REAL_PD

Published: 31-12-2014
Last updated: 21-04-2024

The study will be conducted in two sequential phases. In the first phase 5-7 physiotherapists and 20 subjects with Parkinson*s disease will be enrolled to test the feasibility of the study protocol to evaluate the value of ambulatory sensor...

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

Summary

ID

NL-OMON41844

Source
ToetsingOnline

Brief title
REAL_PD

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Michael J. Fox Foundation for Parkinson's Research

Intervention

Keyword: Ambulatory sensors, Feasibility study, Parkinson's disease

Outcome measures

Primary outcome

Barriers and facilitators for prolonged use of wearable sensors, as experienced by patients; feasibility of recruiting physiotherapists and patients for the study; feasibility of the clinical assessment as experienced by physiotherapists; perceived value of the role of physiotherapists as personal coaches.

Secondary outcome

not applicable

Study description

Background summary

Today*s management of patients with a chronic disorder like Parkinson*s disease (PD) is imperfect. Our understanding of clinical profiles is based on observations in small, selective populations with brief follow-up. Moreover, treatment decisions are based on averaged population results that may not apply to a specific individual context. These drawbacks will be addressed with a *big data* approach. Ambulatory sensors will be sued as an objective measure of patients* performance under everyday circumstances, for longer periods of time. We aim to explore the potential of using longitudinal ambulatory data to enrich a standardized clinical dataset, which reflects current clinical practice for the assessment of disease status.

Study objective

The study will be conducted in two sequential phases. In the first phase 5-7 physiotherapists and 20 subjects with Parkinson*s disease will be enrolled to test the feasibility of the study protocol to evaluate the value of ambulatory sensor monitoring. In the second phase, 250 physiotherapists and 1000 patients will be included. The current study protocol covers the first pilot phase only. The aims of this pilot are: (a) to test our ability to identify motivated therapists; (b) to get a feeling for the ease and speed of recruitment per therapist; (c) to test the feasibility (mainly the time needed for the

assessments) and quality of the baseline clinical assessments by the therapists; (d) to test the patients* experiences with the ambulatory devices, and to create an impression for their compliance in everyday life; and (e) to field-test the data streaming from the ambulatory devices to the Intel platform.

Study design

This is an observational study. 5-7 ParkinsonNet physiotherapists will identify 20 eligible patients from their practice. The physiotherapist first performs a standardized clinical assessment, based on the PPMI protocol (www.ppmi-info.org). This assessment will last for 60 minutes. Next, patients will be asked to wear a wrist watch that contains accelerometers, combined with a smartphone, during day and night, for 4 weeks. The sensor consists of a wrist watch (with tri-axial accelerometers). The smartphone is used to transmit data the de-identified accelerometer data to a data platform. The physiotherapist will act as a personal coach during this period.

The data platform is owned by the MJFF and managed by Intel, who developed a dedicated data analysis platform for ambulatory data. Intel will receive de-identified data only.

Patients will have a baseline PPMI assessment, 2 call from the research team to ask for the experiences with the devices (after 1 and 3 weeks), and a face-to-face meeting after 2 weeks with their therapist to discuss feasibility, possible barriers, as outcomes of the recordings. After completion of the 4-week follow-up phase patients will complete a written evaluation form about the use of the sensor and the support offered by the physiotherapist. For examining daily functioning, a self-monitoring App on the smart phone asks for answers on two simple questions: medication intake and how they are feeling in general.

Study burden and risks

First, data will be recorded 24/7, for total duration of 4 weeks. Second, data will be transmitted to a data platform developed and managed by Intel. This is an open access platform, though patients remain ownership over their own data, and remain in control in regards to which data can be shared for research purposes. They will be asked for permission to share the raw data in a de-identified form for analysis and use in future publications in the informed consent form.
Both of the above-mentioned issues can give a breach of privacy. However, the feasibility of this approach has been demonstrated by our research partners in the FP7-funded SensePark project, which demonstrated that patients are able and willing to wear multiple ambulatory devices, given they remain owner of their own data.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 4
Nijmegen 6525 GC
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 4
Nijmegen 6525 GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Dutch Parkinson patients
- Male or female
- Age 30 years or older at time of PD diagnosis
- Subjects must have at least two of the following: resting tremor, bradykinesia, rigidity (must have either resting tremor or bradykinesia); OR either asymmetric resting tremor or asymmetric bradykinesia
- Ability to provide written informed consent in accordance with Good Clinical Practice (GCP), International Conference on Harmonization (ICH), and local regulations

Exclusion criteria

- Little or no response to adequate doses of levodopa or a dopamine agonist
- Atypical PD syndromes due to either drugs (e.g., metoclopramide, flunarizine, neuroleptics) or metabolic disorders (e.g., Wilson*s disease), encephalitis, or degenerative diseases (e.g., progressive supranuclear palsy)
- A clinical diagnosis of dementia as determined by the investigator
- Any other medical or psychiatric condition or lab abnormality, which in the opinion of the investigator might preclude participation
- Previously obtained CT MRI scan is suggestive of another cause of parkinsonism, or with evidence of clinically significant other neurological disorder (in the opinion of the investigator)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-10-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	31-12-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	15-04-2015
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	NL51065.091.14