

Parkinson's Pen Project

Submission date 10/12/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/06/2022	Condition category Nervous System Diseases	<input type="checkbox"/> 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

ORCID ID

<https://orcid.org/0000-0002-9597-5446>

Contact details

Department of Medicine

North Tyneside General Hospital

Rake Lane

North Shields

United Kingdom

NE29 8NH

Additional identifiers

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

Acceptability of the Manus Platform to users.

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

Healthy volunteers allowed

No

Age group

All

Sex

All

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

United Kingdom

England

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

ROR
<https://ror.org/01gfeyd95>

Funder(s)

Funder type
Government

Funder Name
Innovate UK (ex Technology Strategy Board)

Results and Publications

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?
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
Other publications		21/03/2014		Yes	No