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A pilot trial of devices monitoring symptoms of Parkinson’s disease

Submission date
19/12/2016

Recruitment status
No longer recruiting

Registration date
15/03/2017

Overall study status
Completed

Last Edited
04/03/2021

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Parkinson’s disease (PD) is a long-term medical condition which is caused by the gradual loss of nerve cells (neurons) in a part of the brain called the substantia nigra. These neurons are normally responsible for producing dopamine, a chemical messenger (neurotransmitter) which carries signals around the brain that help to coordinate movement. In people suffering from PD, these neurons gradually die over time, causing the level of dopamine in the brain to gradually fall. As the levels of dopamine become lower, the brain is unable to coordinate movement as effectively, causing many troublesome symptoms that affect their ability to move, and many other aspects of their lives, including swallowing and speaking. These symptoms fluctuate a lot making it difficult for health professionals to assess the nature of the problems of individual patients and make appropriate treatment decisions. The PD_Manager project has designed some devices that patients can wear that will continuously monitor their symptoms and provide detailed information to health professionals that may help them to identify more effective management strategies. These devices, which include an insole worn in shoes and a wristband, linked to a smart phone, have been tested on people with Parkinson's in a hospital setting. The aim of this study is to test whether people with Parkinson's living in their own homes to use and evaluate the devices and if doctors find the information obtained more useful than traditional symptom diaries.

Who can participate?
Parkinson’s disease patients and their live-in carers.

What does the study involve?
Those agreeing to participate are given an appointment to attend the hospital to meet a Parkinson’s disease specialist nurse who collects some basic information about their condition and background. Participants are then randomly allocated to one of two groups who are asked to monitor their symptoms for two weeks using either PD_Manager or by recording their symptoms in diaries. Those allocated to the PD_Manager group are given instructions on the use and maintenance of all the devices, and a phone number to call for assistance, if needed. Those allocated the diaries are also given necessary instructions on how to complete them. At the end of the two weeks, participants return to the hospital for a consultation with the Parkinson's specialist doctor. All the data gathered by the PD_Manager devices or by the symptom diary is

available to the doctor who assesses the information and implements any changes in treatment or referrals that may be indicated. The research team then asks patients, carers and doctors for their views on the PD_Manager devices and the diaries, especially how easy they are to use and how useful the information is for determining the treatment for people with Parkinson's.

What are the possible benefits and risks of participating?
Patients with PD in both groups groups will benefit from some additional monitoring of their symptoms and consultation with a specialist doctor which they would not otherwise receive. There are no risks to participants in the intervention group because the devices have previously been tested and found safe and acceptable to patients. Participants will be reimbursed for any reasonable out of pocket expenses, such as their trips to the hospital for the purposes of their research.

Where is the study run from?
1. Royal Surrey County Hospital (UK)
2. St Peter's Hospital (UK)
3. University of Ioannina (Greece)
4. IRCCS Fondazione Opsedale San Camillo (Italy)

When is the study starting and how long is it expected to run for?
August 2016 to June 2018

Who is funding the study?
European Commission (Belgium)

Who is the main contact?
1. Professor Heather Gage (scientific)
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2. Mr Morro Touray (public)
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Study website
http://www.parkinson-manager.eu/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
643706

Study information

Scientific Title
PD_Manager: mHealth platform for Parkinson’s disease management

Acronym
PD_Manager

Study objectives
PD_Manager designed devices (insole, wristband and smartphone) are a more cost-effective form of collecting such timely, reliable and accurate information from patients about their symptoms, compared to the use of traditional diaries.

Ethics approval required
Old ethics approval format

Ethics approval(s)

NHS Health Research Authority, South East Coast - Surrey Research Ethics Committee, 11/05/2017, ref: 17/LO/0574

Study design
Multi-centre non-blinded randomised controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Parkinson's Disease

Interventions
Baseline data will be collected by a specialist nurse by interview with the person with Parkinson's and the carer and through reference to the clinical records. Participants will then be randomised to receive either PD_Manager devices (the intervention) or to be in the control group (symptom diary / no PD-manager). A researcher will provide the symptom diary and give full information about how they are to be used. An appointment for the follow up visit at the end of testing (two weeks later) will be made at a time convenient for the participants.

The PD_Manager mHealth intervention comprises a smart phone, a wristband, a pair of sensor insoles and a knowledge platform. The devices are unobtrusive. Their wearability, sensitivity and reliability have already been tested previously. Data that will be captured include: motor symptoms in legs (insoles) and arms (wristband); speech quality (smartphone); emotional state, cognition, nutrition and medication adherence (apps on smartphone). The PD_Manager platform includes an education section containing videos and animations on symptoms and tips and other relevant information regarding personal care and how to cope with daily life challenges. During the 14 day trial, data from the devices and apps will be sent via a cloud medium in a secure and encrypted manner to the clinician's hospital computers. The servers where the information in the cloud platform is stored is based in the UK and operated in accordance with the data protection act. Data will also be accessible from the clinician's mobile phone.

Participants from the control group will be asked to complete a symptom diary for recording motor fluctuations and the other symptoms that are captured by the PD_Manager devices over a 14 day period.

At the end of the two week period, participants will return to the clinic for a consultation. For patients in the intervention group, the responsible clinician will review reports from the devices with relevant information and with management suggestions from the PD_Manager software. On the basis of this information, the clinician will be able to decide if modification to the patient' s management plan is required. In the control group, the clinician will be able to modify the patient's management plan according to the information captured through the symptom diaries. For both groups, the information may also give rise to referrals to other therapists such as speech and language therapist, dietician, occupational therapist and physiotherapists.

Intervention Type
Device

Primary outcome measure
Clinician:
1. Usefulness and value of information from PD_Manger versus symptom diary is measured using a purposefully designed questionnaire at a final interview with a clinician after all participants have completed the trial
2. Confidence/reliability of information is measured using a purposefully designed questionnaire at a final interview with a clinician after all participants have completed the trial
3. Acceptability and usefulness in clinical practice is measured using a purposefully designed questionnaire at a final interview with a clinician after all participants have completed the trial
4. Change in care plan is recorded by the clinician on the case report form of the person with Parkinson's at the follow-up consultation with the clinician

Secondary outcome measures
1. Acceptability of the respective components of PD_Manager / symptom diary is measured using a purposefully designed questionnaire at the final interview which will be immediately after the follow-up consultation with the clinician
2. Ease of use is measured using a purposefully designed questionnaire at the final interview which will be immediately after the follow-up consultation with the clinician
3. Comfort is measured using a purposefully designed questionnaire at the final interview which will be immediately after the follow-up consultation with the clinician

Economic Analysis:
Cost of PD Manager (technology, user training and troubleshooting, clinician time) vs symptom diary is measured using data obtained from the device manufacturers, study records and observations at the end of the study.

Overall study start date
01/08/2016

Completion date
30/06/2018

Eligibility

Key inclusion criteria
People with Parkinson's and caregivers will be recruited as dyads. The inclusion criteria for people with Parkinson's are:
1. Diagnosis of idiopathic Parkinson's disease according to the UK Brain Bank Criteria;

2. Hoehn & Yahr disease stage 3 in OFF state
3. Presence of motor fluctuations with an average of at least 2 hours of OFF state during the day;
4. Has a live-in carer who is willing to take part in the study
5. Aged 18 years and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200 (England - 20; Greece - 20; and Italy - 160)

Total final enrolment
75

Key exclusion criteria
1. Presence of severe cognitive impairment (Parkinson's Disease Dementia)
2. Co-morbidities with stroke or other brain disease
3. Absence of a caregiver living with the patient
4. No WiFi at home
5. Unable to understand English language

Date of first enrolment
17/10/2017

Date of final enrolment
31/03/2018

Locations

Countries of recruitment
England

Greece

Italy

United Kingdom

Study participating centre

Royal Surrey County Hospital
Egerton Road
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Study participating centre
St Peter's Hospital
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Sponsor type
University/education

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ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
The plans are to publish the results in relevant journals. As to which particular journal will be decided later. The results will also be presented in various conferences within and outside the European Union.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan

The current 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?
Protocol article	protocol	14/09/2018		Yes	No
Results article	results	29/06/2020	04/03/2021	Yes	No
HRA research summary			28/06/2023	No	No