The influence of stress on Parkinson*s tremor * a behavioural pilot study

Published: 15-10-2018 Last updated: 10-01-2025

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

Summary

ID

NL-OMON48944

Source ToetsingOnline

Brief title Effect of stress on Parkinson's tremor

Condition

• Movement disorders (incl parkinsonism)

Synonym Parkinson's disease, tremor

Research involving Human

Sponsors and support

Primary sponsor: Donders Institute for Brain, Cognition and Behaviour Source(s) of monetary or material Support: VENI beurs

Intervention

Keyword: Parkinson's disease, Stress, Tremor

Outcome measures

Primary outcome

During each of the three behavioral tasks we will record the following primary

outcome measures:

- Tremor power (quantified using accelerometry and EMG)
- Pupil diameter (a marker of noradrenergic activity; quantified using eye

tracking)

Secondary outcome

Additionally, we will obtain measure of:

- Task performance (using choice and reaction times)
- Heart rate (quantified using ECG)
- Disease severity (UPDRS part III and TRS)

Study description

Background summary

Parkinson*s disease is the second most common neurodegenerative disease worldwide. Clinically, Parkinson*s disease is characterized by motor slowing (bradykinesia), stiffness (rigidity) and resting tremor. The pathological hallmark of Parkinson*s disease is striatal dopamine depletion, but the dopaminergic basis of resting tremor is disputed. For instance, striatal dopamine depletion correlates with all motor symptoms except resting tremor. Furthermore, resting tremor is often resistant to dopaminergic medication. Instead, resting tremor worsens consistently during psychological stress, and recent findings suggest that the noradrenergic (stress) system is hyperactive in Parkinson*s disease. However, it is not clear which type of stress (cognitive effort, fear) has the largest effect on Parkinson*s tremor.

Study objective

The goal of this research is to assess whether cognitive effort (mental arithmetic) or fear (threat of shock) have a similar or different effect on Parkinson*s tremor and noradrenergic activity. In the following, obtained knowledge and empirical evidence will be used to prepare an amendment for a follow-up fMRI study, which will be investigating how enhanced noradrenergic activity modulates Parkinson*s tremor (CMO 2016-3101).

Study design

Cross-sectional observational study

Study burden and risks

This research involves capacitated adults. This research has no direct benefit for the participants. The scientific benefit of this study is to achieve a better understanding of the pathophysiology of a severe symptom (Parkinson's tremor).

There is minimal risk and minimal burden associated with this experimental protocol. The protocol will be performed during one session (duration approximately 3 hours). It will consist of clinical measurements and behavioral performance of three cognitive tasks as well as recording of autonomic responses. This study is purely observational, i.e., no invasive or interventional procedures are involved. Patients taking dopaminergic medication will be asked to delay one dose (i.e. the morning dose) until after the experiment. This may temporarily worsen Parkinson symptoms, but we will minimize this by only including patients with mild disease severity.

Contacts

Public

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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 according to UK brain bank criteria.
- Presence of a clear resting tremor of at least one arm (UPDRS tremor-score ><= 2).
- Mild phenotype (defined as Hoehn and Yahr stage < 3)

Exclusion criteria

- Neuropsychiatric co-morbidity
- Cognitive impairment (MMSE < 26)

Study design

Design

Study type: Observational non invasiveMasking:Open (masking not used)Control:UncontrolledPrimary purpose:Basic science

Recruitment

NL Recruitment status:

Completed

Start date (anticipated):	30-01-2019
Enrollment:	18
Туре:	Actual

Ethics review

Approved WMO	15-10-2018
Date.	15 10 2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	28-03-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
 NL66771.091.18

Study results

Date completed:	07-05-2019
Results posted:	29-04-2020

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First publication

29-04-2020