

# Association between awareness, coping and neuropsychiatric symptoms in people with Alzheimer\*s disease, vascular dementia or mixed dementia

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To examine if coping style is associated with levels of awareness and to examine if awareness is associated with anxiety, apathy and depression in dementia.

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

## Summary

### ID

NL-OMON46248

### Source

ToetsingOnline

### Brief title

Awareness, neuropsychiatric symptoms and coping strategies in dementia

### Condition

- Other condition

### Synonym

Alzheimer, dementia

### Health condition

dementie

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Lentis (Groningen)

**Source(s) of monetary or material Support:** Lentis

## Intervention

**Keyword:** Awareness, Coping, Dementia

## Outcome measures

### Primary outcome

Primary endpoints are three types of awareness and three types of neuropsychiatric symptoms, as well as nine coping strategies.

### Secondary outcome

To examine the moderating effect of coping style on the association between awareness and neuropsychiatric symptoms in dementia.

## Study description

### Background summary

At the moment, the distinct association between neuropsychiatric symptoms and awareness is unclear. The influence of coping strategies on awareness and/or neuropsychiatric symptoms has not yet been studied, but this could potentially explain how people with dementia experience their feelings and how they react on problems, which could result in concrete interventions and guidance.

### Study objective

To examine if coping style is associated with levels of awareness and to examine if awareness is associated with anxiety, apathy and depression in dementia.

### Study design

Cross sectional study.

### Study burden and risks

The study contains a group of people with (very) mild to moderate Alzheimer dementia, vascular dementia or mixed dementia. The burden and potential risk of the study are minimal for participants, as participation takes approximately one and a half hours in total. When needed, participants can take a break while filling in the questionnaires. It is not expected that participants will experience any disturbance by the study, but it will be explained that they may discontinue from the study at any moment without consequences.

We expect that this study will shed more light on measuring awareness in people with dementia and may be the first step in developing an insight on the influence of coping strategies in people with dementia. This could be of great help to improve dementia health care.

## Contacts

### Public

Lentis (Groningen)

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NL

### Scientific

Lentis (Groningen)

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

- The subject has a caregiver who lives with him/her and who is willing to participate
- The subject has been diagnosed with Alzheimer\*s disease, vascular dementia or mixed dementia
- The subject scores a 0.5 (very mild dementia), 1 (mild dementia) or 2 (moderate dementia) on the Clinical Dementia Rating Scale
- The subject is able to communicate in Dutch without a translator

## Exclusion criteria

- There is no caregiver
- The present caregiver has cognitive disabilities or is too overburdened
- Subjects with psychiatric disorders will be excluded
- Subjects with a history of substance abuse, head trauma or brain illness other than dementia will be excluded

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 03-01-2019

Enrollment: 80

Type: Actual

## Ethics review

Approved WMO

Date: 03-08-2018  
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	NL65921.042.18