

# Subjective cognitive impairment and mild cognitive impairment: a sign of incipient Alzheimer\*s disease?

**\* A longitudinal study of functional and structural brain changes in healthy older adults with and without cognitive complaints.**

Published: 05-03-2014

Last updated: 24-04-2024

1. To investigate the differences between healthy older adults with and without cognitive complaints (SCI) and MCI patients in: a) resting state functional connectivity; b) brain structure; and c) cognitive function. 2. To investigate longitudinal...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Neurological disorders congenital
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON40552

### Source

ToetsingOnline

### Brief title

Subjective cognitive impairment: a sign of incipient AD?

### Condition

- Neurological disorders congenital
- Dementia and amnesic conditions

### Synonym

1 - Subjective cognitive impairment and mild cognitive impairment: a sign of incipie ... 7-05-2025

memory complaints, Subjective cognitive impairment

## **Research involving**

Human

## **Sponsors and support**

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** veni beurs NWO-grant van Jeske Damoiseaux

## **Intervention**

**Keyword:** Alzheimer's disease, fMRI, longitudinal, Subjective cognitive impairment

## **Outcome measures**

### **Primary outcome**

1) MRI (resting state fMRI, task related fMRI, DWI and structural MRI), 2)

cognitive parameters, 3) APOE \* genotype.

### **Secondary outcome**

not applicable

## **Study description**

### **Background summary**

Previous imaging research has significantly increased our knowledge on how the brain changes in patients with Alzheimer's disease (AD), the most common form of dementia. AD is characterized by a slow decline in cognitive function, and its neuropathology may be present long before clinical symptoms become apparent. Amnesic mild cognitive impairment (MCI) refers to the symptomatic pre-dementia phase of AD. Subjective cognitive impairment (SCI) is a common condition in which a person has memory complaints but no deficits on formal cognitive testing. It is still unclear whether SCI represents the latent phase of AD, but the idea of SCI as a precursor of AD is supported by several longitudinal studies that identified SCI as a predictor of AD. To date only a few imaging studies have focused on the detection of incipient AD, and no longitudinal resting state fMRI studies have been conducted in healthy at-risk populations. If resting state fMRI is able to show functional connectivity differences in SCI patients, and is also able to predict the cognitive status

of a patient at a later point in time, it will substantiate its promise as a biomarker for the early detection of AD.

### **Study objective**

1. To investigate the differences between healthy older adults with and without cognitive complaints (SCI) and MCI patients in: a) resting state functional connectivity; b) brain structure; and c) cognitive function. 2. To investigate longitudinal changes in functional connectivity, brain structure, and cognitive function in people with SCI and older adults without cognitive complaints; and whether these longitudinal changes differ between groups.

### **Study design**

Combined cross-sectional and longitudinal study.

### **Study burden and risks**

This is a non-therapeutic group relatedness study. This research may help to elucidate early functional and structural biomarkers in the brain for the onset of dementia and Alzheimer's. The study consists of two visits, one at baseline, and one after 18 months and during a visit the following procedures will be done: MRI scan, neuropsychological assessment (SCI and controls only) and collection of 2 ml saliva. These procedures have no consequences for the health of the participants. Contra-indications will be carefully investigated per subject to minimize the risks. Burden will be kept at a minimum by using short protocols.

## **Contacts**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Healthy adults aged 40-90 with or without memory complaints. Adults with SCI must have undergone a formal medical assessment that concluded that no objective cognitive impairment was apparent. Adults with MCI must have undergone a formal medical assessment that concluded that impairment in memory and intraindividual change was apparent, but no evidence of a significant impairment in social or occupational functioning.

### Exclusion criteria

Left-handedness; any significant diagnosed medical, neurological or psychiatric illness; a history of brain damage; or the use of psychoactive medication will exclude volunteers from participating. Participants will also disqualify if they have any MRI contraindications such as: implanted electrical device (e.g., cardiac pacemaker) or metallic clip (e.g., aneurysm clip). We will also warn participants that some individuals experience claustrophobia in the scanner. We will seek equal representations of men and women.

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	23-09-2014
Enrollment:	80
Type:	Actual

## Ethics review

Approved WMO	
Date:	05-03-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	01-08-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO	
Date:	01-12-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO	
Date:	14-04-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

## 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	NL46557.058.13