Financial decision-making in patients with neurodegenerative disorders - a pilot study.

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

Summary

ID

NL-OMON50611

Source
ToetsingOnline

Brief title
Financial decision-making in patients with neurodegenerative disorders.

Condition

- Mental impairment disorders

Synonym
Neurodegenerative disorders; dementia

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Alzheimer's disease, Financial decision-making, Mild Cognitive Impairment, Parkinson's disease

Outcome measures

Primary outcome

The primary parameters of this study are the performances of patients with AD,

MCI and PD on FDM tasks compared to healthy controls.

Secondary outcome

The secondary parameters of this study are the performances of patients with

AD, MCI and PD on standard neuropsychological tasks.

Study description

Background summary

Financial decision-making (FDM) is a daily-performed activity that is highly relevant for independent living. FDM requires the integrity of various cognitive functions and it is likely that FDM is vulnerable to the changes in cognition and emotion that accompany neurodegenerative disorders. However, the assessment of FDM is difficult since (1) there is a lack of guidelines and of standardized and valid instruments and (2) the tests that are available often only assess one (basic) aspect of FDM. The aim of the present study is to assess FDM in patients with neurodegenerative disorders, namely Alzheimer*s disease (AD), Mild cognitive impairment (MCI) and Parkinson*s disease (PD), using a newly developed test battery, which is sensitive to the effects of aging and has a good divergent validity.

Study objective

The primary objectives are to investigate multiple aspects of FDM in patients with AD, MCI and PD compared to healthy controls and to investigate whether FDM problems in these patients can be related to specific neurocognitive dysfunctions. The secondary objective is to distinguish specific profiles of FDM in patients with AD, MCI and PD in terms of strengths and weaknesses.

Study design

Cross-sectional pilot study.

Study burden and risks

Participants will be invited to visit the University Medical Center Groningen or the Hospital Network Antwerp once for a neuropsychological assessment. Three weeks before the assessment the participants will receive several questionnaires (administration time of approximately 0.5 hours) which can be filled out at home. The assessment in the University Medical Center Groningen or the Hospital Network Antwerp has a duration of approximately 3,5 to 4 hours. The assessment will require a certain amount of concentration from which a participant can recover after a short break. The risks of this study are thus negligible and the burden can be considered minimal.

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 must be diagnosed with Alzheimer's Disease (AD), Mild Cognitive Impairment (MCI) or Parkinson's disease (PD) by an experienced neurologist according to published criteria:
1. Patients with probable AD dementia according to the criteria of The National Institute on Aging and the Alzheimer*s Association (McKhann et al., 2011).
1a. Only patients in the early stages of the disease (i.e. within two years after diagnosis) will be included, since in the later stages of disease the understanding of test instructions might be questioned.
2. Patients with amnestic MCI (single and multi-domain) according to the criteria of The National Institute on Aging and the Alzheimer*s Association (Albert et al., 2011).
3. Patients with idiopathic PD according to the UK Parkinson*s Disease Society Brain Bank Criteria (Hughes, Daniel, Kilford, & Lees, 1992).
3a. Only patients in the early stages of the disease (i.e. within five years after diagnosis) will be included, since in the later stages of disease the understanding of test instructions might be questioned., In case of medication use, patients and healthy controls must be on a stable dosage of medication for at least one month.

Exclusion criteria

1. Presence of a neurological central nervous system disorders other than AD, MCI or PD.
2. Surgical treatment for idiopathic PD, such as deep brain stimulation.
3. Other significant co-morbidity which might have an influence on cognition:
3a. Cardiovascular diseases, including severe hypertension.
3b. Cardiovascular risk factors, such as diabetes.
3c. Clinically evident psychological / psychiatric disorders, such as depression, anxiety, apathy and fatigue.

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2016
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	20-11-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-04-2020
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	NL54161.042.15