Evaluating the occupation-based complex intervention for living well with anxiety and Parkinson's disease (OBtAIN-PD): A feasibility cluster randomised controlled trial

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Background: Anxiety is a common symptom of Parkinson's. Current interventions have inconclusive and mixed results. Occupational therapy is effective at promoting participation and is recommended in international guidelines. This cluster randomised controlled trial (RCT) tested the feasibility and fidelity of a new occupation-based complex intervention for living well with anxiety in Parkinson's (OBtAIN-PD). No such evidence-based intervention currently exists.

Objectives: To estimate the feasibility and acceptability of the OBtAIN-PD and trial procedures.

Methods: This assessor-blinded multicentre cluster feasibility RCT compared the OBtAIN-PD to usual occupational therapy. People with Parkinson's were recruited by community rehabilitation teams (i.e. clusters) in Devon, UK, between April and October 2023. Feasibility objectives were evaluated using quantitative methods and interviews with participants and clinicians. Assessor-blinded clinical outcomes (Canadian Occupational Performance Measure, Activity Card Sort) were collected at baseline, 12-, and 24-weeks to explore the preliminary effects of the OBtAIN-PD. Participant-reported outcomes were collected 4-weekly. Analysis was by intention-to-treat according to participants' cluster allocation and involved descriptive data analysis and inductive thematic analysis of the interviews. The target sample size was n=50. People with Parkinson's (n=15), care partners (n=5), and occupational therapists (n=124) contributed to the design of the study via multiple Patient and Public Involvement consultations.

Results: Each of the four clusters (two per trial arm) supported recruitment. Total recruitment was n=11 (OBtAIN-PD n=10, usual occupational therapy n=1). Analysis showed clinically important improvement in outcome measures for the OBtAIN-PD group. Qualitative interviews (8 participants, 11 occupational therapists) found the OBtAIN-PD acceptable to participants, with clinicians making suggestions to improve recruitment and intervention delivery. No adverse events associated to trial participation occurred.

Conclusion: While the OBtAIN-PD is acceptable to participants and results suggest clinically important improvements, recruitment is the biggest obstacle to a definitive trial.

BtAIN-PD

Evaluating the occupation-based complex intervention for living well with anxiety and Parkinson's disease (OBtAIN-PD) in community rehabilitation teams in the UK: a feasibility cluster randomised controlled trial

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Aim

To determine the feasibility of a cluster randomised controlled trial (RCT) design of the OBtAIN-PD in a real world setting.

Background

- Anxiety is a common symptom of Parkinson's.
- Studies of anxiolytic medications and non-pharmacological interventions to reduce anxiety are inconclusive.
- An occupation-based and participation-focused complex intervention for living well with anxiety and Parkinson's (OBtAIN-PD) was co-produced with people with Parkinson's, care partners, and occupational therapists.
- Feasibility testing was required.

Methods

- Ethical approval; REC reference 23/NE/0027.
- Study design developed with patient, carer, and healthcare professional stakeholders. Cluster RCT chosen to minimise contamination.
- Aim to recruit 50 participants across two sites in Southwest of England, UK. Two community rehabilitation teams at each site–allocated to provide OBtAIN-PD or usual occupational therapy.
- Eligibility;
  - formal Parkinson's diagnosis
  - score ≥10 on the GAD-7
  - without severe cognitive impairment not receiving end-of-life care, nor another clinician-delivered non-pharmacological anxiety intervention
- Blinded assessor, completed remotely to reduce unblinding risk and reduce participant burden.
- Electronically-delivered patient-reported and clinical outcomes to preserve blinding, increase participant and clinician convenience, & safeguard against COVID-19.
- Candidate primary outcome measures (for a future definitive trial); Canadian Occupational Performance Measure (COPM, figure 1) and Activity Card Sort (ACS3, figure 2). Follow-up at 12 and 24 weeks.
- Patient-reported outcome measures (PROMs) at base line, 12, and 24 weeks; GAD-7 (figure 3), PDQ-39, EQ-5D-5L, Barthel Index.
- Participants completed a 4-weekly log recording falls, resource use, medication details, and any other care changes.
- Process evaluation: iterative intervention optimisation, implementation, and identifying contextual factors.
- Embedded qualitative study to explore subjective experiences of OBtAIN-PD and trial design, including brief decliner interviews.
- Traffic light progression (green=go, amber=amend, red=stop) criteria to determine feasibility of and progression to a future definitive RCT. Based on feasibility outcomes: recruitment rate, intervention fidelity, retention, follow-up rates.

Figure 1: Canadian Occupational Performance Measure individual scores at each time point.

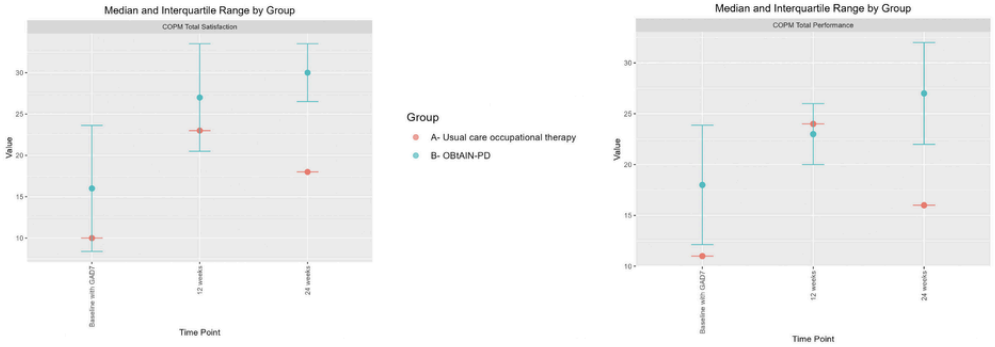


Figure 2: Activity Card Sort individual scores at each time point.

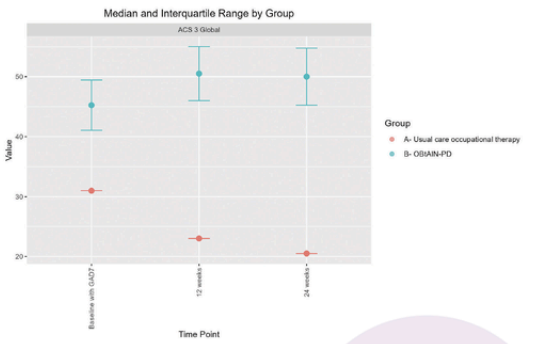
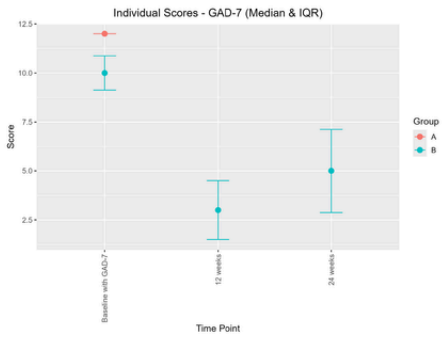


Figure 3: Generalised Anxiety Disorder questionnaire individual scores at each time point.



Results

- Under recruited (n=11).
- Usual care occupational therapy n=1.
- OBtAIN-PD n=10 (n=5 in each team).
- One team providing usual care occupational therapy did not recruit any participants.
- High data completeness for candidate primary outcomes measures at 24 weeks of 91% (n=10).
- Drop off in data completeness of PROMs from 91% (n=10) at baseline to 9% (n=1) at 24 weeks.
- Feasibility study design and low recruitment does not support data modelling or inferential statistics at this stage.
- Process evaluation
  - OBtAIN-PD; on average four sessions (range 3-6), each session lasted on average 52 minutes (range 20-90). 28 minutes of administration time per session (range 10-90).
  - Usual occupational therapy care; one 20 minute session with 10 minutes of administration time.
- Resource use
  - Delivery of OBtAIN-PD per session; £30.64
  - Delivery of usual care occupational therapy; £11.50
- No unplanned hospital admissions, GP attendance, loss of work hours, no unplanned financial expenditure.
- Interviews (n=20)
  - Participants (n=8); study procedures acceptable, lots of paperwork, no evidence of contamination, PROMs not prioritised. Positive experience of OBtAIN-PD with continued change.
  - Professionals (n=11); technical issues & unsure who to contact, recruitment issues, positive experience of OBtAIN-PD but felt didn't sit well in community given current NHS context, group setting might be better), concerned about inequity, desire to be involved in future research.
- Progression criteria based on feasibility outcomes
  - Green (GO) ; participant retention rate ≥ 80%, intervention fidelity ≥ 75%, primary outcome data completeness ≥ 80%, interview completion ≥ 75%, site willingness ≥ 75%
  - Red (STOP) ; participant recruitment feasibility ≤ 50%, overall recruitment rate ≤ 50%, monthly recruitment rate ≤ 50%
- No serious adverse events linked to trial participation.

Conclusions

- Progression criteria indicate we cannot advance to a full trial at this stage.
- Based on interview data from people with Parkinson's and occupational therapists, the trial procedures require further refinement to enable effective recruitment. To minimise the burden on community rehabilitation teams, this will likely involve engaging external research teams to support screening and recruitment processes.
- The OBtAIN-PD was well received by participants, who found it acceptable and feasible, and reported subjective benefits. However, based on healthcare professional feedback, the OBtAIN-PD content will likely require further co-development to improve its feasibility within NHS services. This may involve reconsidering its delivery as a group-based intervention and evaluating whether community rehabilitation teams represent an appropriate delivery setting, particularly in the context of the 'Ageing Well' initiative within the NHS Long Term Plan. This will be explored in a future study.
- The issues raised by the occupational therapists and healthcare professionals during the interviews warrant a secondary analysis of the qualitative data in the context of clinical research and occupational therapy in the UK.

Contact

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