A study of emotional responsiveness and apathy in Parkinson*s disease

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON34379

Source
ToetsingOnline

Brief title
study of emotion and apathy in PD

Condition

- Movement disorders (incl parkinsonism)

Synonym
parkinson's disease; emotional response

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Apathy, Emotional responsiveness, Parkinson's disease

Outcome measures

Primary outcome

In this study the main parameters is emotional responsiveness measured on a

visual analogue (VAS) scale.

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Secondary outcome

Physical concomitants of emotional responsiveness: heart rate, blood pressure,

skin conductance and pupil width

Salivary cortisol levels will be measured at the beginning of the study and

after emotional pictures are viewed.

Performance on neuropsychiatric and neuropsychological questionnaires and tests

Study description

Background summary

Apathy is a neuropsychiatric syndrome defined as a lack of motivation characterized by reduced goal-directed behavior, reduced goal-directed cognitive activity and a decreased spontaneous emotions or emotional responsiveness to positive and negative stimuli and events. In Parkinson*s disease (PD) it is associated with greater cognitive dysfunction, worse performance of activities of daily living and reduced quality of life. The pathophysiology of apathy is not well studied. Studies addressing emotional responsiveness in PD may provide new insights into the neurobiology of apathy, which may eventually lead to new treatment strategies and an improved quality of life for PD patients suffering from apathy.

Study objective

The first objective of this study is to assess whether emotional responsiveness

in PD patients is different from that of matched healthy controls and whether emotional responsiveness in PD patients with apathy is different from that in PD patients without apathy.

Study design

This is a cross-sectional study which will follow a two stage approach;
1. The present study is done to assess emotional responsiveness and to investigate differences in emotional responsiveness between PD patient and healthy controls and between PD patients with apathetic symptoms and PD patients without apathetic symptoms.
2. After the present study, a functional MRI study is done to identity differences in activation of specific brain structures involved in emotional responsiveness in PD patients with and without apathetic symptoms and healthy controls

Study burden and risks

The burden and risks associated with the present study are minimal. For this study participants will spend approximately 1.5 hour at the MUMC. It is unlikely that the neuropsychiatric assessment will cause any harm to participants.

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

Inclusion criteria for PD patients are:
-Idiopathic Parkinson*s disease according to the Queen Square Brain Bank criteria (De Rijk, Rocca et al, 1997).
-The use of a stable dose of antiparkinsonian medication.
-Signed informed consent;Inclusion criteria for healthy controls are:
-signed informed consent

Exclusion criteria

Exclusion criteria for PD patients are:
-patients with other neurodegenerative disorders other than PD
-Major Depressive Disorder as defined by the criteria of the fourth edition of the Diagnostic and Statistical Manual (DSM-IV) of the American Psychiatric Association (APA) (American Psychiatric Association 1994).
-cognitive deterioration operationalised as a score of <26 on the Mini Mental State Examination (MMSE) (Folstein, Folstein et al. 1975) or fulfilling diagnostic criteria for Parkinson*s Disease Dementia (PDD) (Dubois, Burn et al. 2007).
-use of psychopharmacological medication, with the exception of benzodiazepines
-abuse of alcohol and/or drugs
-exclusion criteria for MRI scanning;Exclusion criteria for healthy controls are:
-neurodegenerative disorders
-Major Depressive Disorder as defined by the criteria of the fourth edition of the Diagnostic and Statistical Manual (DSM-IV) of the American Psychiatric Association (APA) (American Psychiatric Association 1994).
-cognitive deterioration operationalised as a score of <26 on the Mini Mental State Examination (MMSE) (Folstein, Folstein et al. 1975) or fulfilling diagnostic criteria for Parkinson*s Disease Dementia (PDD) (Dubois, Burn et al. 2007).
-use of psychopharmacological medication, with the exception of benzodiazepines
-abuse of alcohol and/or drugs

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:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL33147.068.10