Neural Correlates of Apathy In Mild Cognitive Impairment (MCI)

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The main objective of this study is to determine the neural correlates of apathy. These neural correlates will be compared with the neuropsychological tests At a later stage, the predictive value of the neural correlates will also be assessed.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mental impairment disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41265

Source
ToetsingOnline

Brief title
Apathy and Memory

Condition

- Mental impairment disorders
- Dementia and amnestic conditions

Synonym
apathy, dementia

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: apathy, cognitive impairment, memory

Outcome measures

Primary outcome

Functional MRI data will be analysed for areas of activation and functional

connectivity between these areas while Diffusion Weighted Imaging will be used

to study the structure of tracts. Metabolite abnormalities will be assessed

using a Magnetic Resonance Spectroscopy scan.

Secondary outcome

n.a.

Study description

Background summary

With the general population getting increasingly older, there is a clear societal need for a scientific focus on healthy ageing. One issue that deserves more attention than it currently does, are the neuropsychiatric problems in dementia and Mild Cognitive Impairment (MCI). Apathy, which is among the most common symptoms, has been shown to predict progression to dementia. Moreover, the prevalence of apathy is known to increase with the severity of Alzheimer*s Disease (AD). Nevertheless, the neural factors underlying apathy and its relation with MCI and AD have yet to be elucidated.

Study objective

The main objective of this study is to determine the neural correlates of apathy. These neural correlates will be compared with the neuropsychological tests At a later stage, the predictive value of the neural correlates will also be assessed.

Study design

The proposed study will examine the differences in the MRI data and neuropsychological test results from MCI subjects with and without apathy. A

follow up is planned after three years to assess the subjects for progression to dementia and to explore the predictive value of the collected MRI data.

Study burden and risks

This study entails minimum risks to the participants. Subjects will have to visit the memory clinic for the neuropsychological assessment. The tests will be completed along with the routine assessment in the memory clinic to reduce the burden on the subjects. All subjects will also visit the Neuroimaging Center (NiC, UMCG) for the MRI scan. The duration of the scan will be less than 75 minutes. Participants will be exposed to a field-strength of 3 Tesla and scanner noise. Thus far, there is no evidence to suggest that exposing humans to a magnetic field of this strength has a negative influence on health. Subjects will be contacted once again after three years for the follow-up assessment. There is no direct benefit to the subjects from the study. The study will contribute valuable scientific knowledge to the fields of dementia, AD, MCI, and apathy.

Contacts

Public
Universitair Medisch Centrum Groningen

Ant. Deusinglaan 2
Groningen 9713 AW
NL
Scientific
Universitair Medisch Centrum Groningen

Ant. Deusinglaan 2
Groningen 9713 AW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All subjects:
- Age from 60yrs to 80yrs
- Willingness to cooperate and sign written informed consent;Normal Healthy Controls:
- MMSE scores between 28 and 30;aMCI with apathy
-Diagnosis of aMCI as assessed by clinician and neuropsychologist, according to Petersen 1999.
-Apathy diagnosed by apathy criteria (Robert 2009), assessed by clinician and neuropsychologist ;aMCI without apathy
-Diagnosis of aMCI as assessed by clinician and neuropsychologist, according to Petersen 1999
-Apathy excluded according to apathy criteria (Robert 2009), assessed by clinician and neuropsychologist

Exclusion criteria

All subjects:
-Medications which may affect the experimental outcomes
-Existence of psychiatric conditions with exception of depression or neurological conditions or problems with eyesight
-MR incompatible implants in the body (such as ear prosthesis, pacemakers, implanted heart valves etc). All subjects have to fill out a detailed questionnaire covering safety aspects of the research in relation to the 3 Tesla magnetic field and the MRI environment.
-Any risk of having metal particles in the eyes due to manual work without proper eye protections
-Tattoos containing red pigments that form a safety risk
-Claustrophobia
-The refusal to be informed of structural brain abnormalities that could be detected during the experiment ;Normal Heathy Controls:
-Abnormal result on any neuropsychological test
-Diagnosis of AD by NINCDS/ADRDA criteria (McKhann 1984) and DSM-IV criteria, assessed by clinician and neuropsychologist

aMCI with apathy, aMCI without apathy
-Diagnosis of AD by NINCDS/ADRDA criteria (McKhann 1984) and DSM-IV criteria, assessed by clinician and neuropsychologist

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-04-2013
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	25-01-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-03-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-05-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-07-2015
Application type:	Amendment

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	NL42413.042.12