The influence of stress on cognitive functioning in Parkinson*s disease

Published: 01-05-2012
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To investigate whether stress (chronic and acute) influences cognitive functioning in PD.

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

Summary

ID

NL-OMON37748

Source
ToetsingOnline

Brief title
Stress and cognitive functioning in Parkinson

Condition

- Neurological disorders NEC

Synonym
mental processes, Psychological disstress

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cognitieve functioning, Medical decision making, Parkinson, Stress

Outcome measures

Primary outcome

Different parameters for stress will be taken into account (cortisol levels, scores on a perceived stress questionnaire). Furthermore, performance on cognitive tasks will be assessed in the PD group and control group. Both groups will be compared with each other. There will be assessed whether:

- stress (chronic and acute) influences cognitive functioning in PD
- chronic stress is associated with an accelerated cognitive decline in PD

Secondary outcome

Different parameters for stress will be taken into account (induced stress, vulnerability to perceive stress). Furthermore, performance on cognitive tasks as well as medical decision making tasks will be assessed in the PD group and control group. Both groups will be compared with each other. There will be assessed whether:

- induced stress influences cognitive functioning in PD
- vulnerability to perceive stress moderates the influence of (chronic and acute) stress on cognitive functioning in PD.
- cognitive functioning mediates the influence of stress on medical decision making in PD.

Study description

Background summary

Parkinson*s disease (PD) is a progressive neurodegenerative disorder. Besides motor symptoms, cognitive impairments are well recognized. Cognitive impairment

occurs in approximately half of the PD population and is in most cases progressive in nature. Over the course of the disease PD patients have to make complex decisions about medical care. Research findings suggest that medical decision making is affected in cognitive impaired PD patients. It remains unclear which factors contribute to the progression of PD. Considering low quality of life in PD patients with dementia, it is in particular interesting whether psychological factors contribute to cognitive decline in PD. It is known that minimal psychological stress can increase motor symptoms. Furthermore, an association was found between neuroticism and increased risk of PD. However, there are no studies conducted investigating the influence of psychological stress on cognitive functioning in PD. As for the impact of (chronic and acute) stress on cognitive functioning in other diseases, studies indicate an association between stress and cognitive functioning. Since minimal psychological stress increases motor symptoms in PD, we expect that psychological stress also has an impact on cognitive functioning and therefore also on medical decision making. This is important to PD patients and their families, who have to make complex decisions about medical care over the course of the progressive neurodegenerative disease. With regard to secondary prevention of PD dementia, psychological interventions focusing on stress management could have an important surplus value next to medical treatment.

Study objective

To investigate whether stress (chronic and acute) influences cognitive functioning in PD.

Study design

Prospective longitudinal cohort study comparing PD patients to a healthy control group.

Study burden and risks

Participants will be neuropsychological assessed twice (baseline and two year follow-up). The duration of the neuropsychological assessment is approximately 150 min. Participants are also asked to take five salivary samples (cortisol measurement) with swabs at home prior to the assessments (15 min.). Prior to the baseline assessment participants are asked to fill out questionnaires at home (30 min.). Between the baseline and follow-up neuropsychological assessment participants are asked to fill out a stress questionnaire once every two months at home. The time for filling out the questionnaire is estimated to take 15 min. The neuropsychological assessment, taking salivary samples and completing questionnaires will require a certain amount of concentration from which a participant can recover after a short break. During the first neuropsychological assessment, a neuropsychological task is conducted that will be used as stress induction. After the assessment debriefing and a relaxation

exercise will take place to ensure participants go home relaxed. The risks of the study are negligible. PD patients are used to neuropsychological assessment in clinical practice. Participants will have no direct benefit from the study. We consider the burden of the study worthwhile comparing to the gains of the study. There is little to no knowledge about the influence of stress on the course of PD. Research on this topic may have great implications for the treatment of PD.

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

- Parkinson's Disease according to the UKPDS Brain Bank Criteria as diagnosed by a neurologist.

- Stabel dosage of "anti-parkinsonian" medication at onset of the study

Exclusion criteria

- Surgical treatment for PD, such as deep brain stimulation.
- Suspected dementia at the onset of the study.
- Presence of co-morbid neurological disorder (e.g. CVA) or infection (e.g. meningitis) within last 5 years other than PD that influences cognitive functioning.
- Medication (e.g. corticosteroid) that influences daily cortisol levels.
- Presence of posttraumatic stress disorder and/or psychotic disorders which influences cognitive functioning.
- Depression according to the Beck Depression Inventory (BDI), cut-off score 15 for PD patients and cut-off score 10 for healthy controls.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-08-2012
Enrollment:	204
Type:	Actual

Ethics review

Approved WMO

Date:	01-05-2012

Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL40173.096.12