

Oral health in patients with cognitive complaints referred to a memory clinic.

Published: 22-02-2022

Last updated: 31-01-2025

Primary Objective:- To assess oral health in patients with memory complaints visiting a memory clinic. Oral health is defined for this study as the presence of deep caries lesions, periodontal pockets >6 mm, swollen and red gums, chewing problems...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON57270

Source

ToetsingOnline

Brief title

DeMo study

Condition

- Other condition

Synonym

Oral health

Health condition

mondgezondheid

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognitive complaints, Comprehensive geriatric assessment, Memory clinic, Oral health

Outcome measures

Primary outcome

Due to the exploratory character of the study, the endpoints are only descriptive:

- Oral health outcome: Screening and registering of oral health problems such as: caries, periodontitis, masticatory function (is the patient able to eat properly), occlusion (functional units), oral status (dentate/edentulous), dental visits, oral pain.

Secondary outcome

- Whether the recommended oral health care advice was followed.
- Composition of oral microbiome.

Study description

Background summary

The risk of developing cognitive problems increases with age. Patients with cognitive problems can be referred to a memory clinic. In such clinics, cognitive and general health status of these patients is assessed amongst others by a comprehensive geriatric assessment (CGA). CGA is considered to be a complete assessment from a medical and psychological perspective. An assessment of oral health, however, is not included in the CGA, although oral health has been linked to general- and mental health and quality of life in the recent literature. Therefore, an assessment of oral health is presumed to be of added

value to the GCA in the diagnostic work-up of patients referred to a memory clinic; it is important to gain insight in oral health status of patients referred to these clinics and which factors in this heterogeneous groups of patients are related to poor oral health. Furthermore, there are indications that the microbiome (oral microflora) is involved in the development and progression of neurodegenerative disorders. In this study an oral health assessment (including sampling the oral microbiome) will be added to the routine CGA in the diagnostic work-up of patients with cognitive problems referred to a memory clinic. All patients and/or their informal caretakers will be informed during their visit about the oral health status. They will also receive oral health care advice, e.g., how to maintain and or improve their oral health (e.g., using specific toothpaste, brushing teeth more often and or to visit a dentist). The recommendations will be given on paper. When agreed upon by the patient and/or their informal caretaker, information on the actual oral health status will also be send to the family dentist. Six weeks later, it will be assessed whether this advice was followed or not by the patient.

Study objective

Primary Objective:

- To assess oral health in patients with memory complaints visiting a memory clinic. Oral health is defined for this study as the presence of deep caries lesions, periodontal pockets >6 mm, swollen and red gums, chewing problems (one cannot eat properly), mobile elements, mucosal pathology and/or bone pathology.

Secondary Objectives:

- To assess whether an oral health care advice given to the patients is followed (e.g., checking if patients are using the advised oral care products, if they visited a dentist as advised etc).
- To assess the composition of the oral microbiome.

Study design

Explorative study

In patients who are prepared to participate in this pilot study, when they visit the memory clinic, the following will be added:

- administered two questionnaires about their oral health and dental visits.
- intra-oral photographs
- dental radiographs (orthopantomogram and bite wings)
- sampling of the oral microbiome (mouthwash).

Study burden and risks

All the patients who have an appointment/invitation in the memory clinic will receive a letter from the clinician at the memory clinic with written

information about the oral health study and the options to participate.

Patients who want to participate need to send the informed consent (that is attached to the information letter for the patient) back to the memory clinic.

When the memory clinic receives the informed consent, the questionnaires will be sent to the patient and the patient will be asked to return the questionnaires when they visit the memory clinic.

The day the patient visits the memory clinic it will be checked if the patient is incapacitated. If not, the patient will be included. Next, intra-oral photographs and conventional dental radiographs (orthopantomogram and two bitewings) are made and the oral microbiome is sampled (mouth rinse). The oral health assessment will take approximately 10-15 minutes on average. There are no risks as all procedures are routine dental examinations that are commonly applied during routine dental check-ups. The benefit for the patients is that they will be informed about their oral health and that they will receive oral health care advice when oral health is considered poor. This can help patients to prevent further decline of their oral health and thereby prevent possible general health problems that are related to poor oral health. The proposed study will give insight into the possible added value of oral health assessment next to the CGA for patients referred to the memory clinic as oral health is not included yet in the CGA assessment. The exploratory study will give also more insight whether oral health and the oral microbiome differs in subgroups of patients based on cognitive function, frailty. If differences are noted further research can be performed to gain more insight in the potential role of oral health and the oral microbiome in the process of dementia.

When added value is proven an oral health assessment can be considered to become a component of the GCA. This way, oral health problems will be recognized early as well as that patients will be advised how to take care of their oral health.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- All patients who referred to the memory clinic of the University Medical Center Groningen because of memory complaints.
- Seen at the memory clinic by a geriatrician or specialized geriatric nurse for a diagnostic work up including a CGA.

Exclusion criteria

- Patients who unable or unwilling to cooperate with dental screening due to their general condition.
- Incapacitated patients

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated):	01-04-2022
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO	
Date:	22-02-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL76845.042.21