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Parkinson's Pen Project

Submission date
10/12/2014

Recruitment status
No longer recruiting

Registration date
16/01/2015

Overall study status
Completed

Last Edited
08/06/2022

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 chronic condition where nerve cells in a small part of the brain called the substantia nigra become damaged and die. The nerve cells in this region send signals that controls the muscles of the body. Dopamine is the main neurotransmitter produced by these nerve cells. As more of these cells die, the amount of dopamine produced also falls. Over time, the lack of nerve cells and low levels of dopamine affects how well the person affected can control their muscles. The most common symptoms of the condition are slowness of movement, muscle stiffness and shaking (tremors). PD affects both the fine control of the fingers and larger movement of the upper limb. Handwriting tests are commonly performed as part of the initial assessment of people suspected of having PD and can help doctors diagnose the condition. Diagnosis of PD is normally done by a specialist, based on signs and symptoms. In more difficult cases, brain imaging (DaTSCAN) can be carried out to help with the diagnosis. However, this is expensive (approximately £1000 per scan) and can be an unpleasant experience for patients. We want to test the usefulness of a novel digital pen system (the Manus platform) to help doctors diagnose PD.

Who can participate?
Patients that have been referred to one of 5 NHS Healthcare Trusts in the North East for possible Parkinson’s disease.

What does the study involve?
Participants are asked to perform a number of simple writing and drawing tasks using the Manus platform, which includes a digital pen on a flat digital screen. The test takes about 20-30 minutes to do. The system then uses a number of automated mathematical methods to diagnose PD. The ability of the system to diagnose PD accurately is then investigated compared to current best practice diagnosis of clinical opinion or DaTSCAN.

What are the possible benefits and risks of participating?
There will be no direct benefit to patients included in the study and their subsequent care will be unaffected by their participation. However, if the trial proves successful, we envisage that, in the foreseeable future, use of the digital pen system during assessment for PD may avoid the need for DaTSCAN in some patients. The risks for a patient recruited to the study are thought to be low. They will perform a series of drawing and writing tasks for 20-30 minutes in total. Although unlikely, some patients may experience fatigue or discomfort during the tasks. Patients will be

free to stop at any point and either rest and resume the tasks or not complete the tasks and leave the study. Those who do not complete the tasks will not need to give a reason.

Where is the study run from?
Five NHS Healthcare Trusts in North East England (UK)

When is the study starting and how long is it expected to run for?
February 2014 to July 2018

Who is funding the study?
Technology Strategy Board (UK)

Who is the main contact?
Professor Richard Walker
richard.walker@nhct.nhs.uk.

Contact information

Type(s)
Scientific

Contact name
Prof Richard Walker

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Department of Medicine
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NE29 8NH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Developing a novel noninvasive aid for early diagnosis of Parkinson's disease: a feasibility study

Acronym
PPP

Study objectives
We will test a novel, user-friendly and inexpensive system to aid in the differential diagnosis of Parkinson’s disease (PD). It is hypothesized that the system can differentiate between PD patients, healthy subjects, and those with other related conditions, such as essential tremor, with a sensitivity of 90% and a specificity of 80%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES committee North East -York, 24/07/2014, ref. 14/NE/1037

Study design
Feasibility study of the clinical usefulness of an aid to diagnosis of Parkinson's disease

Primary study design
Observational

Secondary study design
Study of diagnostic accuracy

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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

Interventions
The Manus platform is a novel sensor system with automated mathematical methods, integrated with a digital pen, for differential diagnosis of PD that allows an objective assessment of handwriting. The person being assessed performs series of simple writing and drawing tasks using the pen on a flat digital screen. The assessment takes 20-30 minutes.

Intervention Type
Device

Phase
Not Specified

Primary outcome measure

It is anticipated that a sensitivity of 90% and specificity of 80% can be obtained.

Secondary outcome measures
Acceptability of the Manus Platform to users.

Overall study start date
01/02/2014

Completion date
31/07/2018

Eligibility

Key inclusion criteria
1. Patients that have been referred for possible Parkinson's disease to one of five NHS Healthcare Trusts in North East England
2. Healthy age-matched controls will be included to help assess specificity. These will be recruited from any spouses of patients who volunteer to be tested

Participant type(s)
Mixed

Age group
All

Sex
Both

Target number of participants
202

Key exclusion criteria
1. Unable to give fully informed consent for any reason
2. Unable to hold the assessment pen for any reason
3. Significant cognitive impairment based on Montreal Cognitive Assessment score
4. Presence of a pacemaker

Date of first enrolment
01/02/2015

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Gateshead Health NHS Foundation Trust
Gateshead
United Kingdom
NE9 6SX

Study participating centre
City Hospitals Sunderland NHS Foundation Trust
Sunderland
United Kingdom
SR4 7TP

Study participating centre
South Tees Hospitals NHS Foundation Trust
Northallerton
United Kingdom
DL6 1JG

Study participating centre
County Durham and Darlington NHS Foundation Trust
Darlington
United Kingdom
DL3 6HX

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details

North Tyneside General Hospital
Rake Lane
North Shields
England
United Kingdom
NE29 8NH

Sponsor type
Hospital/treatment centre

Website
https://www.northumbria.nhs.uk/

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Government

Funder Name
Innovate UK (ex Technology Strategy Board)

Results and Publications

Publication and dissemination plan
We hope that the study will results in a number of publications in academic peer-reviewed journals in the area of Parkinson's disease. In addition, within 6 months of the end of the data collection period, we will provide a detailed written report on key findings and provide feedback to study participants via a short summary report. Participants will also be invited to attend one of three feedback sessions held near their local PD clinic within 9 months of the end of data collection.

Intention to publish date
08/06/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study are not expected to be made available because the data set contains both confidential and non-confidential information.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		21/03/2014		Yes	No
Protocol article	protocol	01/05/2014		Yes	No
Abstract results	Presented at MDS Congress	12/09/2020	08/06/2022	No	No
HRA research summary			28/06/2023	No	No