Objective home-based bradykinesia assessment in Parkinson*s disease - a pilot study

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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-OMON44312

Source
ToetsingOnline

Brief title
Objective bradykinesia

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's; Slowness of movement

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bradykinesia, Objective measurement, Parkinson's disease

Outcome measures

Primary outcome

The analyses of the usual typing behaviour will provide two outcomes: typing cadence and inconsistence in typing cadence. Discriminative function analysis will evaluate the predictive power of the free typing behaviour to distinguish between Parkinson's Disease patients, Ataxic patients and healthy controls. Correlations between 1 - typing cadence or 2 - inconsistence in typing cadence with validated assessments will be used to determine the validity of typing cadence in determining the severity of bradykinesia in akinetic patients.

Secondary outcome

This study has one secondary study parameter: the sequence effect. The sequence effect will be expressed by the sum of keys pressed by the most affected hand per each second of the test. Sequence effect in the dominant hand will also be investigated. Furthermore, sequence effect will also be calculated from the video recording. The intensity of sound will be used to calculate amplitude and frequency of movement.

Study description

Background summary

Bradykinesia is one of the cardinal symptoms of Parkinson*s disease. Objective measurements, for instance the finger tapping keyboard test, have been developed as evaluation instruments for this symptom. However, the standardized and punctual format of the keyboard test is not suitable for continuous

assessment of bradykinesia in a home environment. In addition, the averaged final score produced by these tools hampers the assessment of a specific bradykinesia fingerprint: the sequence effect.

Study objective

This project aims to determine the validity of a home-based continuous bradykinesia assessment using free typing behaviour analysis. Secondarily, we aim to capture the presence of sequence effect in Parkinson's Disease patients using a computer based test and sound analysis.

Study design

Observational descriptive study.

Study burden and risks

For Parkinson's Disease patients, the study visit will begin at an OFF status. Although this visit is expected to take less than 1:30 hours in total (with 30 minutes at OFF status), there is still a small risk of participants feeling overwhelmed or, for instance, experience a fall episode during the assessment. To diminish the risk, we have minimized the number of assessments, specially for Parkinson's Disease patients at an OFF status. In addition, to ensure safety and efficiency, the assessments will be performed by a trained and experienced physiotherapist. In any case, if the participant wishes so, the assessment can be stopped or cancelled at any time. Finally, participants anonymity is protected during the video recording by not recording any recognizable body parts, such as the face. Participants are not expected to directly benefit from the study. However, under their request, clinical and technical data collected during the study can be made available to them. Once in their possession, participants are allowed to share them with any health professional or family member if they wish so.

Contacts

Public
Selecteer

Geert Grooteplein 21
Nijmegen 6525 EZ
NL
Scientific
Selecteer

Geert Grooteplein 21
Nijmegen 6525 EZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for Parkinson's disease and Cerebellar Ataxia only: (1) confirmed idiopathic Parkinson's Disease or Cerebellar Ataxia and (2) presence of slowness of movement. Inclusion criteria for all participants are: (1) usage of a computer with a QWERTY keyboard; (2) 18 years or older at the time of the recruitment; (3) no signs of depression or cognitive impairment; (4) no untreated hearing, visual or upper limb impairment; and (5) ability to provide written informed consent.

Exclusion criteria

The exclusion criteria for healthy elderly is: self-reported history of neurologic disease. For Parkinson's disease and Cerebellar Ataxic patients exclusion criteria are: self-reported incapacitating tremor, dystonia or dyskinesia, and an irregular medication intake scheme.

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:	Recruitment stopped
Start date (anticipated):	01-08-2018
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	12-06-2018
Application type:	First submission
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	NL64042.091.17