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# To determine whether smartphone and internet assisted self-management tools can help improve medication adherence in patients with Parkinson's disease

**Submission date**
06/09/2013

**Recruitment status**
No longer recruiting

**Registration date**
05/11/2013

**Overall study status**
Completed

**Last Edited**
18/10/2018

**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
This study aims to find out how new digital technologies can improve treatment in Parkinsons disease (PD). Patients track their symptoms and adherence to medications, and use this information during appointments with their doctor. This is likely to improve adherence to medication, control of symptoms and the quality of clinical consultation. This study aims to find out the effect of using an app called the Parkinsons Tracker App.

Who can participate?
English-speaking patients diagnosed with PD, aged over 21 years, on a stable treatment regime and who have a smartphone and/or internet access can participate in this study.

What does the study involve?
Participants will be randomly allocated to one of two groups: the app group receives the app and the control group receives treatment as usual. Allocation to either group is decided by a computer-generated programme and not by the doctors. This is done to ensure that allocation to either group is done without bias. Using a control group ensures that any changes that are detected as part of the study are due to the use of the app rather than other factors. Irrespective of the group the participant is allocated to, they will be requested to complete questionnaires about their condition, general wellbeing, medicine regime and their experience of consultation with their doctors. These questionnaires take about an hour to complete and can be filled in online at home within a week after their outpatient appointment. Participants allocated to the app group will get a demonstration of the app and an invitation code. They then use the app for 16 weeks. They are encouraged to use the app at least once a day but are free to use it more than once a day. At the end of the study all participants will attend another appointment with their doctor and will be asked to fill in the same questionnaires they filled in at the start of the study. Those allocated to the app group will also be asked for permission to interview them personally to get in-depth feedback about the use of the app. This interview will last for a maximum of 45 minutes.

What are the possible benefits and risks of participating?
For those allocated to the app group there is the benefit of using the app to help manage their symptoms better with their doctors. For those allocated to the control group there may be no direct benefit to the participant but it is an opportunity to help the wider PD community by helping the research team better assess the use of digital technology in managing PD and of using the app at the end of the study. The information both groups provide will contribute to the future roll-out of the app to more people suffering from PD. All data will be kept confidential at all times. Members of the clinical team will have access to the data but will not use it to contact patients at any time during the study. They will only use it at the follow-up appointment. The research team will use the data for analysing the results. However, data will be anonymised i.e. no personal details relating to the patient or where the patient works will be recorded anywhere. We do not believe there are any risks in taking part, as use of the app will not change patients treatment plan in any way.

Where is the study run from?
The study will be run across the following NHS trusts in the UK:
1. Anne Rowling Regenerative Neurology Clinic, Edinburgh
2. Barts NHS Trust, London
3. John van Geest Centre for Brain Repair, Cambridge University Hospitals NHS Trust
4. Kings College Hospital NHS Foundation Trust
5. Newcastle upon Tyne Hospitals NHS Foundation Trust
6. St.Georges Healthcare NHS Trust, London
7. The Walton Centre NHS Foundation Trust

When is study starting and how long is it expected to run for?
It is anticipated that recruitment will start in early 2014. Participants will be enrolled in the study for a period of 4 months and will be followed up after 16 weeks.

Who is funding the study?
This study is funded by the Department of Health, UK.

Who is the main contact?
Dr Rashmi Lakshminarayana

# Contact information

### Type(s)
Scientific

### Contact name
Dr Rashmi Lakshminarayana

### Contact details
uMotif Ltd
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London
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# Additional identifiers

### Protocol serial number
N/A

# Study information

### Scientific Title
A randomised controlled trial to evaluate the impact of SMARTphone and Internet assisted self-management and adherence tools to manage Parkinsons Disease (PD): the SMART-PD trial

### Acronym
SMART-PD

### Study objectives
We hypothesise that encouraging patients to track their symptoms and medication intake regularly will result in increased medication adherence. Furthermore, we postulate that it may lead to better symptom control, quality of life (QoL) and quality of clinical consultation by using data collected by the patient.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Westminster NRES Committee, London, date of ethics meeting Nov 26th 2013, Ref no. allocated: 13/LO/1783

### Study design
Single-blind randomised controlled trial

### Primary study design
Interventional

### Study type(s)
Quality of life

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

### Interventions
For patients
A mobile app which consists of:
1. A self-tracking interface
2. A reminder system that gives alerts and helps track medication intake
3. Games to track physical and cognitive responsiveness
Web portal:
1. For patients to review and interact with their data
2. For clinicians to view patient list, patient data and pre-set reports

Randomization: Permuted block randomisation with varying block size. Randomisation code will be generated using SAS PROC PLAN.
Control: Controls will receive out-patient (OP) clinical assessments including symptom review

followed by a medication review at the start of the trial and at the end of the 16 weeks.
Follow-up: Follow-up will be at 16 weeks after download of mobile app/use of web portal.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
Adherence to medication determined by Morisky Medication Adherence Scale (MMAS-8) at 16 weeks

### Key secondary outcome(s))
1. QoL determined by the Parkinsons Disease Questionnaire-39 (PDQ-39)
2. Quality of consultation for PD patients (questions from PatientCentered Questionnaire for Parkinsons Disease [PCQPD])
3. Non Motor Symptoms Questionnaire (NMSQuest)
4. Hospital Anxiety and Depression rating scale
5. Beliefs about Medication Questionnaire (BMQ)

### Completion date
31/08/2014

## Eligibility

### Key inclusion criteria
1. Adults aged 21-75 years or over diagnosed with, or with probable, idiopathic PD
2. Prescribed one or more anti-parkinsonian medications by a consultant neurologist or consultant physician or GP with specialist knowledge of movement disorders
3. English speaking and literate i.e can read, write, and speak in English and compute and solve problems at levels of proficiency necessary to function daily at job and/or daily living
4. Has access to a smartphone and/or internet on a regular (> weekly) basis in their home
5. Stable medication regime i.e. not altered within the previous month and not expected to change during the period of the trial (16 weeks)
6. Not diagnosed with dementia or significant cognitive impairment

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Senior

### Sex
All

### Key exclusion criteria

1. Suspected Parkinsonism due to other causes than idiopathic PD
2. Treated with anti-parkinsonian medications (anti-cholinergics) for side effects of prolonged neuroleptic treatment
3. Diagnosed with dementia or significant cognitive impairment
4. Diagnosed with mental illness associated with psychosis  schizophrenia, severe depression with psychosis, bipolar affective disorder
5. Detrimental illness with a short life expectancy

### Date of first enrolment
01/01/2014

### Date of final enrolment
31/08/2014

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**uMotif Ltd**
London
United Kingdom
W1B 4BD

## Sponsor information

### Organisation
uMotif Limited (UK)

## Funder(s)

### Funder type
Government

### Funder Name
Commissioned by NHS Midlands and East (UK) and funded by the Department of Health, UK

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 09/01/2017 | | Yes | No |
| Protocol article | protocol | 25/09/2014 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |