Using video based assessments to measure Sleep Benefit in patients with 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-OMON42516

Source
ToetsingOnline

Brief title
Vision based assessment for Sleep Benefit

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinsons, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Mobility, Parkinson's Disease, Sleep benefit, Vision based assessment

Outcome measures

Primary outcome

Spatiotemporal and kinematic data (such as walking speed, joint angles, step length, arm swing etc) will be automatically extracted from the video registration. Parameters extracted have been shown to be related to PD diagnosis and disease progression. However, on forehand we do not know what parameters will give the best indication of motor function at awakeningand we will therefore apply a hypothesis-free approach.

Secondary outcome

Patient experiences with longitudinal camera observation and quality of the data gathered.

Study description

Background summary

A substantial proportion of Parkinson*s disease (PD) patients experience sleep benefit (SB); an improved mobility upon awakening, as if in the medication induced on state. However, the relationship between the subjective experience of SB and objective improvement in motor function is unclear. Because of day-to-day variation in the occurrence of SB, longitudinal assessment of SB using objective and accurate measures is highly needed

Study objective

The aim of this study is to explore whether subjectively experienced SB can be objectively assessed using computerized vision based analysis of motor performance upon awakening. Secondarily, patient experiences and data quality of the assessment method will be gathered.

Study design

A cross-sectional study with a 4 week follow-up will be performed. Patients will have a video camera, that will record from one hour before to one hour after awakening, installed in their bedroom during the 4 week follow-up period.

Study burden and risks

This study can be classified as low risk. Patients will only be asked to perform daily activities under normal circumstances. However, they will be asked to perform the activity lying on a bed to standing up and walking to the bedroom door (reference activity) a number of times in OFF medication state during the installation of the camera. This will be guided by the research team. The burden of this study consists of having a video camera placed in the bedroom. To overcome privacy issues the camera will only be recording during two hours a day (one hour before walking up until one hour after waking up). Moreover, patients will have the possibility to turn off the camera at any time, to erase recordings and to program to not record the next morning.

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 PD, diagnosed by a neurologist according to the UK Brain Bank criteria
-Hoehn &Yahr stage I-III
-Able to walk at least 10 meter independently.

Exclusion criteria

-PD Hoehn & Yahr stage IV-V
-Cognitive impairment (MMSE<24).

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-05-2016
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO Date:	12-11-2015
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	NL54504.091.15