2, insurance claims data of DAK are used to select an anonymous population of older people in Germany.

Inclusion criteria

SP1a: Members of the DAK statutory health insurance, ≥60 years on 31 December 2021, in need of care according to the SGB XI since 31 December 2020. *SP1b*: FG will be conducted inviting stakeholders of OHC (family caregivers, GPs, dentists, nurses and dental assistants).

SP2: For the study group, all continuously insured persons of DAK with incident (new onset of) need of ambulatory care in 2017 (index date), ≥60 years and a regular utilisation of OHC in the 2 years prior to the onset of ambulatory need of care are selected. For the control group, randomly selected insured persons of DAK with regular utilisation of OHC in the 2 years before the index date, no need of home care and ≥60 years are chosen. The control group comprises at least five times as many persons as the study group. Persons from the control group are randomly selected and a balancing procedure, entropy balancing, will be used to balance groups with with regard to the distributions of concerning person characteristics such as age, sex or degree of urbanisation at place of residence.

SP3: Members of the DAK statutory health insurance, ≥60 years on 31 December 2021, in need of care according to selected one of the five care levels as assessed by the Medical Service since 31 December 2020.

SP4: Experts from different associations will be invited: Federal Association of Private Providers of Social Services, Hamburg State Association, Hamburg Nursing Association, Hamburg Association of General Practitioners, autonomous bodies (Hamburg Association of Statutory Health Insurance Dentists, Hamburg Association of Statutory Health Insurance Physicians and patient organisations (Patient Initiative, Patient Protection Foundation), as well as persons in charge in the executive part of the administration (Hamburg Ministry of Labor, Health, Social Affairs, Family and Integration)).

Exclusion criteria

There are no exclusion criteria in *SP1*, *SP2*, and *SP4*. In *SP3*, persons who are not able to be transported in a sitting position are excluded, as it is indispensable for taking a radiological image using panoramic X-ray. No further exclusion criteria apply.

Recruitment of patients and participants

SP1a: Participants are contacted by a letter of invitation from the DAK statutory health insurance. Enclosed in the letter are a study information sheet, a questionnaire on OHC as well as a prepaid envelope. SP1b: Convenience sampling of practice experts in the field, familiar with

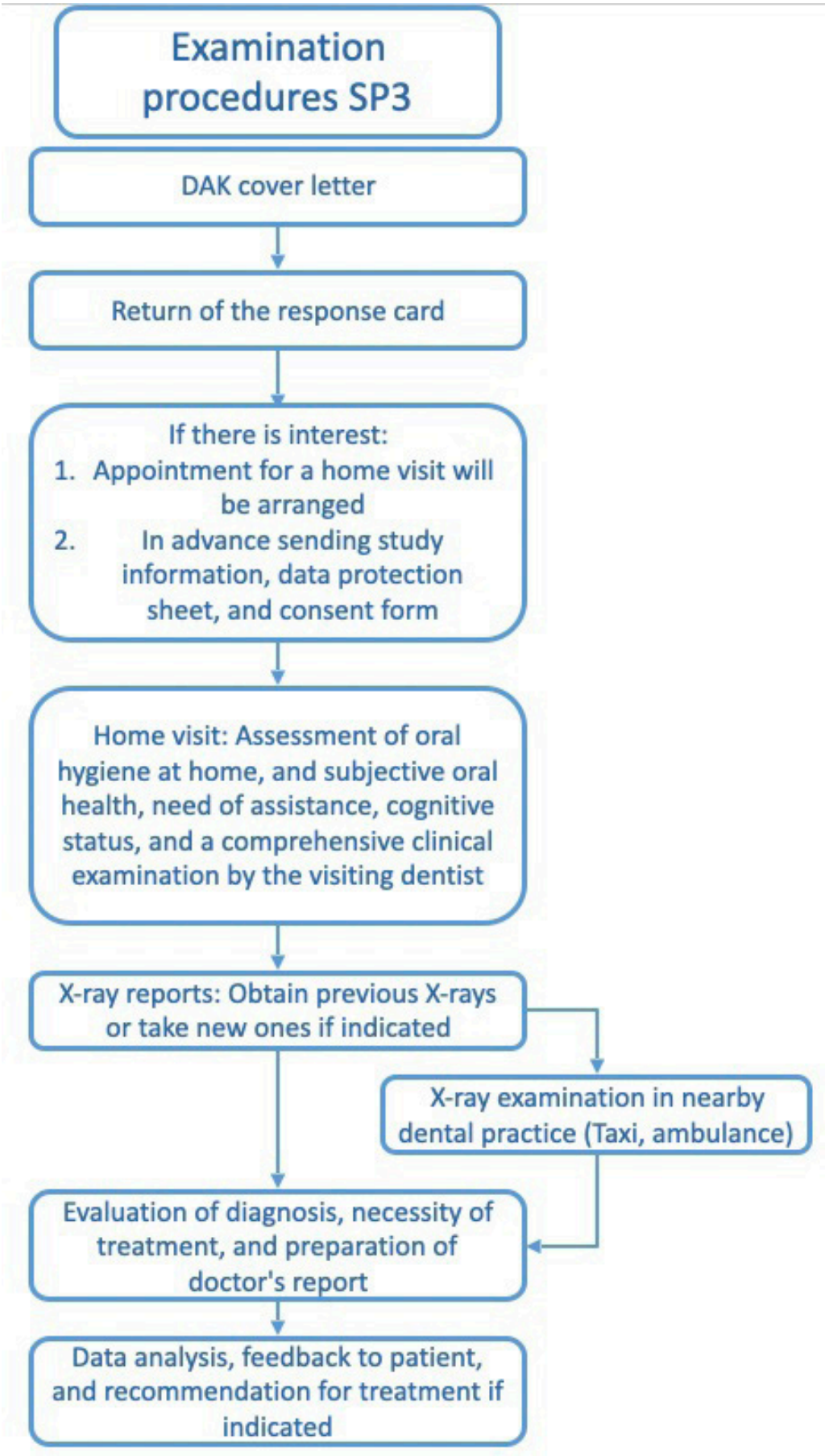

Figure 3 Examination procedures in subproject 3

oral and general healthcare of patients in need of home care (family caregivers, GPs, dentists, nurses and dental assistants).

SP2: Not applicable in this SP.

SP3: Analogous to SP1, participants are contacted by a letter of invitation from the DAK statutory health insurance. Enclosed in the letter are a study information sheet and a prepaid envelope to get in contact with the clinical study team. Because we expect considerable difficulties in motivating older persons in need of home care to participate, we plan to recruit additional participants via local nursing care services, GPs and dentists.

SP4: Convenience sample of experts in the field, involved in ambulatory OHC and general healthcare for older persons in need of home care.

Outcomes, measurements and instruments

Depending on the respective research questions, all SPs target different outcomes and measurements. Table 1 gives a complete overview.

Primary outcome measures

Following the objective to assess quality of OHC in persons in need of home care, in SP1a the German version of the 14-item Oral Health Impact Profile (OHIP-G14)[34 35] is used to assess participant's quality of OHC. Outcomes in SP2 are the excess discontinuation of regular utilisation of OHC, subsequent comorbidities and related healthcare costs. In SP3, the objective-clinical oral examination is used as main outcome parameter, ideally complemented by a panoramic X-ray. If no radiological findings are available, the clinical evaluation at home must be used. The Oral Health Assessment Tool[36 37] is set as the primary outcome in subjective oral health. Primary outcome in SP4 is a strategy to implement InSEMaP research findings in the different sectors of healthcare, documented in a consortium working paper.

Secondary outcome measures

In SP1, general health quality of life (EuroQoL-5 Dimension[38]) of the participants will be analysed, as well as their evaluation of barriers and facilitating factors in their perceived oral health. There will be an evaluation of the extent of cooperation between healthcare providers in different sectors (GP, dentists), a reconstruction of the OHC process in persons in need of home care and a description of the set of requirements for clinical pathways in OHC as a source for SP4.

There is no secondary outcome in SP2.

In SP3, oral hygiene at home and various dental parameters will be observed as secondary outcomes.[39–42] Instrumental Activities of Daily Living[43] will be assessed, as well as the cognitive status of the participants using the Clock Drawing Test,[44] and the intensity of the commitment to the GP.[45] For more details, see table 1.

In SP4, options to identify feasible, scalable clinical pathways of OHC in older persons in need of home care will be explored.

Sample size

Based on projections of the DAK for SP1a, we expect about n=1100 participants (approximately 20% of the persons initially contacted) to send back the questionnaire using the prepaid response envelope. The FG in SP1b will be set up and planned pragmatically based on stakeholder groups: one group of family caregivers (six participants), one group of GPs (six participants), one group of dentists (six participants), one group of nurses (six participants) and one group of dental assistants (six participants). To cross-validate these perspectives, we will initiate two heterogeneous FGs by five participants (one participant from each profession). Furthermore, 15 personal interviews (three participants from each profession) will be conducted.

According to projections of the DAK, the study group in SP2 comprises n=6000 persons and the control group comprises n=30 000 persons. The sample size in SP3 is pragmatically estimated based on procedural restrictions (equipment, time and personal resources) for a clinical evaluation of the oral health status at home. A meaningful and manageable sample size will be n=400 (n=200 with OHC, ie, having seen a dentist in the last 12 months; n=200 without OHC, ie, not having seen a dentist in the last 12 months). For the expert workshops in SP4, we will recruit participants active in the practical level as well as in the administrative level of oral and general health care. n=30 in three expert workshops with 10 persons each should be sufficient.

Adverse events

Any adverse event as well as any protocol changes will be reported to the ethical committee without delay. Written informed consent will be obtained from all patients (SP3) and participants for personal interviews/FG (SP1b and SP4). Risk assessment for patients in SP3 will be conducted based on standard operating procedures and a hygienic plan set in place to meet the requirements of local authorities.

Dropouts

In all study information sheets (SP1a, SP1b, SP3 and SP4), a contact person is named, answering questions related to the InSEMaP study. All participants in SP1b, SP3 and SP4 can actively withdraw their informed consent and demand to delete personal data as long as it is not yet anonymised. However, if the data are already anonymised, the objection can be filed, but complying with the objection is no longer possible.

In the transcriptions following the FG and personal interviews in SP1b and SP4, personal data are pseudonymised. Once the audio recordings have been deleted, the data are anonymised, and removal of individual data is no longer possible.

In SP3, we expect a certain amount of dropout: approximately 10% of the recruited participants with radiological indications will not have an image taken. Ten per cent of the recruited participants will not allow the use

Table 1 Outcomes and measurements

Outcomes	Instrument	Measurements
SP1a: cross-sectional survey questionnaire (online supplemental file 1**)** **Target population: older persons in need of home care (≥60 years), selected according to one of the five care levels as assessed by the Medical Service of the statutory health insurance**		
OHC-related quality of life (*primary outcome*)	OHIP-G14	Oral Health Impact Profile, German version, 14 items[34 35]
Health-related quality of life	EQ-5D-5L	Health-related quality of life questionnaire, 6 items[38]
Sociodemographic, medical care, dental care, oral health and information of the need for support, structure, process and outcome parameter	Questionnaire developed for the study	Questionnaire, 27 items ► Barriers and facilitating factors of quality of OHC. ► Extent of cooperation between healthcare providers. ► Explanatory patterns from the perspective of the care providers. ► Reconstruction of the OHC process. ► Strengths/weaknesses profile of OHC. ► Catalogue of requirements for OHC pathway as working basis for SP4.
SP1b: FG and personal interviews **Target population: stakeholders of oral and general healthcare**		
Structure, process and outcome parameter	Specifically developed, semistructured focus group and interview guidelines	► Barriers and facilitating factors of quality of OHC. ► Extent of cooperation between healthcare providers. ► Explanatory patterns from the perspective of the care providers. ► Reconstruction of the OHC process. ► Strengths/weaknesses profile of OHC. ► Catalogue of requirements for OHC pathway as working basis for SP4.
SP2: retrospective cohort study—health insurance claims data analysis **Target population: older persons (≥60 years) insured with DAK**		
1. Excess discontinuations of regular utilisation of OHC. 2. General health status and extent of systemic diseases. 3. Healthcare costs.	Analysis of health insurance claims data of DAK	1. Discontinuation and number of (regular) dental visits. 2. Occurrence, number and severity of systemic diseases. 3. Healthcare costs in total and per healthcare sector.
SP3: observational study—questionnaire and clinical examination **Target population: older persons in need of home care (≥60 years), selected according to one of the five care levels as assessed by the Medical Service of the statutory health insurance**		
Clinical status of the oral cavity, supplemented by orthopantomogram X-ray image (*primary outcome in clinical assessment*)	Clinical oral examination, panoramic X-ray	Evaluation of pathological changes in the oral region
Oral health status (*primary outcome in questionnaire assessment*)	OHAT	Oral Health Assessment Tool, 8 items[36 37]
Tooth status	DMF-S	Decayed-Missing-Filled Surface[39]
Periodontal condition	CAL BOP PISA	Clinical Attachment Loss[40 41] Bleeding on Probing[40 41] Periodontal Inflamed Surface Area[40 41]
Oral hygiene quality	API	Approximal Plaque Index[42]
Frailty	IADL	Instrumental Activities of Daily Living, 8 items[43]
Cognitive status	CDT	Clock Drawing Test, 2 items[44]

Continued

Table 1 Continued

Outcomes	Instrument	Measurements
Intensity of GP commitment	F-HaBi	Questionnaire on the intensity of GP commitment, 7 items[45]
Sociodemographic factors	Single items	Gender, age, level of care, migration status
SP4: three consecutive expert workshops Target population: sample of experts from stakeholder's associations, patient's organisations and executive policymakers		
Strategy to implement InSEMaP research findings in the different sectors of healthcare documented in a consortium working paper (*primary outcome*)	Workshops	Semistructured focus group guidelines and personal interviews are supposed to yield expert knowledge and implementation recommendations
Exploring options for clinical pathways to identify feasible, scalable clinical pathways of OHC in older persons in need of home care		

DAK, Deutsche Angestellten-Krankenkasse; EQ-5D-5L, 5-Level version of EuroQoL-5 Dimension; FG, focus group; GP, general practitioner; InSEMaP, Interaction of Systemic Morbidity and Oral Health in Ambulatory Patients in Need of Home Care; OHC, oral healthcare; SP, subproject.

of the radiological image that is already available in their dental practice. Data of those patients who withdraw their consent after the radiological imaging can only be deleted as long as they have not been anonymised.

Data collection

All SPs need to manage data, though data will carry different characteristics: anonymised data (SP1a, SP2) and personalised FG data, interview data (SP1b, SP4) and personalised questionnaire data (SP3). Anonymised questionnaire data (SP1a) will be transferred into a database. Anonymised (SP2) and pseudonymised (SP3) data from the DAK will be retrieved and stored in a database. A data linkage to merge health insurance claims data with clinical data in SP3 will be established through a trust centre. All qualitative data (SP1b, SP4) generated in FG and personal interviews will be transcribed and pseudonymised for a maximal retention period of 3 years. After that, a complete anonymisation is due, retaining data for another 7 years. The clinical data (SP3) must be on record for a maximal retention period of 10 years. After a clinical recommendation following data analysis of the individual patients' clinical examination, these data will be pseudonymised as well.

Data management

For data security and data management issues, the study group filed a data protection compliance assessment, being guided, and approved by the data protection officer of the University Medical Centre Hamburg-Eppendorf.

It cannot be ruled out that personal information such as the names of the participants will be mentioned and recorded during the FGs and personal interviews in SP1b or SP4. However, during the transcription of the audio recordings, any personal information will be removed. The transcription of the audio recordings is done by the Department of General Practice and Primary Care. The materials containing the assignments of personal information such as names, addresses and declarations of consent will be stored separately in lockable cabinets immediately after an FG or a personal interview. Lists with personal data of participants (pseudonyms) will be destroyed after study completion.

Data analysis

Statistical methods

SP1a: Descriptive analyses, correlation analyses, followed by linear regression analyses for the primary outcome (OHIP-G14[34 35]) with stepwise inclusion of covariates will be the statistical procedures to analyse data. A non-responder analysis should supposedly show similar or different patterns in the characteristics of responders and non-responders in the target population. Regression models will be risk adjusted for sociodemographic and other variables in the data set. Confidence levels (95%±SE) and levels of statistical significance ($p<0.05$) are set. Data analysis will be carried out using statistical software Stata v.16.

SP1b: Qualitative content analysis of the transcribed FG and personal interviews. The software program MAXQDA will be used for computer-based analyses of the FG and personal interviews. A combined approach of inductive and deductive category development is planned. FG as well as personal interviews will be audio recorded and transcribed. Two different researchers independently code the material, following the recommendations of qualitative content analysis, using both inductive category development and deductive category application. Researchers will discuss the results, aiming at making

a final decision about the explanatory content of the chosen categories.

Results of the sequential mixed-methods study in SP1 will be used to inform the expert workshops in SP4.

SP2: After data extraction by the DAK, data analysis will be carried out with statistical software packages (R, SAS 9.4 and Stata v.16). To analyse the discontinuation of the use of OHC attributable to an incident need for home care, the study group of incident home care patients will be compared with a control group without home care. The study group will be further split into a group that continues to use OHC during follow-up and a group that discontinues regular utilisation. Subsequently, occurrence and aggravation of systemic diseases, as well as healthcare costs, will be compared between these groups over the follow-up period of 3 years. Risk adjustment for patient characteristics and regional factors will be conducted with entropy balancing. Outcomes will be analysed with logit, Poisson, negative binomial, gamma or two-part models depending on the outcome's respective distribution.

SP3: Values of the indices of the examination will be calculated and analysed. The outcomes will be processed from the raw data and analysed descriptively. In addition, the group assignment (with/without utilisation of OHC) and outcomes will be examined using multivariate analyses. Bivariate associations with systemic diseases will be calculated. The corresponding statistical models (with appropriate distribution hypotheses depending on the outcome) will be adjusted for patient characteristics. Oral health status will be ascribed a clinical diagnosis. If a need for immediate therapy is identified, the patients will be eligible for a treatment plan, even though InSEMaP itself cannot provide the necessary service. In this process, it is checked whether the radiologically recognised findings had already been clinically suspicious. The association of subjectively expressed complaints with corresponding clinical or radiological findings is compared descriptively. The oral inflammatory processes and their covariation with existing systemic diseases will be tested by means of a χ^2 test.

SP4: Qualitative content analysis of the transcribed expert workshops. The software program MAXQDA will be used for computer-based analyses of the FG. Researchers will discuss the results, aiming at making a final decision about the explanatory content of the chosen categories. A combined approach of inductive and deductive category development is planned.

Data sharing

Data of the DAK statutory health insurance shall not be shared by third parties according to the German social law. Data are not supposed to be transferred to any other use but the initially commissioned purpose. Other data sharing is optional, depending on purpose of the request, being it commercial or scientific. As different institutions are involved in the InSEMaP study group (consortium), there will be a process implemented to evaluate research questions and check methodology of the data request for soundness.

Patient and public involvement

Patients were not involved in planning this project. Outcome measures were not informed by patients' priorities, experiences and preferences. Patients were not involved in the design of this study. Patients are not involved in the recruitment for and the conducting of the study.

ETHICS AND DISSEMINATION

Ethical considerations

Written informed consent and an agreement for data linkage with claims data will be obtained from all patients (SP3) and participants for personal interviews/FG (SP1b and SP4). Any risks related to the SARS-CoV-2 pandemic will be addressed in the hygienic plan the study group has implemented. The study does not involve any restriction to standard care.

Ethics approval was obtained from the Institutional Review Board of the Hamburg Medical Chamber in November 2021 (approval number: 2021-100715-BO-ff) and will be conducted in accordance with the principles of the Declaration of Helsinki. For dissemination, the results will be published in peer-reviewed journals and presented at conferences. There will be an advisory board of experts to support the InSEMaP study group. It convenes twice a year.

Dissemination policy

The final report for the sponsoring Innovation Fund of the German Joint Federal Committee will be published at their website: https://innovationsfonds.g-ba.de/.

The results will be disseminated to the participating providers of OHC, general medical care and their communities. Further information can be found 24/7 at this site: https://www.insemap.de.

The results and findings of the study will be published in peer-reviewed journals and presented at conferences and congresses. No professional writers will be employed.

Results and considerations derived from them will be evaluated by the funding organisation, and at best will be recommended for implementation.

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REFERENCES

1 Vieira CLZ, Caramelli B. The history of dentistry and medicine relationship: could the mouth finally return to the body? *Oral Dis* 2009;15:538–46.
2 Sanz M, Marco Del Castillo A, Jepsen S, *et al*. Periodontitis and cardiovascular diseases: consensus report. *J Clin Periodontol* 2020;47:268–88.
3 Glurich I, Acharya A. Updates from the evidence base examining association between periodontal disease and type 2 diabetes mellitus: current status and clinical relevance. *Curr Diab Rep* 2019;19:11.
4 Pathak JL, Yan Y, Zhang Q, *et al*. The role of oral microbiome in respiratory health and diseases. *Respir Med* 2021;185:106475.
5 Dörfer C, Benz C, Aida J, *et al*. The relationship of oral health with general health and NCDS: a brief review. *Int Dent J* 2017;67 Suppl 2:14–8.
6 Falcao A, Bullón P. A review of the influence of periodontal treatment in systemic diseases. *Periodontol 2000* 2019;79:117–28.
7 Delwel S, Binnekade TT, Perez RSGM, *et al*. Oral health and orofacial pain in older people with dementia: a systematic review with focus on dental hard tissues. *Clin Oral Investig* 2017;21:17–32.
8 Cerutti-Kopplin D, Feine J, Padilha DM, *et al*. Tooth loss increases the risk of diminished cognitive function: a systematic review and meta-analysis. *JDR Clin Trans Res* 2016;1:10–9.
9 Guo Z, Gu C, Li S, *et al*. Periodontal disease and the risk of prostate cancer: a meta-analysis of cohort studies. *Int Braz J Urol* 2021;47:1120–30.
10 Besimo CE, Besimo-Meyer RH. Orale Gesundheit von Menschen mit Demenz. *Schweiz Z Ganzheitsmed* 2015;27:44–9.
11 Romandini M, Baima G, Antonoglou G, *et al*. Periodontitis, edentulism, and risk of mortality: a systematic review with meta-analyses. *J Dent Res* 2021;100:37–49.
12 Ishikawa A, Yoneyama T, Hirota K, *et al*. Professional oral health care reduces the number of oropharyngeal bacteria. *J Dent Res* 2008;87:594–8.
13 Müller F. Oral hygiene reduces the mortality from aspiration pneumonia in frail elders. *J Dent Res* 2015;94:14S–16S.
14 Tonetti MS, Van Dyke TE, working group 1 of the joint EFP/AAP workshop*. Periodontitis and atherosclerotic cardiovascular disease: consensus report of the joint EFP/aapworkshop on periodontitis and systemic diseases. *J Periodontol* 2013;84 Suppl 4S:S24–9.
15 Lee HJ, Choi EK, Park JB, *et al*. Tooth loss predicts myocardial infarction, heart failure, stroke, and death. *J Dent Res* 2019;98:164–70.
16 Reißmann DR, Lamprecht R. *Zahn- und Mundgesundheit im Alter*. Berlin, Boston: De Gruyter, 2017.
17 Islas-Granillo H, Borges-Yañez SA, Navarrete-Hernández J de J, *et al*. Indicators of oral health in older adults with and without the presence of multimorbidity: a cross-sectional study. *Clin Interv Aging* 2019;14:219–24.
18 Rothgang H, Müller R, Mundhenk R, *et al*. *BARMER GEK-pflegereport 2014: Schwerpunkt: Zahnärztliche Versorgung Pflegebedürftiger*. Siegburg: Asgard-Verl.-Service, 2014.
19 Socransky SS, Haffajee AD. Dental biofilms: difficult therapeutic targets. *Periodontol 2000* 2002;28:12–55.
20 Jordan AR, Micheelis W. *Fünfte Deutsche Mundgesundheitsstudie (DMS V)*. Köln: Deutscher Zahnärzte Verlag DÄV, 2016.
21 Preston AJ, Punekar S, Gosney MA. Oral care of elderly patients: nurses' knowledge and views. *Postgrad Med J* 2000;76:89–91.
22 Baumgartner W, Schimmel M, Müller F. Oral health and dental care of elderly adults dependent on care. *Swiss Dent J* 2015;125:417–26.
23 Holm-Pedersen P, Vigild M, Nitschke I, *et al*. Dental care for aging populations in Denmark, Sweden, Norway, United Kingdom, and Germany. *J Dent Educ* 2005;69:987–97.
24 Rothgang H. Sicherung und Koordination der (zahn)ärztlichen Versorgung bei Pflegebedürftigen. In: Jacobs K, Kuhlmey A, Greß S, et al, eds. *Pflegereport 2017: Schwerpunkt: Die Versorgung der Pflegebedürftigen*. Stuttgart: Schattauer, 2017.
25 Kassenzahnärztliche Bundesvereinigung (KZBV). Spitzenverband der Gesetzlichen Krankenversicherungen (GKV-Spitzenverband). Bericht der KZBV und des GKV-Spitzenverbands an die Bundesregierung zur Entwicklung der kooperativen und koordinierten zahnärztlichen und pflegerischen Versorgung von pflegebedürftigen Versicherten in stationäre Pflegeeinrichtungen gem. § 119b abs. 3 satz 3 SGB V 2019;
26 Zimmermann T, Scherer M. Das Gesundheitssystem in Deutschland. In: Chenot J-F, Scherer M, eds. *Allgemeinmedizin*. 1st edn. München: Elsevier, 2022: 67–76.
27 Huettig F, Said F, Sippli K, *et al*. Was berichten Hausärzte und Zahnärzte über ihre Zusammenarbeit? Ergebnisse aus einer qualitativen Exploration. *Gesundheitswesen* 2018;57:262–5.
28 Al-Khabbaz AK, Al-Shammari KF, Al-Saleh NA. Knowledge about the association between periodontal diseases and diabetes mellitus: contrasting dentists and physicians. *J Periodontol* 2011;82:360–6.
29 Chapple ILC, Genco R, working group 2 of the joint EFP/AAP workshop. Diabetes and periodontal diseases: consensus report of the joint EFP/AAP workshop on periodontitis and systemic diseases. *J Periodontol* 2013;84:S106–12.

30 Obulareddy VT, Nagarakanti S, Chava VK. Knowledge, attitudes, and practice behaviors of medical specialists for the relationship between diabetes and periodontal disease: a questionnaire survey. *J Family Med Prim Care* 2018;7:175–8.
31 Poudel P, Griffiths R, Wong VW, *et al*. Perceptions and practices of general practitioners on providing oral health care to people with diabetes - a qualitative study. *BMC Fam Pract* 2020;21:34.
32 Tse SY. Diabetes mellitus and periodontal disease: awareness and practice among doctors working in public general out-patient clinics in kowloon west cluster of hong kong. *BMC Fam Pract* 2018;19:199.
33 Göstemeyer G, Baker SR, Schwendicke F. Barriers and facilitators for provision of oral health care in dependent older people: a systematic review. *Clin Oral Investig* 2019;23:979–93.
34 John MT, Patrick DL, Slade GD. The German version of the oral health impact profile--translation and psychometric properties. *Eur J Oral Sci* 2002;110:425–33.
35 John MT, Micheelis W, Biffar R. Normwerte mundgesundheitsbezogener Lebensqualität für Kurzversionen des Oral Health Impact Profile. *Schweiz Monatsschr Zahnmed* 2004;114:784–91.
36 Chalmers JM, King PL, Spencer AJ, *et al*. The oral health assessment tool -- validity and reliability. *Aust Dent J* 2005;50:191–9.
37 Klotz A-L, Zajac M, Ehret J, *et al*. Development of a German version of the oral health assessment tool. *Aging Clin Exp Res* 2020;32:165–72.
38 Hinz A, Klaiberg A, Brähler E, *et al*. Der Lebensqualitätsfragebogen EQ-5D: Modelle und Normwerte für die Allgemeinbevölkerung. *Psychother Psych Med* 2006;56:42–8.
39 Petersen PE, Bourgeois D, Ogawa H, *et al*. The global burden of oral diseases and risks to oral health. *Bull World Health Organ* 2005;83:661–9.
40 Nesse W, Abbas F, van der Ploeg I, *et al*. Periodontal inflamed surface area: quantifying inflammatory burden. *J Clin Periodontol* 2008;35:668–73.
41 Gemeinsamer Bundesausschuss. Beschluss des Gemeinsamen Bundesausschusses über eine Richtlinie zur systematischen Behandlung von Parodontitis und anderer Parodontalerkrankungen (PAR-Richtlinie): Erstfassung. 2020. Available: www.g-ba.de/downloads/62-492-2817/PAR-RL_2021-12-16_iK-2022-05-13.pdf [Accessed 24 Jan 2023].
42 Lange DE, Plagmann HC, Eenboom A, *et al*. Klinische Bewertungsverfahren zur Objektivierung der Mundhygiene. *Dtsch Zahnärztl Z* 1977;32:44–7.
43 Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. The Gerodontologist; 1969. 179–86.Available: www.eurohex.eu/bibliography/pdf/Lawton_Gerontol_1969-1502121986/Lawton_Gerontol_1969.pdf [Accessed 24 Jan 2023].
44 Park J, Jeong E, Seomun G. The clock drawing test: a systematic review and meta-analysis of diagnostic accuracy. *J Adv Nurs* 2018;74:2742–54.
45 Hansen H, Schäfer I, Porzelt S, *et al*. Regional and patient-related factors influencing the willingness to use general practitioners as coordinators of the treatment in northern Germany-results of a cross-sectional observational study. *BMC Fam Pract* 2020;21:110.