

# Implementation of oral health care and normal diet on the psychogeriatric ward; the relationship with quality of life

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In the current study, the effect of oral health care and normal diet on quality of life of elderly persons suffering from dementia. The results from the baseline assessment will be used as cross-sectional data to establish correlations between the...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON38304

### Source

ToetsingOnline

### Brief title

Mastication and quality of life in elderly people suffering from dementia.

### Condition

- Other condition
- Dementia and amnestic conditions

### Synonym

senile dementia - dementia

### Health condition

aandoeningen van de mond en kauwfunctie

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit

**Source(s) of monetary or material Support:** Innovatiefonds zorgverzekeraars

## Intervention

**Keyword:** Cognition, Dementia, intervention, Mastication, Quality of life

## Outcome measures

### Primary outcome

The primary study parameter is quality of life.

### Secondary outcome

Secondary study parameters are cognition, mood and physical outcomes such as bloodpressure and masticatory function.

## Study description

### Background summary

Oral health is commonly compromised in elderly persons, especially in those receiving institutionalized care. Elderly persons with a mental disability, for example dementia, have an increase chance of having oral health problems. A MMSE score of 24-26 (mild cognitive impairment) combined with functional disability is associated with a higher chance of root caries. Edentulism is also commonly observed and can cause a diminished nutrient intake. This is associated with several ailments such as Parkinson\*s disease (shortage of vitamin E), cardiovascular disease (shortage of vitamin C) and ailments of the central nervous system (shortage of vitamin B).

Quality of life (QoL) of an elderly person with dementia is influenced by the disease itself, but also by several other factors. Loss of teeth is a risk factor for developing Alzheimer\*s disease, but the number of remaining teeth in elderly persons also predicts possible disability and mortality. A study showed a positive relationship between chewing ability, and memory and executive function in healthy independently living elderly persons. Chewing ability is also directly related to QoL in this population. Oral health care can improve chewing ability and thus improve QoL.

Interventions aimed at increasing physical activity can improve QoL for elderly persons suffering from dementia. Animal experiments show that offering a soft diet and/or removal of teeth can diminish cognitive performance in mice. By offering a normal consistency diet instead of mashed foods, masticatory activity will increase. This could also positively influence QoL.

## **Study objective**

In the current study, the effect of oral health care and normal diet on quality of life of elderly persons suffering from dementia.

The results from the baseline assessment will be used as cross-sectional data to establish correlations between the several variables.

## **Study design**

This is a multicentre randomised study; participants will be included in the study for six months, and will be assessed four times: during a baseline assesment, six weeks later, 12 weeks after baseline and 24 weeks after baseline. Assessments include neuropsychological testing and assessment of several physical parameters (e.g. blood pressure and masticatory function).

## **Intervention**

Participants will be included in either an intervention or control group. The control group will receive care as usual; the intervention group will receive improved oral health care and an improved diet (i.e. a diet of normal consistency). The intervention is always executed in concurrence with the local medical and care staff.

## **Study burden and risks**

The risk of participation is minimal; the intervention is in fact an improvement of daily care, in accordance to national guidelines and therefore no risk is expected. The duration of the (neuropsychological) assessments could be burdensome, since they can be tiring. However, the assessments can be broken up into smaller parts, thus minimizing the burden.

The assessment of the masticatory function only includes voluntary actions (e.g. bite down as hard as you can; open your mouth as far as you can); the risks of these assessments are judged by a dentist and medical technician and are deemed to be of minimal risk.

## Contacts

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Suffering from senile dementia, including subtypes such as Alzheimer's disease, vascular dementia and frontotemporal dementia.

Older than 65 years of age.

### Exclusion criteria

Age younger than 65 years.

Abuse of alcohol or other substances.

Extended history of psychiatry (major depression, bipolar disorder, psychosis).

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

**Primary purpose:** Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2013
Enrollment:	224
Type:	Actual

### Medical products/devices used

Generic name:	Bite Force Gauge
Registration:	No

## Ethics review

Approved WMO	
Date:	18-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

## 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	NL33230.029.10