Improving the early diagnosis of Alzheimer*s disease and other dementias

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To improve the behavioural (neuropsychological) methods for the early diagnosis of Alzheimer*s disease (AD) and other dementias.

Ethical review	Approved WMO
Status	Pending
Health condition type	Structural brain disorders
Study type	Observational non invasive

Summary

ID

NL-OMON29838

Source
ToetsingOnline

Brief title
IDADO

Condition

- Structural brain disorders
- Dementia and amnestic conditions

Synonym
dementia, mental disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Alzheimer's disease, dementia, diagnostics, neuropsychological tests

Outcome measures

Primary outcome

Clinical status at follow-up after 2, 4 or 6 years (demented / stable /

improved).

Secondary outcome

Abnormal results of MRI.

Study description

Background summary

The differential diagnosis of mental complaints that may signify an early stage of dementia is notoriously difficult. One reason for this difficulty is that the transition between normal cognitive aging and cognitive impairment due to degenerative cerebral disease is a gradual one. A second reason for the diagnostic difficulty is the frequent co-occurrence of cognitive impairment and emotional-behavioural or psychiatric symptoms. Estimates of this co-occurrence in pre-dementia patients vary from 25% in population-based studies to more than 60% in clinical samples. This causes frequent misclassification of pre-dementia and functional psychiatric states in elderly patients. There is a relative lack of research that takes this co-occurrence into account. Dementia researchers often evade the problem by excluding patients with psychiatric disorders, while psychiatry researchers evade it by limiting the age range in their studies or by excluding patients with cognitive impairment. This state of affairs does not do sufficient justice to clinical reality. The present research project expressly addresses the co-occurrence of cognitive and emotional-behavioural symptoms.

Study objective

To improve the behavioural (neuropsychological) methods for the early diagnosis of Alzheimer*s disease (AD) and other dementias.

Study design

Standard neuropsychological tests with proven validity for the early detection of dementia will be adapted to increase their precision of measurement. These improved tests, plus structured psychiatric assessment, and Symptom Validity Testing (SVT) will be applied to distinguish (1) patients with mental complaints secondary to degenerative brain disease from (2) patients with mental complaints that are probably due to non-organic influences, i.e. emotional-behavioural problems and functional psychiatric disorders.
Structural MRI scans will be made at baseline, and blood samples will be collected and stored for later neurogenetic and neurochemical analysis.
Patients will be followed-up biannually.
Controls will be given the improved neuropsychological test only.

Study burden and risks

Two visits to the AMC at baseline (max 3 hours each): neuropsychological testing, psychiatric interview, MRI scan, blood sampling (once; three tubes of 7 ml each).
Brief visits to the AMC biannually (max 1 hour each; brief interview and brief neuropsychological testsing; max 3 visits) until a change in clinical status has occurred.
There are no risks involved.
Benefit of the individual patient may be new diagnostic findings that are directly relevant to the treatment.

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

1) complaints of decline in cognitive or behavioural functioning (expressed by patient or close relative);
2) age between 50 and 85 years.

Exclusion criteria

1) dementia as established by a dementia specialist according to DSM-IV criteria;
2) other brain disease or systemic disease sufficient to cause the complaints and symptoms;
3) current substance abuse or addiction;
4) serious somatic disease or handicap that prevents neuropsychological evaluation;
5) pre-existent mental retardation;
6) contra-indication for MRI scanning;
7) insufficient command of the Dutch language.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	320
Type:	Anticipated

Ethics review

Approved WMO

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	NL12924.018.06