Parkinson Smartwatch Cost and Efficacy Study

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Primary Objective: to study the feasibility, effectiveness and user experience of the Parkinson smartwatch in Parkinson patients with response fluctuations (with dyskinesia).Secondary Objective(s): to study the effect on cost, by monitoring the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON48249

Source
ToetsingOnline

Brief title
Parkinson Smartwatch Study

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson disease

Research involving
Human

Sponsors and support

Primary sponsor: Parkinson Smartwatch b.v.
Source(s) of monetary or material Support: deels door zorgverzekeraar CZ;deels door Parkinson Smartwatch b.v.

Intervention

Keyword: Parkinson, Smartwatch

Outcome measures

Primary outcome

Primary: the percentage of good hours, i.e. the total time without *off* or *dyskinesia* (moderate or severe).

This covers the *middle green third* of the VAS at the smartwatch [which indicates OK, slightly off, or slight dyskinesia].

Rationale: while Parkinson Smartwatch produces data which allow improvement of the treatment plan, these same data also provide a solid image of the quality of life.

Secondary outcome

Secondary: the number of patients who had an advanced therapy within the study period; the percentage of patients with a score of 7 or higher in a 10 point VAS score about user satisfaction; the number of dropouts; the number of patients who consider an advanced therapy after the study period; cost at end versus start. The percentage of patients where the neurologist indicates the usefulness of accelerometery >6.5 on a VAS of 1 to 10. Side effects and tolerability. User satisfaction of the doctor.

Study description

Background summary

Parkinson Smartwatch is an electronic diary for management of pharmacokinetic fluctua-tions in movement disorders like Parkinson*s disease.

Levodopa is the most effective medicine for treating the symptoms of Parkinson*s disease. Because of short half-life (each pill only works for a few hours) most people take levodopa a few times a day. The timing and dosage of pills is crucial for staying OK in more advanced stages, to prevent fluctuations. If symptoms fluctuate, for example good hours alternating with either stiff and slow hours or periods with too much movement, then adjustments to the treatment schedule may help significantly.
For the optimal treatment of Parkinson*s the level of levodopa in the blood should stay within the so called therapeutic window. To manage this, a doctor needs to know when and how symptoms change during the day, so called response fluctuations.
That*s where an electronic diary like the Parkinson smartwatch can help to keep track of fluctuations. Whenever a change in condition is noticed, a patient can easily record this using the *Status Rainbow*.
Simply touching the color on the smartwatches *Rainbow* (a semicircular visual analog scale) records the (subjective, perceived) status: yellow means *off* or *bad* (slow, stiff, tremor etc.), green is *good*, and red is for involuntary movements.
The event of taking pills or eating a meal is also recorded in the electronic diary with the simple touch of an icon at the watch. (Meals can reduce gastrointestinal uptake of levodo-pa).
The information recorded at the watch is then sent to the Cloud where it is stored securely. Smart charts of the data can be viewed on a personal, private Parkinson Smartwatch webpage. The charts are designed to provide a doctor with useful information to adjust the treatment plan. The webpage is accessible from anywhere using either a computer, tablet, or mobile phone.
On a personal Parkinson Smartwatch webpage, charts comprise the data recorded on the watch.
The charts indicate when pills and meals were taken. Different colours (on the charts) show how the status changed from one hour to the next. The smartwatch is also capable of au-tomatically gauging how much someone moved, from accelerometer data, in a global sense (an RMS algorithm, comparable to a VU meter for sound volume).

Parkinson Smartwatch also helps to take medicines correctly: at individually specified times a reminder will appear on the watch with a self-chosen photo, e.g. personal medication. This will assist taking the right pills at the right time.

Study objective

Primary Objective: to study the feasibility, effectiveness and user experience of the Parkinson smartwatch in Parkinson patients with response fluctuations (with dyskinesia).

Secondary Objective(s): to study the effect on cost, by monitoring the number of patients who require advanced therapies like DBS (deep brain stimulation) or

a pump (levodopa gas-trointestinal gel or apomorphin).

Claims and intended performance to be verified:
- Parkinson Smartwatch is feasible: low dropout rate
- Parkinson Smartwatch is functioning without problems in a clinical setting, as measured by user satisfaction and an inventory of problems, wishes and suggestions
- Parkinson Smartwatch is cost-effective: the number of patients who need advanced therapies after 12 months treatment is low compared to historical data
- Parkinson Smartwatch improves quality of life

Study design

Open One-Group Pretest-Posttest Design (O1 X O2). All patients will (have the possibility to) use the Parkinson smartwatch for 12 months, in a home-setting. Questionnaire forms are presented after the first week, at 6 months, and in the last week, also to their doctor. Doctors are asked to use the data recorded on the Parkinson smartwatch to optimize pharmacotherapy.

Intervention

to use the Parkinson smartwatch for 6 months

Study burden and risks

1 Allergy for the strap or the case of the watch: Low Acceptable risk, mitigated by instructions to remove the watch in case of skin irritation or redness
2 Data validity issues: Low Acceptable risk, mitigated by instructions
3 Data integrity issues: Low Acceptable risk
4 Battery issues (empty, leakage, explosion): Low Acceptable risk
5 System availability (cloud dysfunction): Low Acceptable risk
6 Reminder dysfunction: Low Acceptable risk, mitigated by instructions

Contacts

Public
Parkinson Smartwatch b.v.

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NL
Scientific
Parkinson Smartwatch b.v.

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Zevenaar 6901 GS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Parkinson's disease with response fluctuations with dyskinesia

Exclusion criteria

dementia

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2019
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Parkinson Smartwatch
Registration:	No

Ethics review

Approved WMO Date:	04-10-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL70474.028.19