Capturing Changes in Cognition: developing a measure for progression in dementia

Published: 24-08-2015
Last updated: 19-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Observational non invasive

Summary

ID

NL-OMON45175

Source
ToetsingOnline

Brief title
CatCh-Cog

Condition

- Dementia and amnestic conditions

Synonym
alzheimer's disease, dementia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Zon-MW

Intervention

Keyword: Cognition, Dementia, Disease progression, Instrumental Activities of Daily Living

Outcome measures

Primary outcome

The main study parameter is clinical progression in cognition and everyday functioning, as measured with the CFC. Reference measures for this progression consist of cognitive screening tests, caregiver-based anchor measurements of change and Magnetic Resonance Imaging (MRI). Progression of disease burden will be assessed using caregiver burden, quality of life and level of apathy measures and social functioning. For the validation of the CFC, we will relate changes on the CFC to these other measures of disease progression.

Secondary outcome

Secondary parameters are age, gender, education, culture and disease severity at baseline. We will investigate their possible influence on the CFC.

Study description

Background summary

Neuropsychological testing is burdensome to patients with dementia. However, it is essential for the monitoring of disease progression and the evaluation of treatment effects. Neuropsychological assessment should therefore be short, reliable, valid, sensitive to change and reflect clinically meaningful changes. Commonly used neuropsychological tests do not meet these criteria. There is therefore a need to specify and validate measures suitable for assessing disease progression in dementia.

Study objective

The overall aim of this study is to develop a short and clinically relevant composite measure, which is able to detect changes in cognition and everyday

functioning across the disease spectrum of Alzheimer*s Disease (AD). We will achieve this aim by addressing the following key objectives: First (1), we will identify the relevant cognitive and everyday functioning measures and create the Cognitive-Functional Composite (CFC). Next (2), we aim to investigate the psychometric properties of the CFC and investigate whether it is able to detect changes over time. Lastly (3), we aim to investigate possible influence of age, gender, educational and cultural differences on the CFC.

Study design

This multicenter study has a mixed methods design. First, we will use both qualitative and quantitative methods to develop the CFC. Following this, we will perform a longitudinal validation study consisting of a prognostic cohort with baseline 3-, 6-, and 12-month follow-up assessments.

Study burden and risks

Patients participating in our study will undergo a neuropsychological assessment and clinical evaluation at four measurement moments: namely baseline, 3, 6 and 12 months. Each measurement moment has an assessment time of approximately 90 minutes for the patient and 45 minutes for the caregiver. The time intervals between measurement moments are chosen to correspond to clinical and intervention trials. We realize that the frequency of these moments could provide a high burden. To minimize respondent burden, we will offer testing at home. Questionnaires for caregivers can be completed at home as well. Patients only need to visit their memory clinic for the MRI scan at baseline and 12 months follow-up. However we aspire to inlude a diagnostic scan as baseline scan if available. In that case, only a follow-up scan at 12 months will be acquired. The conduction of the MRI scan might be uncomfortable and is therefore not obligatory for participation in the study. The additional risk of this study is considered negligible, as no experimental intervention is conducted. The current study will not benefit patients and caregivers directly. However if successful, the CFC will contribute to the improvement of longitudinal measurements in early stages of dementia.

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

Patients: 1) A diagnosis of subjective cognitive decline, mild cognitive impairment (MCI) or dementia due to Alzheimer's Disease (AD) OR MCI or mild dementia due to Dementia with Lewy bodies (DLB); 2) MMSE >= 18; 3) Age >= 50; 4) Written informed consent; 5) Availability of a primary caregiver;Control group: age >= 50, cognitively normal

Exclusion criteria

Presence of a neurological disease other than AD or DLB; Presence of another major psychiatric disorder (according to Diagnostic and Statistical Manual of Mental Disorders, 4th version); Current abuse of alcohol or drugs; Currently participating in a clinical trial.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-11-2015
Enrollment:	560
Type:	Actual

Ethics review

Approved WMO Date:	24-08-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2017
Application type:	Amendment
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	NL53667.029.15