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Translating digital healthcare to enhance clinical management: evaluating the effect of medication on mobility in people with Parkinson's disease

Submission date
12/02/2021

Recruitment status
No longer recruiting

Registration date
09/03/2021

Overall study status
Ongoing

Last Edited
06/02/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
COVID-19 has reinforced the need for tools for remote patient management; ultimately these tools will transform future clinical care and research. Wearable technology (e.g. body worn devices, smartwatches) has the potential to address this need.
In Parkinson's (PD), motor symptoms (e.g. balance and mobility problems) are disabling and can be improved with medication (e.g. Levodopa). Levodopa is prescribed in multiple doses over the course of a day and therefore timing is critical for alleviating symptoms. Medication response can be highly variable across people with PD leading to fluctuating symptoms over the course of the day, compromising mobility and quality of life. Adhering to a complex medication regime is hard and understanding fluctuations in response to medication is almost impossible to evaluate through clinic visits, recall and diaries.
Understanding medication adherence and its effect on motor function during everyday life would ensure effective patient management, by allowing clinicians to use this information to adapt medication regimes (dose and frequency) to provide optimal treatment.
This project aims to collect data, over a week, with a wearable multi-component "system" for remote monitoring which uses mobility data obtained from the individual to improve management and optimise treatment effects in people with PD.

Who can participate?
People with Parkinson's disease

What does the study involve?
55 people with PD will be recruited and assessed once (single visit) over a week: in addition to real-world walking data collected with a wearable monitoring device (placed on the lower back), contextual information (e.g. weather) will be captured via a smartphone and adherence to medication regimes will be collected via a smartwatch.
This study will therefore use a wearable multi-component "system" (smartphone, smartwatch and mobility monitoring wearable device) to collect real-world data to assess medication

adherence, quantify mobility outcomes and create reliable data-driven models to demonstrate that digital measures of mobility can monitor and predict response to medication.

What are the possible benefits and risks of participating?
Benefits: There will be no direct benefit to participants of this study. Participants will be making a valuable contribution to our understanding about the link between medication and mobility in Parkinson's. In the future this may aid the assessment of efficacy of medication and the development of new treatments for Parkinson's.
Risks: There are no obvious disadvantages or risks to taking part in the study.
The mobility monitoring device, smartwatch and smartphone that participants will be required to wear and use are non-invasive and have no associated risks.

Where is the study run from?
The Newcastle Upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2020 to December 2025

Who is funding the study?
1. Medical Research Council Confidence in Concept (CiC) Newcastle Award (UK)
2. Engineering and Physical Sciences Research Council (EPSRC) (UK)
3. National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Silvia Del Din, silvia.del-din@ncl.ac.uk

Study website
https://www.bam-ncl.co.uk/cic

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
295771

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 295771

Study information

Scientific Title
Confidence in Concept (CiC) - Translating digital healthcare to enhance clinical management: evaluating the effect of medication on mobility in people with Parkinson’s disease (PD)

Acronym
CiC–PD

Study objectives
Understanding medication adherence and its effect on motor function in people with Parkinson's (PD), during everyday life, would ensure effective patient management, by allowing clinicians to use this information to adapt medication regimes (dose and frequency) to provide optimal treatment.
This study aims to collect data, over a week, with a wearable multi-component “system” for remote monitoring which uses mobility data obtained from the individual to improve management and optimise treatment effects in people with PD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/05/2021, London - Westminster Research Ethics Committee (HRA RES Centre Manchester, Barlow House 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8196; westminster.rec@hra.nhs.uk), ref: 21/PR/0469

Study design
Cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)

Other

Study type(s)
Other

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 (PD)

Interventions
A total of 55 people with Parkinson's (PD) will be recruited as part of the Mobilise-D: Clinical Validation Study* (sub-study) and if necessary as an independent study.
*Mobilise-D Clinical Validation Study: IRAS Number: 289543, ISRCTN Number: 12051706, SPONSORS Number: 09672, FUNDERS Number: 820820).

Study visit
The study consists of a single visit.
1. If the participant is recruited as part of the “Mobilise-D Clinical Validation Study” visit data will be taken from the “Mobilise-D Clinical Validation Study” Baseline (T1) visit.
2. If the participant is recruited as part of the independent study, the single visit can be completed immediately after screening. If this is not completed as a single visit, the baseline must be completed a maximum of two weeks after the screening visit.

Study Assessments
Mobilise-D Clinical Validation Sub-study:
1. If the participant is recruited as part of the “Mobilise-D Clinical Validation Study”, during the baseline (T1) Digital Mobility Assessment (DMA)**, in order to assess medication adherence:
a. participants will be provided with an additional smartphone (to collect contextual information) and smartwatch (to log medication intake times) to use over a 7 day period.
b. In addition, during the 7 day period, participants will be asked to fill diary for each day indicating their “off status” (when they feel the medication is not working) and dyskinesias.
c. At the end of the DMA and medication adherence 7 day assessment, participants will be asked to complete a usability questionnaire to assess acceptability of the wearable technology (WT) system (mobility monitoring device, smartwatch and smartphone) as detailed in section Diaries and questionnaires (last paragraph "d").
**The “Mobilise-D Clinical Validation Study” DMA already consists of 7 day unsupervised monitoring of mobility. The mobility monitoring device will be attached to the participant (lower back area) by the assessor at the clinic visit, and will be worn continuously for at least seven days.

Independent study:
2. If the participant is recruited as part of the independent study, the following assessments will be performed during a 30 minute single visit.
a. Descriptive Measures (e.g. age, gender, etc.)
b. Clinical scales and measures (e.g. UPDRS, Medication regime, MOCA, etc.)
c. Digital Mobility Assessment (DMA) and medication adherence assessment:
The DMA will consist of seven days’ unsupervised monitoring of mobility.
- The mobility monitoring device will be attached to the participant (lower back area) by the assessor at the clinic visit, and will be worn continuously for at least seven days.

- We will ask participants to wear a smartwatch to monitor medication intake times and some other elements of movement.
- Participants will be also provided with a smartphone (mobile phone) to measure contextual factors (e.g. probability of being indoors or outdoors, weather conditions).
d. Diary and questionnaire
• Medication diary: during the DMA and medication adherence 7 day assessment, participants will be asked to fill diary (table) for each day indicating their “off status” (when they feel the medication is not working) and dyskinesias.
At the end of the DMA and medication adherence 7 day assessment, participants will be asked to complete a usability questionnaire to assess acceptability of the WT system (mobility monitoring device, smartwatch and smartphone).
• The Usability questionnaire (to assess the WT system (wearble device, smartwatch and smartphone)), is a 12-item measure investigating usability on a 5-point ordinal scale. The questions are simple and focus on the impact of using a WT system on participants’ comfort and the ease of use of the device.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Smartwatch, smartphone

Primary outcome measure
Measured continuously for 7 days:
1. Medication intake using smartwatch acknowledged medication intake time events
2. Real walking speed using (walking speed determined in real-world settings (Real walking speed) collected using the mobility monitoring device

Secondary outcome measures
1. Obtained from the mobility monitoring device continuously for 7 days:
1.1. Volume (e.g. step count)
1.2. Pattern and variability of walking activity
1.3. Other gait pace (e.g. step length)
1.4. Rhythm (e.g. step time)
1.5. Variability (e.g. step time variability)
1.6. Asymmetry (e.g. step time asymmetry)
2. Obtained from the smartphone continuously for 7 days:
2.1. Probability of being indoor/outdoor
2.2. Stay-points
2.3. Common paths
2.4. Weather condition

Overall study start date
06/01/2020

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Adults aged 18 years or over
2. Able to walk 4 meters independently with or without walking aids
3. Ability to consent and comply with any study-specific procedures
4. Willingness to wear the wearable device, a smartwatch and use a smartphone
5. Able to read and write in first language in the respective country
6. Patients with the clinical diagnosis of PD according to the recent criteria of the Movement Disorder Society
7. Hoehn & Yahr stage I-III
8. On stable Parkinson's disease medication doses

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
55

Total final enrolment
55

Key exclusion criteria
1. Occurrence of any of the following within 3 months prior to informed consent: myocardial infarction, hospitalization for unstable angina, stroke, coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI), implantation of a cardiac resynchronization therapy device (CRTD), active treatment for cancer or other malignant disease, uncontrolled congestive heart disease (NYHA class >3), acute psychosis or major psychiatric disorders or continued substance abuse
2. History consistent with Dementia with Lewy Bodies (DLB), atypical parkinsonian syndromes (including multiple system atrophy or progressive supranuclear palsy, diagnosed according to accepted criteria)
3. Repeated strokes or stepwise progression of symptoms, leading to a diagnosis of 'vascular parkinsonism'
4. Drug-induced Parkinsonism

Date of first enrolment
28/06/2021

Date of final enrolment
23/06/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Freeman Hospital
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Newcastle Joint Research Office
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Regent Point
Newcastle upon Tyne
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NE3 3HD
+44 (0)1912824461
Tnu-tr.sponsormanagement@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council Confidence in Concept (CiC) Newcastle award

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be disseminated via:
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Newsletter (for feedback results to participants)

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
We plan to share anonymised data (referenced only with study number) with approved collaborators both nationally and internationally (inside and outside of the EU) for scientifically sound, peer reviewed studies. Data sharing offers a more open approach that allows us to maximise the impact of the study for the health and wellbeing of the population.
This is explained in the Participants Information Sheet and participants will be able to consent or not to this.
Our data management committee, according to the following procedures, will manage data sharing:
1. Collaborators interested in accessing data from the study will send the data management committee an expression of interest, for example, using data request from.
2. The committee will then review the data request. If required, the data management committee may request changes to the proposed study by collaborators. The data management committee may then approve or reject the proposed study.
3. A data use agreement will be drafted, and once terms and conditions are agreed by all parties concerning the use and analysis of the data, the agreement will be signed by all parties.
4. As agreed by data managing committee and collaborators, and according to signed data agreement forms, anonymised data will be transferred to the collaborators.

Data will be securely transferred to collaborators. Collaborators will securely store data for a fixed duration, as stated in the signed data use agreement. Only anonymous and unidentifiable data will be sent.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Feasibility and usability of a digital health technology system	15/03/2023	15/03/2023	Yes	No

HRA research summary		28/06/2023	No	No
Protocol article	04/09/2023	05/09/2023	Yes	No
Statistical Analysis Plan	04/09/2023	05/09/2023	Yes	No
Other publications	10/07/2023	06/02/2025	Yes	No
Other publications	28/06/2024	06/02/2025	Yes	No
Other publications	28/08/2024	06/02/2025	Yes	No