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Examining anxiety and depressive features in people with Parkinson's disease

Submission date	Recruitment status	[ ] Prospectively registered
23/04/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/12/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/07/2024	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Approximately 40% of people with Parkinson's disease experience comorbid anxiety or depression, which are strong predictors of quality of life in Parkinson's. Little is known about how anxiety or depression develops in Parkinson's disease, and why some people with Parkinson's disease are more prone to anxiety than others. Anxiety and depression are associated with increased symptom burden; however, this is poorly understood at present. There is little evidence on effective treatments for anxiety in Parkinson's disease. The aim is to explore the aspects of emotional processing that are damaged in patients with Parkinson's disease and Anxiety.

Who can participate?

Patients at different stages of Parkinson's disease, ranging from early stages to advanced Parkinson's disease.

What does the study involve?

4 visits (screening, baseline, 6-month follow-up and 12-month follow-up. Participants will answer questions on their anxiety, and undergo assessment of movement, cognition, and computerised behavioural tasks, and an optional MRI scan.

What are the possible benefits and risks of participating?

None

Where is the study run from?

University College London (UK)

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

March 2021 to July 2024

Who is funding the study?

The research costs for the study have been supported by EU Commission grant (Horizon2020 grant 848002)

Who is the main contact?
Ms Saghi Arabi, s.arabi@ucl.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
279691

Protocol serial number
CPMS 48056, Grant Codes: 848002, IRAS 279691

Study information

Scientific Title
Anxiety and depression in Parkinson's Disease

Acronym
AND-PD

Study objectives
The key objectives are to determine the risk factors and associated clinical features of anxiety and depression in Parkinson’s Disease, and to identify the underlying biological changes associated with emotional dysfunction in Parkinson’s Disease. The eventual aim will be to identify targets to design rational therapies for therapeutic trials to improve anxiety and depression in Parkinson’s disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/03/2021, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8210; bradfordleeds.rec@hra.nhs.uk), REC ref: 21/YH/0016

Study design
Observational cross-sectional

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Anxiety and depression in Parkinson's Disease

Interventions
The study is an observational and longitudinal study. This design and methodology were chosen so that we could look at patients at different stages of Parkinson's disease; ranging from early stages to advanced Parkinson's disease. We will examine anxiety and depression in patients with PD, across disease stages, and subgroups. Healthy controls will be recruited to create an aged-matched group.

The broad timetable for the stages of research are: preparation January 2020 - December 2020, assessments January 2021-December 2022, interpreting and analyzing data - 2023, preparing the final report, and disseminating results via conference presentations/peer-reviewed scientific journals (2024).

All assessments will take place either remotely online or at the Royal Free Hospital Campus, UCL or at King's College Hospital, London. Currently, there are no planned interim analyses or reports. To compensate for any possible research effects or biases, the analyses will be performed by a researcher blind to group (single-blind).

Visit 1:
Baseline assessment will occur after enrolment in the study. Participants with Parkinson's Disease will receive a combination of self-administered and/or researcher-administered scales to assess their clinical and cognitive symptoms online. Demographic data will be collected at baseline only. Assessments will take place either online or at one of the four NHS sites. Some questionnaires and assessments can be sent to the participant to be completed before the study day.
The optional MRI scans will be carried out at Wellcome Centre for Human Neuroimaging, Queen Square, London or at the Centre for Neuroimaging Sciences, Institute of Psychiatry, Psychology & Neuroscience, London. The scans will be carried out by a radiographer and one of the researchers.

Visit 2 (last visit):
Participants with Parkinson's will receive a combination of self-administered and/or researcher-

administered scales to complete, assessing their clinical and cognitive symptoms. This will take place online or when it is safe to do so, at one either Royal Free Hospital Campus, UCL or at King's College Hospital, London.

Intervention Type
Other

Primary outcome(s)
Measured at baseline, 6 and 12 months:
1. Anxiety measured using the Parkinson Anxiety Scale (PAS)
2. Depression measured using the Patient Health Questionnaire (PHQ-9)

Key secondary outcome(s))
Measured at baseline, 6 and 12 months:
1. Anxiety and depression measured using a visual analogue scale of anxiety and mood
2. Non-motor symptoms measured using the MDS Non-Motor Rating Scale (MDS-NMS)
3. Non-motor and motor experiences of daily living and motor complications using the MDS-Unified Parkinson's Disease Rating Scale (MDS-UPDRS)
4. Activation in the ROIs measured using fMRI BOLD

Completion date
01/07/2024

Eligibility

Key inclusion criteria
1. Participants must be judged by the investigator to have capacity to understand the nature, design, and procedures of the study and must be able to provide a signed and dated informed consent in accordance with Good Clinical Practice (GCP), International Conference on Harmonization (ICH), and local regulations. All subjects must be willing and able to comply with scheduled visits, required study procedures and laboratory tests.
2. Willing and able to provide written consent
3. All participants must have adequate visual and auditory acuity according to investigator’s judgement to complete the neuropsychological testing.
4. People with PD should have confirmed diagnosis of PD according to Movement Disorder Society Clinical Diagnostic Criteria and must have at least two of the following: resting tremor, bradykinesia, rigidity (must have either resting tremor or bradykinesia); OR either asymmetric resting tremor or asymmetric bradykinesia.
5. Aged 18 - 89 years
6. Can tolerate behavioural and psychological testing
7. Score of or above 14 on the PAS

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
89 years

Sex
All

Key exclusion criteria
General exclusion criteria
1. Past/present psychotic disorder, bipolar disorder/mania or alcohol/substance use disorder (outside a comorbid psychiatric episode) that would interfere in completing assessments or impair the safety of the participant.
2. History of medical illness that may impair cognitive function (e.g. serious head injury, endocrine disorder)
3. Atypical PD syndromes due to either drugs (e.g. metoclopramide, flunarizine, neuroleptics) or metabolic disorders (e.g. Wilson's disease), encephalitis, or degenerative diseases (e.g. progressive supranuclear palsy).
4. Previously obtained MRI scan with evidence of clinically significant other neurological disorder (in the opinion of the Investigator).

MRI exclusion criteria
5. MRI contraindications such as a pacemaker, aneurysm clip, cochlear implant, neurostimulator, IUD, shrapnel, metal fragments in the eye, a weight of above 250lbs or claustrophobia.
6. There are no exclusionary medications for this study.
7. Females who are pregnant, planning pregnancy, or breastfeeding.

Date of first enrolment
01/07/2021

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
University College Hospital
235 Euston Road
Fitzrovia
London
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Study participating centre
Luton & Dunstable University Hospital
Lewsey Rd
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Study participating centre
King's College Hospital
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Study participating centre
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Study participating centre
Royal Cornwall Hospital
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TR1 3HD

Study participating centre
Gwynedd Hospital
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Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes