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Using a wearable smartwatch diary to improve patient's understanding of Parkinson´s disease

Submission date
07/10/2022

Recruitment status
No longer recruiting

Registration date
09/06/2023

Overall study status
Completed

Last Edited
16/12/2024

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Parkinson's disease (PD) currently has no curative or disease-slowing treatment, but many symptoms are highly responsive to dopamine replacement therapy, in particular levodopa. A problem with levodopa is that is quickly eliminated from the blood. This has no consequence early in disease when the product of levodopa, dopamine, can still be stored in the brain. However, within 3-8 years of disease the effect of levodopa becomes shorter in duration and less predictable. As a result, symptoms re-occur during the day, so-called fluctuations. Fluctuations to poor symptom relief are called "OFF". In some patients there is excessive medication effects at times resulting in involuntary movements, so-called "ON with dyskinesia". The occurrence of either of these states reduces the available time during the day with good treatment effect and is negative for quality of life and daily function. The terms for different treatment states can be difficult to understand and patients often have their own descriptions of the different symptom constellations they can experience. A correct understanding of symptom fluctuations is necessary for treatment adjustments.
The Parkinson Smartwatch system is a wrist-born diary which due to its placement is available during all time awake. Unlike traditional diaries, the patient is only asked to report change in state.
We hypothesize that using the Smartwatch diary after first learning about symptom variations, how Parkinson's drugs act in the body and how medication can be adjusted to obtain a more stable symptom relief will improve the sense of empowerment in PD patients.
Patients will be recruited at the two neurology departments.

Who can participate?
Patients with PD will be recruited at the two neurology departments.

What does the study involve?
Participation involves using an online education platform regarding Parkinson's symptom fluctuations and strategies to reduce them as well as using the Smartwatch to analyze and self-adjust medication within prescribed limits for up to 6 weeks. Participants will undergo a structured interview and fill out patient-reported outcome questionnaires as well as symptom ratings by the investigators.

What are the possible benefits and risks of participating?
Participation involves using an online education platform regarding Parkinson's symptom fluctuations and strategies to reduce them as well as using the Smartwatch to analyze and self-adjust medication within prescribed limits for up to 6 weeks. Participants will undergo a structured interview and fill out patient-reported outcome questionnaires as well as symptom rating by the investigators. Possible benefits of participating are an increased understanding of Parkinson’s disease and tools to better control and adjust medication. The potential risk is that self-adjustment of medication leads to adverse effects. This risk is limited by only using drugs that the participants have experience with and by predefining safe limits of change in medication.

Where is the study run from?
Västra Götaland Regional Council (Sweden)

When is the study starting and how long is it expected to run for?
April 2022 to January 2024

Who is funding the study?
The study is funded by ALF, the agreement between the Swedish government and the health care regions, with Prof Filip Bergquist as the Coordinating investigator

Who is the main contact?
Prof. Filip Bergquist, filip.bergquist@gu.se

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
https://www.researchweb.org/is/vgr/project/279229

Study information

Scientific Title
Prospective open interventional case-control study of the effect of using a smartwatch diary on patient empowerment in Parkinson´s disease evaluated by qualitative interviews and questionnaires

Study objectives
The use of a wrist-born digital diary, Parkinson Smartwatch improves patient empowerment in persons with Parkinson´s disease with symptom fluctuations

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/08/2022, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: 2022-03906-01

Study design
Open prospective interventional study with case-control design

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Parkinson´s disease

Interventions
Intervention includes the availability of online teaching modules to improve knowledge about symptom fluctuations and their treatments, the use of a wrist-born digital diary, Parkinson Smartwatch® and a predefined medication adjustment interval. The control group will be given a predefined medication adjustment interval, but otherwise standard care. The intervention will continue for 4-6 weeks.

Intervention Type
Mixed

Primary outcome(s)
Qualitative structured interview at 2-4 weeks of intervention will be used to evaluate the sense of empowerment in patients.

Key secondary outcome(s))

1. Patient reported symptom burden will be measured using “Patient Reported Outcomes in Parkinson’s disease” (PRO-PD) at baseline and at the last visit (4-6 weeks)
2. Patient reported disease specific health related quality of life will be measured using “Parkinson Disease Quality of life 8 Question questionnaire”, (PDQ8) at baseline and at the last visit (4-6 weeks)
3. Patient reported health related quality of life will be measured using EuroQoL Eq5D5L at baseline and at the last visit (4-6 weeks)
4. Patient reported time in ON and OFF and severity of dyskinesia and OFF-related symptoms will be measured with the “ON-OFF” - score (as reported in the MDS-UPDRS part IV) at baseline and at the last visit (4-6 weeks)
5. The patient experienced effect of education will be assessed with the “Health Education Impact Questionnaire (heiQ) at 2-4 weeks of intervention.
6. Patient´s global impression of change (PGIC) will be assessed at the last visit (4-6 weeks).

Completion date
30/01/2024

Eligibility

Key inclusion criteria
Parkinson's disease for no more than 8 years, with 4-6 doses of levodopa per day and experiencing some symptom fluctuation relieved by medication

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
14

Key exclusion criteria
Presence of dementia or other limitations that, according to the investigator, precludes participation due to inability to follow the protocol, OR not possible to adjust total daily LED by +/10% or more , as determined by the patients regular managing physician.

Date of first enrolment
17/10/2022

Date of final enrolment
15/12/2023

Locations

Countries of recruitment
Sweden

Study participating centre
Sahlgrenska University Hospital, Neurology
Blå stråket 7
Göteborg
Sweden
41345

Study participating centre
SÄS, Neurology
Brämhultsvägen 53
Borås
Sweden
50182

Sponsor information

Organisation
Västra Götaland Regional Council

ROR
https://ror.org/00a4x6777

Funder(s)

Funder type
Government

Funder Name
ALF agreement, Västra Götaland

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			16/12/2024	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes