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The 100 for Parkinson's Project: a new form of social action – the collection and donation of data by patients and the public - to improve treatment and self-care for Parkinson's Disease.

Submission date
08/01/2016

Recruitment status
No longer recruiting

Registration date
13/01/2016

Overall study status
Completed

Last Edited
13/05/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The rapid adoption of the Internet and smartphones is giving rise to new opportunities for supporting people to engage with their health and for using the data generated to help researchers gain new insights to improve health outcomes. The 100 for Parkinson's is a web and smartphone based project for people (with or without Parkinson's) to collect health data for 100 days each using an mobile phone app and combining this with data collected from wearable devices such as, for example, pedometers (a device for measuring body motion and counting the number of footsteps taken by the wearer) and blood glucose readers and patient reported outcomes via surveys. The information collected will help with finding new discoveries and developing improvements to care. The project aims to use digital technology to understand if and how people use self-management support as a way to take ownership of their own health.

Who can participate?
Adults (over 18), either with Parkinson's or healthy volunteers interested in taking part.

What does the study involve?
Participants download and use the uMotif for Parkinson's app on their smartphone or their tablet for 100 days. They are asked to use the app to record their symptoms and activities, medications and tasks (by setting themselves reminders and checking each off as they are completed), record a daily diary (if they wish), play a game that assesses their motor function (body movement) 2-3 times a week and also record biomedical science data such as weight, blood pressure or blood glucose. The data is sent to a secure database and some of this data is used for research. All data collected is anonymised (so no participants can be identified using this data)

What are the possible benefits and risks of participating?
Some questions might male participants uncomfortable but they can skip them if they wish.

Where is the study run from?
uMotif Ltd, London (UK)

When is the study starting and how long is it expected to run for?
January 2016 to October 2016

Who is funding the study?
National Endowment for Science Technology and the Arts (UK)

Who is the main contact?
Dr Rashmi Narayana

Study website
http://www.100forparkinsons.com/

Contact information

Type(s)
Scientific

Contact name
Dr Rashmi Narayana

Contact details
201 Borough High Street
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United Kingdom
SE11JA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v9

Study information

Scientific Title
The 100 for Parkinson’s Project: a web and smartphone based cross-sectional study on links between health self management and quality of life in Parkinson’s disease v9

Study objectives
Hypothesis and objectives:
1. Hypothesis: A significant number of people both with and without Parkinson’s will participate in the project and track their health using the self-management app and philanthropically

donate their data for academic research.
2. Objectives:
2.1. Primary objective: Engage people with and without Parkinson’s in self-managing their health using a smartphone app and to study how such a direct-to-the-public project is delivered.
2.2. Secondary objective: Quality of Life questionnaires will be administered before and after the study to determine the effect of engaged health tracking.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Liverpool School of Tropical Medicine, Liverpool, 04/01/2016, ref: 15.050RS

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Internet/virtual

Study type(s)
Other

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

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

Interventions
Participants will use their own smartphones to download and use the (free) uMotif self-management app for 100 days. This application assists people in tracking and self-managing their health to improve their quality of life.

Participants will be guided online to download the app to their Android or iPhone smartphones or tablet devices. The app primarily consists of:

1. Self- tracking interface: Using a sliding petal interface participants adjust their daily scores on 10 self-monitoring measures, on a five-point scale. Participants who have difficulty manipulating the interface due to their motor symptoms will have the option of an accessibility mode with a zoom to magnify the screen. Participants are able to review their scores and compare two to three aspects of self-tracking together. 5 measures are pre-selected for participants with and without PD (sleep quality, mood, exercise, healthy eating, stress). Participants choose the remaining 5 segments from a range of measures relating to general health and specific to Parkinson’s.

2. Reminders: A reminder system gives alerts and track medication intake and key tasks
3. Health report: An option to generate a compiled report of data entered by the patient over a certain period if they so wish to
4. Games: Games to track physical responsiveness (finger tap task)
5. Finger tap test: Participants have to tap the screen of the phone as many times as they can in a 30 second period, alternating between two circular targets. The game displays the participants' cumulative score. The app also records variation in responses.

Participants will be invited to use the app on their mobile phones and/or tablets for 100 days from the day they register to use the app. Participants will be encouraged to use the app during the study period every other day (i.e. at least 3 days a week), but are able to use the app every day if they desire. Participants will receive summary feedback based on the data they enter at 25, 50, 75 and 100 days.

Intervention Type
Device

Primary outcome measure
Engagement, which is defined by understanding how people use the app to self-manage their condition (i.e. Parkinson's) or their health (i.e. if participant doesn't have Parkinson's). Engagement will be categorised under the following:
1. Number of times any data is logged into the app in a day
2. Number of times any data logged into the app in a week
3. Type of data logged in a day and a week:
3.1. Self-tracking measure (via motif interface)
3.2. Medication reminder
3.3. Task reminder
3.4. Diary note
3.5. Playing the finger tap test
4. Data from any linked devices such as pedometers or weighing scales

Secondary outcome measures
1. The relationship between self-management data collected using the app and key health outcomes collected using standardised measures:
1.1. Quality of life (EQ-5D, PDQ- 8)
1.2. Non-motor symptoms of Parkinson's (NMS-Quest)
2. The comparability of data from games (i.e. finger tapping test) delivered through smartphones and tablets with those collected at clinics in previous studies

Participants without Parkinson's will not complete the NMS-30 or PDQ-8 questionnaires specific to Parkinson's, but both groups will capture the same quality of life questionnaire data (EQ5D).

Overall study start date
11/01/2016

Completion date
31/10/2016

Eligibility

Key inclusion criteria

1. Adults aged over 18
2. English speaking and literate i.e. can read, write, and speak in English at levels of proficiency necessary to function daily at job and/or daily living
3. Have access to a smartphone and/or tablet on a daily basis
4. Parkinson's sufferers
5. Friends and families of people with Parkinson's
6. Other interested members of the public

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20,000

Key exclusion criteria
Participants not fulfilling the eligibility criteria

Date of first enrolment
11/01/2016

Date of final enrolment
11/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
uMotif
201 Borough High Street
London
United Kingdom
SE1 1JA

Sponsor information

Organisation
uMotif Ltd

Sponsor details
201 Borough High Street
London
United Kingdom
SE1 1JA

Sponsor type
Industry

Website
https://umotif.com/

Funder(s)

Funder type
Not defined

Funder Name
National Endowment for Science Technology and the Arts

Alternative Name(s)
National Endowment for Science, Technology and the Arts, National Endowment for Science, Technology & the Arts, NESTA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Cabinet Office UK Centre for Social Action Innovation Fund

Results and Publications

Publication and dissemination plan

A Data Access Committee, will oversee access to the resulting dataset from the project. The Committee will include representation from patient groups, patients, researchers, academia and industry. The Committee will put in place a framework for access by industry and for commercial research, with the majority of any revenue generated to be channeled to R&D for patient benefit.

Researchers who use the data will be required to disseminate the results of their research as rapidly and widely as possible, subject to ethics and confidentiality considerations. They will be encouraged to discuss their research findings with other scientists and the public, and to share relevant data and materials. Users will be required to notify the 100 for Parkinson's steering group in advance of publishing such findings, to acknowledge the contribution of the resource, and to provide a copy of any published reports. In addition, researchers will be required to provide the 100 for Parkinson's steering group and Data Access Committee with a copy of the results of their research based on the resource (including any negative findings and relevant supporting data) for incorporation into the central database.

Intention to publish date

31/01/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	non-peer-reviewed results on association between non-motor symptoms and quality of life in preprint	27/05/2020	13/05/2021	No	No
Results article	quality of life results	13/11/2018	13/05/2021	Yes	No