Apathy in patients with Parkinson*s disease and major depressive disorder, a structural brain imaging study using Voxel Based Morphometry

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Primary objective: the primary objective of the present study is to assess whether apathy can be linked to structural brain changes (both atrophy of grey matter, as well as changes in white matter), whether apathy in PD is related to certain…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON30824

Source
ToetsingOnline

Brief title
Imaging and Apathy in patients with Parkinson*s disease

Condition

- Neurological disorders NEC
- Mood disorders and disturbances NEC

Synonym
pathological indifference

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Apathy, Depression, Imaging, Parkinson's disease

Outcome measures

Primary outcome

- Atrophic brain processes observed in all groups (both grey matter atrophy and

white matter hyper-intensities), measured by Voxel Based Morphometry imaging.

- Performance on neuropsychiatric and neuropsychological tests.

- Correlation between the abovementioned points.

Secondary outcome

Not applicable.

Study description

Background summary

Background: *Apathy* is a psychopathological syndrome characterised by lack of interest, desire, emotion and motivation. It is commonly reported in patients with various neuropsychiatric disorders, such as Parkinson*s disease (PD), Alzheimer*s disease (AD), and depressive disorder. In PD, the reported prevalence of apathy ranges between 16.5% and 42% (Isella, Melzi et al. 2002; Robert, Clairet et al. 2002). Apathy has a great influence on everyday functioning of patients, and can be a great source of stress to the patients* relation with his or her partner (Aarsland, Alves et al. 2005; Aarsland, Bronnick et al. 2006). Moreover, together with other psychiatric and non-motor symptoms, apathy contributes significantly to disability in PD (Weintraub, Moberg et al. 2004). Although apathy occurs frequently, it is not frequently recognized (Rabinstein and Shulman 2000). It is important to gain more knowledge about the possible causes of apathy in PD, since this may open the way for treatment of this syndrome and improve the quality of life of both the patient and their partners. At present, no specific treatment for apathy is

available. Knowledge about the clinical and anatomical correlates of apathy may result in the development of treatment options and thus improve prognosis. So far, only a limited number of studies have focussed on apathy in relation to clinical (mainly neuropsychological) dysfunction. Even less studies have focused on the neuro-anatomical correlates of apathy. Functional neuro-imaging studies have shown that hypo-perfusion of the prefrontal brain areas and cingulate gyrus may play a role in the pathophysiology of apathy (Isella, Melzi et al. 2002; Pluck and Brown 2002). However, it is presumed that neuronal networks rather than demarcated brain areas fulfil an important function in the maintenance of complex behavioural aspects such as initiative, motivation, and interest, which are all impaired in apathy (Daffner, Mesulam et al. 2000). To date, hardly any studies have been performed investigating the relation between apathy and structural changes in the brain. Studies like these, can provide very useful information about the link between apathy in PD and changes in white and grey matter. In turn, this may lead to new insights for improved treatment of apathy in PD.
Relevance for healthcare: Understanding the aetiology of apathy is clinically very relevant since apathy has a direct impact on the overall functioning of the patient and his or her environment. It has negative implications for the prognosis, and contributes significantly to carer burden. Apathy significantly affects quality of life. Insight into the clinical and neuroanatomical correlates of apathy will enhance our understanding of this syndrome and may open the way for the development of potential treatments, thereby increasing the quality of life for patients and their environment.

Study objective

Primary objective: the primary objective of the present study is to assess whether apathy can be linked to structural brain changes (both atrophy of grey matter, as well as changes in white matter), whether apathy in PD is related to certain neuropsychological deficits and whether the findings in the PD group are similar to the AD and depression group. The following specific questions are of importance:
1. In how far does a differential relation exist between apathy and, especially prefrontal, brain areas?
2. Does a relation exist between white matter hyper-intensities and apathy?
3. Can apathy be related to specific cognitive complaints?

Study design

The present study is a cross-sectional controlled study, including four groups of participants: 30 PD patients suffering from apathy, 30 PD patients without apathy, 30 patients suffering from depression, and 30 matched control subjects. The target intervention will be the imaging session and the neuropsychological and neuropsychiatric investigation.

Study burden and risks

Participants will spent approximately 3.5 hours in a single visit to the research site. The study is aimed at patients suffering from Parkinson*s disease with and without symptoms of apathy, patients suffering from a depression and healthy control subjects. It is unlikely that the imaging or the neuropsychological and neuropsychiatric assessments will cause any harm to participants. Therefore, participation is not considered to be a risk.

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

- Idiopathic Parkinson*s disease as defined by the criteria of the United Kingdom Parkinson*s

Disease Brain Bank, regarding the inclusion of Parkinson*s disease patients (Hughes, Daniel et al. 1992).
- Apathy as defined by a score equal or higher than four on the apathy subscale of the Neuro Psychiatric Inventory (NPI), regarding the apathy groups (Cummings, Mega et al. 1994; Cummings 1997).
- Depression as defined by the criteria stated in the DSM-IV, regarding the depressed patients (DSM-IV 1994).
- Informed consent.

Exclusion criteria

- Other concurrent neurological diseases than PD.
- Concurrent psychiatric diseases (e.g. dementia).
- Use of psychopharmacological medication.
- Abuse of alcohol and/or drugs.
- Cognitive deterioration as operationalised by a score of <23 on the Mini Mental Status Examination (MMSE) (Folstein, Folstein et al. 1975).
Voxel Based Morphometry exclusion criteria:
- Pacemaker.
- Hart valve prosthesis.
- Metal fragments in brain or surrounding tissue.
- Ear implants.
- Claustrophobia.
- Infusion pumps.
- Pregnancy.

Study design

Design

Study type:	Observational 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):	17-09-2007
Enrollment:	120
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	14-03-2007
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	NL15863.068.07