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Testing the feasibility of a new intervention to help people with Parkinson's live well with anxiety

Submission date
28/04/2023

Recruitment status
No longer recruiting

Registration date
04/05/2023

Overall study status
Completed

Last Edited
03/03/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background study and aims
The study research team are interested in a new way of supporting people with Parkinson's who have anxiety. The support is a new intervention called “OBtAIN-PD” and involves looking at a patient's lifestyle and what causes their anxiety. The term ‘intervention’ refers to any activity undertaken by healthcare professionals to improve a person’s health and well-being. This study is running with a small number of people to see how successful OBtAIN-PD is. The small study is called a ‘feasibility trial’. The findings of this study will be used to improve the OBtAIN-PD intervention and help the team design a larger future study.

Who can participate?
People with Parkinson's living with moderate to severe anxiety can take part in this study.

What does the study involve?
In this study, people with Parkinson’s who live with anxiety will receive either OBtAIN-PD plus usual Occupational Therapy care or usual Occupational Therapy care alone. Both interventions will be delivered by an occupational therapist working in a community rehabilitation team. OBtAIN-PD and usual Occupational Therapy care sessions will last around one hour, but this may be a little less or a little more. It is estimated that participants will take part in eight sessions over a ten-week period. If you receive OBtAIN-PD, you may receive fewer sessions than this depending on your goal. All participants will be asked to complete some outcome measures with the lead researcher at the start, halfway point, and end of the intervention period. This will include answering some questions and taking part in an activity to evaluate what functions matter to the participant and how often they do them and completing some questionnaires. They will be asked to complete a short diary form that will be emailed to them every four weeks. A sample of around 10 participants will be invited to take part in a telephone/ online interview with the researcher to find out what they thought about the study. If it turns out that the study is not practical to run, or not acceptable to participants, the study may be stopped early. In that case, any involvement may stop sooner than expected, and participants will be contacted about this.

What are the possible benefits and risks of participating?
You will contribute to the development of a new intervention and future research to help people with Parkinson's live well with anxiety. The knowledge gained from this study may help people with Parkinson's live better with anxiety. The main disadvantage would be giving up some of your time to take part in the study. This would include reading information that is sent to you, completing the study questionnaires, and participating in the treatment sessions. Should you feel upset during a treatment session with an occupational therapist, they will support you. In the event of distress outside of your treatment sessions, you will need to contact your GP.

Where is the study run from?
The University of Plymouth (UK)

When is the study starting and how long is it expected to run for?
April 2022 to May 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Mr Chris Lovegrove, Chris.Lovegrove@newcastle.ac.uk

Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
318175

Central Portfolio Management System (CPMS)
55143

Study information

Scientific Title
Evaluating the Occupation-Based Complex Intervention for living well with anxiety and Parkinson's Disease (OBtAIN-PD): a feasibility cluster randomised controlled trial

Acronym
OBtAIN-PD

Study objectives

The study's aim is to establish if a randomised controlled trial (RCT) of the OBtAIN-PD is feasible in a real-world practice setting and to inform an assessor-blinded multi-centre RCT with an embedded economic evaluation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/03/2023, North East - York Research Ethics Committee, (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8143; york.rec@hra.nhs.uk), ref: 23/NE/0027

Primary study design
Interventional

Study design
Pragmatic feasibility cluster randomized controlled trial

Study type(s)
Treatment

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

Interventions
This is a pragmatic feasibility cluster randomised controlled trial, with assessor-blinded outcome assessment, cluster randomising Community Rehabilitation Teams within two sites to implement either the OBtAIN-PD and usual occupational therapy care (intervention) or usual occupational therapy care alone (usual care).

TRIAL SETTINGS
The trial will be conducted in two NHS Trusts. LiveWell Southwest and Royal Devon University Healthcare NHS Foundation Trust. A Principal Investigator at each Trust will oversee and be responsible for research activity in their respective Trust.

Each of the two Trusts has two Community Rehabilitation Teams (CRTs), covering distinct regions within the Trusts catchment area. All CRTs will implement the protocol in the same manner, apart from the treatment they provide, depending on allocation. Occupational therapists within these teams will deliver either standard care, as part of their routine NHS role, or the OBtAIN-PD intervention in addition to standard care, depending on treatment allocation. The unit of allocation, or cluster, is therefore at the CRT level; two of the four CRTs will be allocated to the intervention group (OBtAIN-PD plus standard care), and two will be allocated to the usual care group (standard care alone).

GROUP ALLOCATION
Community Rehabilitation Teams will be allocated on a 1:1 basis to implement the OBtAIN-PD intervention + usual care, or usual occupational therapy care alone, stratified by site (geographical location – Royal Devon University Healthcare NHS Foundation Trust serving North, East, and Mid Devon, and LiveWell Southwest serving South Hams, West Devon, and Plymouth). This will provide logistical convenience and accommodate the current pressures on NHS

services, whilst providing control for contamination. Group allocation will be stratified by site. Randomisation will be undertaken by the Plymouth Clinical Trials Unit (CTU) to allow the lead researcher to remain blinded to group allocation and will occur before recruitment begins.

SAMPLE SIZE
The target sample size is 50. This sample size has been calculated to provide suitable precision to answer the study's aims and objectives.

BLINDING
The trial participants cannot be blinded in this trial due to the nature of the intervention they are receiving. Similarly, the NHS treating occupational therapists are unable to be blinded. The occupational therapists will be aware of their allocation following the randomisation of their community rehabilitation team. Participants will be aware of the treatment that they receive from their first treatment session with the occupational therapist. The recruiting clinicians (consultants, Parkinson's nurses, and CRN research nurses) will not be informed of community rehabilitation teams' group allocation. The only exception will be the clinicians in the community rehabilitation teams who will identify potential participants as part of their usual referral triage process. The OBtAIN-PD lead researcher (CL) conducting eligibility checks, screening assessments, and communicating with participants' completion of the self-reported outcome assessments, will be blinded to the participants' allocated group. Wherever possible, clinical outcomes will be taken remotely, and participants will be asked to not reveal their geographic location or the treatment they have received to preserve assessor blinding.

All outcome measures, at each time-point, are patient-reported assessments, thereby minimising the opportunity for the researcher to influence the outcome assessment. Every effort will be made throughout the trial to maintain blinding of the OBtAIN-PD lead researcher (CL), for example by reminding participants not to discuss their treatment with them. Assessor blinding will be monitored and tested by recording 'guess' participation group allocation at each time point. The blinded OBtAIN-PD researcher will be asked to record on an electronic CRF any cases of inadvertent unblinding to group allocation at the end of the trial. If this occurs, they will be asked to provide details as to how this unblinding happened.

The final unblinding of the research team (including the trial statistician) will be after the creation of a locked analysis data set and analysis has been undertaken.

RECRUITMENT
Potential participants will be provided with an information pack by the clinician who has made contact (consultant, Parkinson's nurse, community therapy team as part of referral triage, CRN research nurse). The information pack will contain an introductory letter, participant information sheet (PIS), GAD-7 for screening purposes, a reply slip (including consent to contact form), a stamped addressed envelope, and the telephone and email contact details for the lead researcher. This information can be emailed to participants also at their request. The PIS and reply slip will encourage those who do not want to take part with their reasons for non-interest. This will provide valuable information for designing the main trial. Information packs sent out will be followed up by CRN research teams one week later via telephone to encourage responses.

CONSENT
On receipt of the completed reply form and GAD-7, the OBtAIN-PD research team (CL) will telephone the potential participant to answer any questions and, following verbal consent, undertake an initial phone screen for eligibility using a pre-formatted screening checklist based on the eligibility criteria. Eligibility will be confirmed during this call. This data can be collected

directly from participants, and the core research team will not need to access patient records. All screen failures will be recorded.

Following the screening procedures, an initial online session to complete the consent and baseline procedures will be arranged at a time convenient for the participant (within normal working hours). If the participant feels that they need no extra time to consider their participation, the baseline assessments can be completed on the initial phone screen to reduce the burden on the participant's time. The OBtAIN-PD lead researcher will be responsible for ensuring informed consent has been obtained and for the collection of baseline data.

All PWPs participating in the study will be informed of the post-trial qualitative interview within the PIS, and consent will be included within the pre-baseline informed consent processes. Prior to the final trial assessment at 24 weeks, consent to participate in the interviews will be reviewed and confirmed by the lead researcher. Verbal confirmation of ongoing consent will be obtained by the lead researcher immediately prior to the interview taking place.

OUTCOME MEASURES

After consent has been completed, the baseline COPM and Activity Card Sort measures will be completed with the participant in the same session if possible. Other baseline assessments will be provided to the participant for them to complete remotely (EQ-5D-5L, PDQ-39, Barthel Index, Falls & Costs Diary). The GAD-7 completed during screening will be used as the baseline assessment unless this was completed more than days ago. In this situation, a repeat GAD-7 will be taken. The outcome measures will be repeated at 12 and 24-week time points and will be anchored to the baseline.

INTERVENTION DELIVERY

The interventions (OBtAIN-PD and usual care) will be provided by NHS occupational therapists based in the community rehabilitation teams. The NHS occupational therapists will be responsible for booking the treatment sessions following recruitment. The NHS occupational therapists must record on paper or electronic 'Therapist Contact Sheets' on completion of each session. The trial therapists do not need to be specialists in Parkinson's care. This will serve to replicate national provision, as not all areas have access to Parkinson's specialist occupational therapists.

USUAL CARE GROUP

The usual care group will receive 'treatment as usual' occupational therapy care based on that delivered in previous pragmatic trials of occupational therapy for PWPs. Descriptions will provide a selection of areas that could be targeted, and approaches used. The exact approaches used will be flexible to provide therapist autonomy and based on individual patient needs. The therapy input received by the participants will be recorded to further facilitate a definition of treatment as usual for a future study using therapist contact sheets. Usual care duration is estimated to last 60- minutes per session with an estimated eight sessions over a 10-week period (n=8) based on individual patient needs.

INTERVENTION GROUP (OBtAIN-PD)

The OBtAIN-PD will focus on re-establishing and maintaining engagement in social and habitual roles, like attending a club or engaging in a hobby that PWPs value. In contrast, traditional NHS occupational therapy interventions, that form the usual care group, tend to focus on compensatory techniques (e.g., equipment to maintain personal care), which PWPs with anxiety have identified as less of a priority. The specific issues experienced by the participant that restrict participation in their chosen meaningful occupations will be discussed and explored by the occupational therapist. Based on this discussion, an overall goal for the treatment will be

negotiated and agreed upon, with SMART goals set to work towards this. This approach is based on the concepts of Acceptance & Commitment Therapy and behavioural activation to promote engagement and adherence with the OBtAIN-PD. Participants will be provided with a copy of their goals to promote engagement and adherence. Depending on the individual's goal, they may be provided with education in the form of information sheets to help manage their condition and support engagement in the OBtAIN-PD programme.

It is estimated that OBtAIN-PD will last 30 minutes per session, with eight sessions over a 10-week period (n=8). The intervention will include additional 30 minutes of usual care i.e., 60 minutes total. The usual care component will include (but is not limited to) the ordering and provision of aids/adaptations to support participation in care and follow-up contact after delivery to ensure the safe use of the equipment. OBtAIN-PD will run alongside usual care and provide a novel means of delivering occupational therapy targeting anxiety-related issues in performance.

QUALITATIVE DATA COLLECTION
Ten purposively (using the Hoehn & Yar score) sampled participants from the trial will include five trial participants randomised to the usual care group and five participants from the intervention group. This will be run through individual one-off semi-structured interviews using an interview schedule. The interviews will be conducted at the end of the trial period at a time, date, and method (face-to-face or remote) convenient for the participant. Interviews will be recorded using a secure digital recorded or web application (Microsoft Teams) to support transcription. Once the interviews have been transcribed and anonymised using pseudonyms, the recordings will be securely deleted. Data will be analysed using thematic analysis adopting Braun and Clarke’s six-phase process of (i) data familiarisation; (ii) coding; (iii) generation of initial themes; (iv) reviewing themes; (v) defining and naming themes and (vi) writing up to identify patterns of meaning within the data sources. Initial themes will be refined by two researchers to maximise credibility and dependability.

MONITORING AND AUDIT
A trial management group (TMG) will oversee the day-to-day running of the trial. It includes representation from the sponsor, research team, South West Peninsula CRN, and PenCTU. The TMG will meet monthly with communication in between these times as required.

A trial steering committee (TSC) will provide overall supervision of the study on behalf of the Project’s Sponsor and Funder and ensure that it is conducted to rigorous standards. The TSC consists of a chair, statistician, occupational therapist, and person with Parkinson's who are all independent of the research team. There will also be two members of the research team (CL and statistician) and a sponsor representative (JM). The TSC will meet three times over the course of the trial with additional communications in between as required.

An independent patient advisory group (PAG) will support the research team with patient-relevant advice and guidance on implementing the trial and addressing any specific issues that arise. This group will meet three times over the course of the trial, with additional communication in between as needed.

Intervention Type
Behavioural

Primary outcome(s)
Self-perception of performance in everyday living measured using the Canadian Occupational Performance Measure (COPM) at baseline, 12 weeks, and 24 weeks

Key secondary outcome(s)
1. Activity participation and activity changes are measured by the Activity Card Sort at baseline, 12 weeks, and 24 weeks
2. Patient-reported outcome measures are captured at baseline, 12 weeks, and 24 weeks and include:
2.1. Anxiety symptoms measured using the GAD-7
2.2. Parkinson's-related health status and quality of life measured using the PDQ-39
2.3. Health-related quality of life measured using the EuroQol EQ-5D-5L
2.4. Falls measured using self-reporting and the resource use log

Completion date
13/05/2024

Eligibility

Key inclusion criteria
Patients must satisfy all the following criteria to be enrolled in the study:
1. PWPs: diagnosis of idiopathic Parkinson’s (47), as diagnosed by a neurologist or movement disorder consultant
2. Experiences anxiety measured as ‘moderate’ (> = 10) by the Generalised Anxiety Disorder Assessment (GAD-7) as part of the screening process
3. Willing and able to undertake eight intervention sessions over 10 weeks
4. Able to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
11

Key exclusion criteria
Patients who meet any of the following criteria will be excluded from study participation:
1. Participants unable to give informed consent
2. People who are unable to physically complete self-report forms and do not have someone to assist them
3. PWPs experiencing anxiety measured as ‘mild’ (9 or less) by the generalised Anxiety Disorder Assessment (GAD-7)
4. PWPs with a severe cognitive deficit that affects their ability to follow instructions assessed using the Montreal Cognitive Assessment (< 23) (48)
5. ‘End-of-life stage’ Parkinson’s or other potentially life-limiting condition which is likely to be

the main source for anxiety e.g., cancer, heart failure, advanced lung disease
6. PWPs currently participating in a research study testing an intervention for anxiety or receiving another clinician-delivered non-pharmacological intervention for anxiety that has started within the last six months.

Date of first enrolment
08/06/2023

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
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Barrack Road
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EX2 5DW

Study participating centre
Mount Gould Hospital
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Study participating centre
University of Plymouth
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Sponsor information

Organisation
University of Plymouth

ROR
https://ror.org/008n7pv89

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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?
Results article		22/02/2026	23/02/2026	Yes	No
Protocol article		27/04/2025	28/04/2025	Yes	No
HRA research summary			26/07/2023	No	No
Protocol file	version 1.9	24/02/2023	04/05/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes