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DEVELOPING AN OCCUPATION-BASED COMPLEX INTERVENTION FOR LIVING WELL WITH ANXIETY IN PARKINSON'S (OBtAIN-PD)

by

Christopher John Lovegrove

A thesis submitted to the University of Plymouth
in partial fulfilment for the degree of

DOCTOR OF PHILOSOPHY

School of Health Professions

March 2024

Acknowledgements

I will always remember the time when I worked on this PhD project as a period of intense professional and personal development. I started this PhD during the COVID-19 pandemic, which presented challenges, upheavals, and uncertainties. Nonetheless, I made it to the finish line! Collaborating with all the inspiring people who accompanied me on this transformative journey has been a privilege.

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inspiring, and ambitious environments. These have been an excellent example of how serious scientific work can be fun.

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I want to thank my mother, Julia, my father, Graham, and my sister, Amy, for their unwavering support throughout my academic journey. Completing this PhD would not have been possible without their love, care, and encouragement. I am also grateful to my friends, who provided a much-needed break from my studies and helped me balance work and leisure. To all my family and friends, thank you for standing by me through the ups and downs of this journey. Your support and faith in me have been a constant source of strength and motivation.

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I deeply appreciate all the participants who invested their time and shared their opinions and everyday experiences with me during this research.

This thesis is dedicated to my grandparents, Alan Lovegrove (1930-2020) and Peggy Bradford (1936-2020), who were unwavering and ardent in supporting my clinical academic pursuits. I wish they could have read it.

Author's Declaration

At no time during the registration for the Degree of Doctor of Philosophy has the author been registered for any other University award without prior agreement of the Doctoral College Quality Sub-Committee.

Work Submitted for this research degree at the University of Plymouth has not formed part of any other degree either at the University of Plymouth or at another establishment.

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Abstract

Lovegrove, C.

Developing an occupation-based complex intervention for living well with anxiety in Parkinson's (OBtAIN-PD)

Background: Parkinson’s is the UK's second most common neurodegenerative condition, affecting approximately 175,000 people. Current anxiolytic medications are ineffective in treating anxiety in Parkinson’s. The most promising behavioural interventions have inconclusive and mixed results. Occupational therapy is effective at promoting participation in activities of daily living and is recommended in national guidelines. An evidence-based occupational therapy intervention for living well with anxiety in Parkinson’s does not exist.

Aim: To design a new occupation-based complex intervention for living well with anxiety in Parkinson’s (OBtAIN-PD) in co-production with people with Parkinson’s (PWPs), care partners, and occupational therapists.

Methods: A scoping review, conducted in line with Joanna Briggs Institute guidance, identified what occupational therapy interventions exist for adults with anxiety and the intervention characteristics. A participatory mixed methods research study involving five stages was conducted using online Group Concept Mapping (GCM). Logic modelling was used to co-produce the OBtAIN-PD with people with Parkinson’s, carers, and occupational therapists.

Results: The scoping review included 18 studies and identified eight interventions and 31 different outcomes of current occupational therapy interventions for adults living with anxiety. Eighty-three participants took part in the GCM study. Cluster map, pattern match, and 'go-zone' charts were created using multivariate statistical analysis based on their responses. The final map contained 119 statements with eight clusters (stress value 0.252): exercise, lifestyle changes, self-help, coping, access to information, professional help, peers and groups, support from others. Significant agreement existed between the importance and feasibility rating activities (r = -0.07). ‘Go-zone’ charts highlighted the priority statements for intervention development. Thirty-two people participated in logic modelling to co-produce the OBtAIN-PD, informed by the findings of previous studies. Resources to support the new intervention (‘Inputs’) include adequate resourcing, education for professionals and people with Parkinson’s, flexibility of delivery methods, and goal setting. The intervention's actions to produce outcomes (‘Processes’) should include 1:1 support, lifestyle management, providing meaningful information, collaborative goal setting, therapeutic use of everyday activities, and involvement of friends and families. The intended outcomes should include anxiety symptom reduction, increased engagement in meaningful activities, improved understanding of anxiety and PD, better clinical outcomes, and enhanced service level outcomes. The resulting intervention manual, educational material, and training video were reviewed by five occupational therapists for content and comprehension.

Conclusion: The scoping review emphasises the necessity of using occupational therapy outcome measures, appropriate impairment-based measures, and economic evaluations for future interventions and research focused on evaluating the clinical and cost-effectiveness of occupational therapy services for individuals with anxiety. The development of the OBtAIN-PD was informed by a Group Concept Mapping study, which identified priority components. The OBtAIN-PD was co-produced with people with Parkinson’s, care partners, and occupational therapists using a logic modelling process. A protocol for a feasibility cluster randomized controlled trial is presented.

Preface

The work presented henceforth was conducted as part of an NIHR Clinical Doctoral Research Fellowship (NIHR301565). This doctoral research thesis adopts a hybrid monograph and article-compilation structure.

Chapters 1, 5, 7, and 8 are monographs authored by Chris Lovegrove.

Chapter 2 consists of a scoping review protocol (published in JMIR Research Protocols) and a scoping review (in review with JMIR Aging at the time of submission).

Chapter 3 presents an article detailing a group concept mapping study published in the Journal of Parkinson's Disease.

Chapter 4 presents an article detailing the logic modelling study used to co-produce the OBtAIN-PD study in peer review with BMJ Open at the time of submission.

Chapter 6 presents an article on the feasibility cluster randomised controlled trial in peer review with BMJ Open at the time of submission.

Chris Lovegrove was the lead author and investigator for the above articles and was responsible for all major areas of concept formation, data collection and analysis, and manuscript composition.

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List of Abbreviations

- 5-HT: Serotonin
- αSyn: Alpha-synuclein
- A&E: Accident and emergency
- ACS-3: Activity Card Sort
- ADIS-IV: Anxiety Disorders Interview Schedule
- AEs: Adverse events
- APRG: Applied Parkinson’s Research Group
- AR: Applied relaxation
- BAI: Beck Anxiety Inventory
- BDI-II: Beck’s Depression Inventory
- BLA: Basolateral amygdala
- BMA: Basomedial amygdala
- BNST: Bed nucleus of the stria terminalis
- BR: Breathing retraining
- CA3: Cornu ammonis 3
- CBT: Cognitive behavioural therapy
- CeA: Central amygdala
- CINAHL: Cumulative Index to Nursing and Allied Health Literature
- CoA: Cortical amygdala
- COPD: Chronic obstructive pulmonary disease
- COPM: Canadian Occupational Performance Measure

- CONSORT: Consolidated Standards of Reporting Trials
- COVID-19: Coronavirus disease 2019
- CReDECI: Criteria for reporting the development and evaluation of complex interventions in healthcare
- CRTs: Community Rehabilitation Teams
- CS: Conditioned stimulus
- CSQ: Client Satisfaction Questionnaire
- DALYs: disability-adjusted life years
- DASS: Depression Anxiety Stress Scale
- DAT: Dopamine transporter
- DSM-5-TR: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision
- EQ-5D: EuroQol-5D
- EQ-VAS: EuroQol visual analogue scale
- FOG: Freezing of gait
- GABA: Gamma-aminobutyric acid
- GAD: Generalised anxiety disorder
- GAD-7: Generalised Anxiety Disorder assessment
- GCM: Group concept mapping
- GHQ-28: General Health Questionnaire-28
- GP: General practitioner
- Haq-II: Health assessment questionnaire
- hd-EEG: High-density electroencephalography
- IAPT: Improving Access to Psychological Therapies
- ICERs: Incremental cost-effectiveness ratios
- ICF: International Classification of Functioning, Disability, and Health
- iRBD: Idiopathic rapid eye movement sleep behaviour disorder
- ISRCTN: International Standard Randomised Controlled Trial Number
- JBI: Joanna Briggs Institute
- JMIR: Journal of Medical Internet Research
- MADRS-S: Montgomery-Åsberg Depression Rating Scale- Self report
- MANSA: Manchester Short Assessment of Quality of Life

- MBIs: Mindfulness-based interventions
- MClinRes: Masters in Clinical Research
- MeA: Medial amygdala
- MEDLINE: Medical Literature Analysis and Retrieval System Online
- MRC: Medical Research Council
- MRI: Magnetic resonance imaging
- NAc: Nucleus accumbens
- NE: Norepinephrine
- NGT: Nominal Group Testing
- NICE: National Institute for Health and Care Excellence
- NIHR: National Institute of Health and Care Research
- NHS: National Health Service
- NMAHP: Nursing, midwifery, and allied health professionals
- NMS: Non-motor symptoms
- OBtAIN-PD: Occupation-based intervention for living well with anxiety in Parkinson’s
- Oval-pd: Occupational value assessment with predefined items
- PaG: Periaqueductal gray
- PAG: Patient Advisory Group
- PANAS: Positive and Negative Affect Schedule
- PDQ-39: Parkinson’s Disease Questionnaire
- PenCTU: Peninsula Clinical Trials Unit
- PenPRIG: Peninsula Parkinson’s Research Interest Group
- PET: Positron emission tomography
- PD: Parkinson’s disease
- PFC: Prefrontal cortex
- PIEL: Participation in Everyday Life
- PLOS: Public Library of Science
- PMS: Pearson Mastery Scale
- PPI: Patient & public involvement
- PPIE: Patient & public involvement and engagement
- PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

- PRISMA-P: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols
- PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping review
- PSP: Progressive Supranuclear Palsy
- PSS: Perceived Stress Scale
- PWPs: People with Parkinson's
- OBQ: Occupational Balance Questionnaire
- QALYs: Quality-adjusted life years
- QCRI: Qatar Computing Research Institute
- REC: Research Ethics Committee
- RCT: Randomised controlled trial
- ReDO®: Redesigning Daily Occupations®
- RTT: Referral to treat
- SAEs: Serious adverse events
- SCL-90-r: Symptom Checklist-90-revised
- SDO: Satisfaction with Daily Occupations
- SF-36: 36-item Short Form Survey
- SERT: Serotonin transporter
- SOC: Sense of Coherence Scale
- SPIRIT: Standard Protocol Items: Recommendations for Intervention Trials
- SSMH: Specialist section mental health
- SSNP: Specialist section neurological practice
- STAI: State-Trait Anxiety Inventory
- SYNERGY: Stroke and Neurological Rehabilitation Research Group
- SUMARI: System for the Unified Management, Assessment and Review of Information
- TIDieR: Template for Intervention Description and Replication
- TMG: Trial management group
- TRIP: Turning research into practice
- TSC: Trial steering committee
- TTM®: Tree Theme Method®

- UCS: Unconditioned stimulus
- UK: United Kingdom
- US: United States
- USD: United States dollar
- VTA: Ventral tegmental area
- WEIS-SR: Work Environment Impact Scale- Self Rating
- WHO: World Health Organization
- WHODAS 2.0: World Health Organization Disability Assessment Schedule
- WRS: Work Readiness Scale
- WSAS: Work and Social Adjustment Scale
- YOPD: Young-onset Parkinson’s disease

Chapter 1: Introduction

Parkinson’s disease, increasingly known as Parkinson’s, is the second most common neurodegenerative condition behind Alzheimer’s type dementia (de Lau & Breteler, 2006). Around 10 million people live with Parkinson’s globally (Ben-Shlomo et al., 2024; Dorsey, Elbaz, et al., 2018). In the UK, this number is estimated to be 153, 000, likely to increase to 172,000 by 2030 (Parkinson's UK, 2018). The cardinal motor symptoms of Parkinson’s include tremors, motor automaticity reduction (loss of automatic movement), bradykinesia (slowed movement), rigidity, and postural instability (Kalia & Lang, 2015). Parkinson’s also results in fatigue and sensory, autonomic, cognitive, and behavioural impairments that cause significant disability and impede participation in everyday roles and activities (Barone et al., 2009; Batzu et al., 2024; Benharoch & Wiseman, 2004), leading to reductions in quality of life (Duncan et al., 2014). These problems are collectively known as non-motor symptoms (NMS). Around 98% of people with Parkinson’s experience NMS (Barone et al., 2009). Anxiety is a NMS that affects approximately 40-56% of people with Parkinson’s (Pontone & Mills, 2021). Reviews indicate no effective pharmacological interventions to reduce anxiety in people with Parkinson’s (Pontone & Mills, 2021). Psychological interventions for anxiety in non-Parkinsonian populations are recommended by NICE guidelines and the NHS Talking Therapies for Anxiety and Depression programme, formerly known as the Improving Access to Psychological Therapies (IAPT) programme in the UK (National Collaborating Centre for Mental Health, 2018; NICE, 2011). The NHS Talking Therapies and IAPTs programmes were developed to improve the access and delivery of cost-effective, evidence-based psychological therapies with long-term financial and health benefits (Heuzenroeder et al., 2004). However, evidence for the effectiveness of mindfulness and cognitive behavioural therapy approaches is limited and inconclusive in people with Parkinson’s (Biundo et al., 2016; Hofmann et al., 2010; Johnsen & Friborg, 2015; McLean et al., 2017). Given the shortage of clinical psychologists in the UK, additional approaches are necessary (The King’s Fund, 2015).

Individuals with Parkinson's disease have expressed a need for an intervention that helps them live well with the complex experience of anxiety (Lovegrove et al., 2017). This intervention should focus on "doing" or participating in meaningful activities as both a means and a goal of the intervention rather than solely discussing thoughts and feelings (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017). With dual training in physical and mental health and expertise in improving wellbeing through participation, occupational therapists are in an ideal position to support people with Parkinson’s experiencing anxiety (Christine, 1990).

This thesis reports on the development and co-production of an occupation-based complex intervention for living well with anxiety in Parkinson’s (OBtAIN-PD) using the Medical Research Council (MRC) framework for developing and evaluating complex interventions (Skivington et al., 2021). This work is important because of the need to find a way to best support people with Parkinson’s to live well with anxiety using a novel intervention for this population. That is, it does not attempt to take an established intervention (such as cognitive behavioural therapy) and make it ‘fit’ people with Parkinson’s. Instead, it involves people with Parkinson’s in co-producing the intervention from the ground up, founded on their experiences and what they feel that they need to live well with anxiety. Care partners and occupational therapists similarly provide their input. The infographic in Figure 1.1 summarises all participants in this research programme. The OBtAIN-PD contributes to original practice by using multiple systematic methodologies to co-produce a new intervention for living well with anxiety in Parkinson's, delivered by occupational therapists in community settings and utilising lifestyle management, motivational interviewing, and behavioural activation concepts. This thesis reports on the development phase of the MRC framework (Skivington et al., 2021). The thesis concludes with a protocol for a feasibility cluster randomised controlled trial (RCT). Ultimately, this work will lead to said feasibility RCT, which will provide the necessary operational experience and preparatory data to inform the design and implementation of a definitive RCT to test the clinical and cost-effectiveness of the OBtAIN-PD should it demonstrate promise as an intervention. The feasibility RCT will address the feasibility phase of the PRC framework (Skivington et al., 2021)

This chapter will present the context of the researcher's position. It will then present the sequelae of anxiety in Parkinson's. An overview of the neurobiology of Parkinson's anxiety will be given, along with an explanation of the personal and societal impacts. Anxiety in Parkinson's is thought to be common due to the dopamine deficiency that is characteristic of the condition. This chapter also describes the limitations of current interventions and justifies a novel approach to living well with anxiety and Parkinson's. An explanation and justification for using an occupation-based approach is provided. Finally, the thesis structure is presented.

Figure 1.1: Summary of participants and stakeholders in this research project.

Language use in this thesis

The term "Parkinson's disease" is used globally. There is an increasing movement to drop the word 'disease' (which has connotations of contagion and infectiousness) and refer to the condition simply as "Parkinson's". This is in keeping with the wishes of people living with Parkinson's. As a result, the condition will be referred to as Parkinson's throughout this thesis without abbreviation. Similarly, the terms "people with Parkinson's" and "care partners" will not be shortened, aligning with the social model of disability (Lawson & Beckett, 2021). Exceptions to these rules will occur in the chapters presenting peer-reviewed articles. In these articles, more traditional terminology and abbreviations are used in keeping with the respective journal's scope and word count. People with Parkinson's and care partners acting as Patient & Public Involvement and Engagement (PPIE) stakeholders have deemed the terminology in these articles acceptable, as getting research findings published is a priority for them. Further, these articles will use either UK or US English, depending on the journal's specific guidelines. This will be highlighted in the introductory text to each article chapter. Figures, tables, and boxes in these articles will be sequentially ordered as they appear in this thesis for ease of reading.

1.1 Researcher's background

This section provides a context to the researcher's position on the research topic.

My journey as an occupational therapist began 17 years ago when I started an undergraduate degree in Occupational Therapy. After graduating, I worked in supported housing for homeless young people before achieving my first professional goal: starting a junior rotation in the NHS. During this time, I discovered that neurology was my clinical passion, which I fortunately had an affinity for. What followed was gaining a specialist split role working in stroke rehabilitation and inpatient subacute neurorehabilitation. As my career progressed, I was fortunate to become a team lead occupational therapist on an acute neuromedical ward in 2012.

It was at this time that I started to work routinely with people with Parkinson's and their care partners. Despite being medically optimised and on the best pharmacological treatment, they remained in the hospital, unable to mobilise and struggling to engage in rehabilitation programmes. I started to work with this group to develop an inpatient Parkinson's Therapy Pathway (Lovegrove & Marsden, 2020). Rapidly, it became apparent that many of the people I was working with were highly anxious. This resulted in substantially prolonged hospital admissions for these people by exacerbating primary symptoms such as postural instability. One of these people described their experience as follows (anonymised):

"It's awful! I can't breathe; I can't move I feel like I'm going to fall over. I feel like I'm going to die!" Neil

I did not know how to support this person best, so I asked my senior colleagues for advice. They were similarly uncertain and allowed me some time to work with the Exeter Health Library to review the literature. With support from the information specialists, it became clear that there was no "gold standard" treatment to help people with Parkinson's affected by anxiety. At the same time, I managed to spend some time with a clinical health psychologist who came to visit Neil on the ward. They explained that, at that time, treatments were limited for this population. Anxiety was perceived as a part of Parkinson's that people had to live with. My internal response was *'absolutely not'*. Remembering Neil's words, I made my first steps towards making a difference.

After a couple of years of being unsure how to get started, I gained a place on an NIHR-funded Masters in Clinical Research (MClinRes) degree at the University of Plymouth. Professor Katrina Bannigan supervised my project, and I am incredibly fortunate that she agreed to be on my PhD supervisory team. The degree course gave me the foundational research skills to challenge the existing evidence base and current treatments to improve care for people with Parkinson’s. Coming from my background as an occupational therapist, I realised that there was an opportunity to work with people with Parkinson’s living with anxiety to tailor an intervention to their needs based on their lived experience. This project resulted in two peer-reviewed publications (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017). These publications provide the foundation for the research programme outlined in this thesis.

A desire to progress my research towards realisation (a new intervention to help people with Parkinson’s to live well with anxiety), as well as my knowledge and skills in clinical research, prompted me to seek supervision from experts in the field. From my MClinRes, I was privileged to work closely with my now Director of Studies, Professor Jon Marsden, a UK expert in neurorehabilitation and Parkinson’s. I travelled to Nijmegen, Netherlands, to meet Dr Ingrid Sturkenboom using funding won from a successful grant application to the Royal College of Physicians Edinburgh (being the first NMAHP candidate awarded the Lindsay Bequest and Reid research grant). A recognised world expert in occupational therapy for people with Parkinson’s, I was privileged that Dr Sturkenboom joined my supervisory team to support my project and development. The invaluable support of my supervisors and colleagues at the Peninsula Clinical Trials Unit (PenCTU) resulted in my being awarded an NIHR Clinical Doctoral Research Fellowship (NIHR301565) in 2021.

I am fortunate to have been invited to join several research groups. These are the Participation In Everyday Life researcher group (PIEL, University of Plymouth), Applied Parkinson’s Research Group (APRG, University of Plymouth), Rehabilitation (University of Plymouth), and the Stroke and Neurological Rehabilitation Research Group (SYNERGY, Glasgow Caledonian University). These multidisciplinary collaborations of academic and clinical members aim to generate evidence and translate the results from published research to influence and inform everyday clinical practice, focusing on the problems faced by people living with various long-term conditions, including Parkinson's.

These associations have inspired and motivated me to focus on improving the lives of people with Parkinson's living with anxiety.

1.2 Anxiety and Parkinson's

1.2.1 What is Parkinson's?

Parkinson's is a progressive neurodegenerative condition with unknown cause and no cure, resulting from the loss of dopamine-containing cells of the substantia nigra that results in a movement disorder with motor and non-motor symptoms (Emamzadeh & Surguchov, 2018; Jankovic & Tan, 2020; NICE, 2022). It affects dopaminergic and non-dopaminergic brain regions and does not become clinically apparent until at least 50% of dopaminergic cell activity has been lost (Dujardin & Sgambato, 2020; NICE, 2022). This definition will be used throughout this thesis. Environmental and genetic factors increase the risk of developing Parkinson's, with prevalence at 0.3% in industrialised countries and 1% in people above the age of 60 (Cherian & Divya, 2020; Islam et al., 2021; Lee & Gilbert, 2016). It is the second most common neurodegenerative condition after Alzheimer's type dementia and is expected to double in the next ten years (Dorsey et al., 2007; G.B.D. Neurology Collaborators, 2019).

Parkinson's presents complex motor and non-motor symptoms (Bloem et al., 2021) (Table 1.1). Diagnosis is based on asymmetrical bradykinesia, rigidity, and/or resting tremor (Rawat & Pandey, 2022). Postural instability is an advanced-stage cardinal symptom (Jankovic &

Tan, 2020). Early postural instability and poor response to medication may indicate a different diagnosis (Tolosa et al., 2021). Parkinson's is diagnosed when motor symptoms appear, but a premotor phase with NMS features is likely (Kumaresan & Khan, 2021). Parkinson's has no cure yet, and treatments only partially relieve symptoms, which may have side effects (LeWitt & Chaudhuri, 2020). People with Parkinson's must manage the condition and its debilitating symptoms.

	Presentation
Motor Symptoms	Bradykinesia, 4-6 Hz resting tremor, rigidity and postural instability. Impaired balance early in the disease is a contra-indication. Impaired gait pattern (e.g. shuffling gait, freezing), reduced voluntary movement control, postural abnormalities, hypomimia (facial masking), dysarthria, dysphagia.
Non-motor Symptoms	Higher cognitive dysfunction (e.g. executive dysfunction, mental rigidity), dementia, personality change, visuospatial perceptual disorder, apathy, depression, anxiety. Sleep disorders including REM sleep behaviour disorder, insomnia, excessive daytime sleepiness. Sensory problems can include visual dysfunction, proprioceptive dysfunction, pain, impaired smell). Autonomic symptoms include constipation, nocturia, and sexual dysfunction. Fatigue (may be related to both motor and NMS).

Table 1.1: Parkinson's symptoms. The number and severity of symptoms vary between individuals and increase with disease progression. Symptom severity may fluctuate throughout the day depending on medication response.

The International Classification of Functioning, Disability, and Health (ICF) can describe Parkinson's disease's impact on people living with it (World Health Organization, 2001) (Figure 1.2). Parkinson's disease affects people in different ways depending on their body structure and functions, activities, participation, and contextual factors. Coping with the disease in daily life is influenced by personal, physical, social, and environmental factors (Hultqvist et al., 2020). As Parkinson's progresses, people often face more difficulties performing everyday activities and participating in meaningful occupations (Haahr et al., 2021; Read et al., 2022; Rosengren et al., 2021).

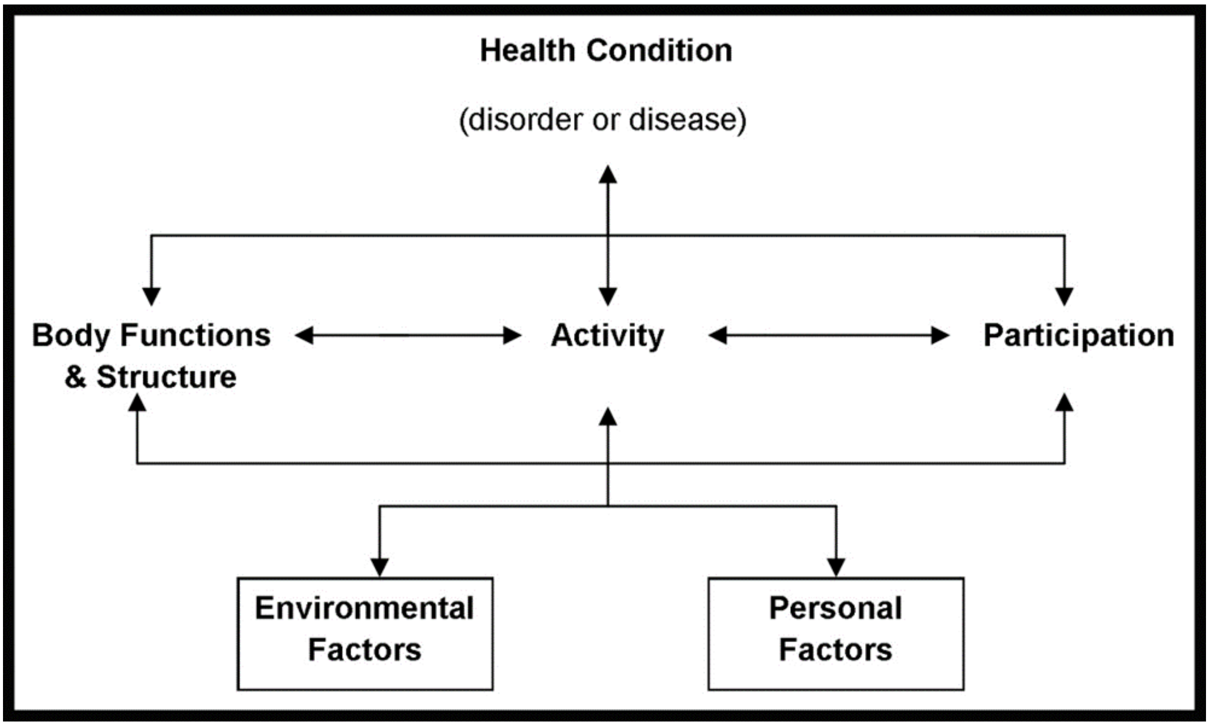


Figure 1.2: International Classification of Functioning, Disability and Health (World Health Organization, 2001)

Body function is impaired by Parkinson's symptoms and can also be affected by medication side effects, inactivity, falls or maladaptive coping (Pontone et al., 2023) (Table 1.1). Co-morbid conditions and ageing contribute to further impairments (Carroll et al., 2024). High cognitive load for complex daily activities hinders motor performance (Nodehi et al., 2021) and executive dysfunction impedes task planning and organisation (Lin et al., 2023). Other NMS, such as visuospatial difficulties and anxiety, also affect daily activities and exacerbate symptoms like tremors and freezing of gait (Chagas et al., 2017; Fernández-Baizán et al., 2022; Ghielen et al., 2020). Environmental restrictions like narrow spaces, crowds or darkness worsen freezing of gait (Nieto-Escamez et al., 2023). Parkinson's can force people to adjust their daily activities due to difficulties and embarrassment (Angulo et al., 2019). As the condition progresses, spontaneous social engagement decreases and paid employment is often stopped earlier than planned (Ahn et al., 2022; Koerts et al., 2016; Read et al., 2022).

1.2.2 What is Anxiety?

Anxiety is a normal, temporary emotional and physical response to stress that can be beneficial in some situations, such as increasing attention or focusing on a work task (Muskin, 2023). Anxiety disorders are not just temporary feelings of anxiousness or nervousness. They involve intense feelings of anxiety or fear that cause clinically significant distress or impairment in daily activities (*Diagnostic and statistical manual of mental disorders : DSM-5™*, 2013; Muskin, 2023). These definitions are used throughout this thesis.

Anxiety is a response to the unknown, while fear is a reaction to a known danger (Steimer, 2002). In normal physiological conditions, both fear and anxiety serve the purpose of anticipating, responding to, and adapting to danger and threats (Steimer, 2002). Increased arousal, expectancy, autonomic and neuroendocrine activation, and specific behaviour patterns are characteristics of both. Although fear and anxiety may appear very similar, it is important to note that they are two separate and distinguishable phenomena. From an evolutionary perspective, fear is a term used to describe the emotions and responses that people experience when the threat is immediate or imminent. In contrast, anxiety is used to describe the emotions people experience when the source of harm is uncertain or distant in space or time (LeDoux & Pine, 2016). Anxiety disorders are a group of psychiatric disorders characterised by feelings of worry, anxiety or fear that interfere with daily activities (Penninx et al., 2021). Anxiety disorders include separation, selective mutism, specific phobia, social anxiety disorder, and generalised anxiety disorder (Penninx et al., 2021). The prevalence of anxiety disorders in the general population, evidenced in the literature, has varied dramatically between 1980 and 2022, ranging from as low as 2.4% to as high as 31% (Baxter et al., 2013; Dettmann et al., 2022). It was reported by the World Health Organization (WHO) that in 2019, around 301 million people were suffering from anxiety disorders, including 58 million children and adolescents. As per the WHO, anxiety disorders are more prevalent among females, with 4.6% compared to 2.6% in males globally, as of 2015.

Fear is a universal biological response shared by humans and animals (LeDoux, 1998). Pavlovian fear conditioning is commonly used to study fear acquisition and its behavioural and neural mechanisms (Shechner et al., 2014). This is a form of associative memory formation where a conditioned stimulus (CS), such as an auditory tone, is paired with an aversive unconditioned stimulus (UCS), such as a foot shock. As a result, the CS forms a memory that triggers freezing, a behavioural response indicating fear. Fear extinction is a process where repeated exposure to fear-related stimuli lessens defensive reactions without harm (Whittle et al., 2021). This way fear conditioning and fear extinction, a process requiring active involvement of cortical areas, interact with each other and influence behaviour (Shechner et al., 2014). Anxiety disorders cause people to focus on fear-inducing information excessively. This can lead to a detailed processing of such information, which can further worsen their anxiety symptoms (Bystritsky et al., 2013). Generalised anxiety disorders are characterised by excessive and unrealistic worry, while panic attacks are defined by repeated episodes of fear in the absence of a fear stimulus.

Previous research suggests that fear is regulated by a distributed neuronal network spanning brain-wide projection pathways and localised neural connections (Tovote et al., 2015). The amygdala, hippocampus, and cortical regions play a critical role in fear and anxiety responses in the limbic system. People living with anxiety have been found to experience volume reductions in the hippocampus and amygdala regions of the brain (van Mierlo et al., 2015; Vriend et al., 2016). The amygdala is a central brain region responsible for processing emotions, particularly fear and anxiety. This is evidenced by studies investigating animal fear circuits (Han et al., 1997; Lang et al., 2000; LeDoux & Pine, 2016; Zelikowsky et al., 2014). Functional imaging studies have reported amygdala activation during fear conditioning and extinction in humans (Agren et al., 2012; LaBar et al., 1998). The amygdala is a complex structure made up of multiple substructures. These substructures work together to process emotions and include the basolateral amygdala (BLA), the basomedial amygdala (BMA), the central amygdala (CeA), the medial amygdala (MeA), and the cortical amygdala (CoA). The BLA and CoA are crucial in processing anxiety and fear(Beyeler & Dabrowska, 2020; Janak & Tye, 2015). It is known that imminent danger activates the BLA, which, through connections to the CeA, triggers defensive behavioural and physiological reactions that are part of the fear response, such as freezing (Kopchia et al., 1992). It is important to note that the microcircuits present within the CeA play a crucial role in the active process of fear extinction (Whittle et al., 2021). The hippocampal circuitry plays a role in fear, anxiety, and memory (Çalışkan & Stork, 2019; Engin et al., 2016; Sanders et al., 2003). Suppressing principal neurons in the dentate gyrus and cornu ammonis 3 (CA3) hippocampus regions reduces anxiety (Engin et al., 2016). Additionally, the direct projection from the ventral hippocampus to the medial prefrontal cortex is required for anxiety-related behaviours (Padilla-Coreano et al., 2016). It has been demonstrated that various regions of both the cortex and subcortex play a role in contributing to this circuitry (Alvarez et al., 2008; Gilmartin et al., 2014; Gogolla, 2017; Myers-Schulz & Koenigs, 2012; Rozeske et al., 2015; Shin & Liberzon, 2010). Among these, the prefrontal cortex (PFC) is crucial in regulating fear behaviour and the extinction of established fear memories (Gilmartin et al., 2014). The PFC plays a role in forming emotional memories with complex context (Gilmartin et al., 2014). Various brain regions contribute to fear and anxiety behavioural responses, including the nucleus accumbens (NAc), the bed nucleus of stria terminalis (BNST), the periaqueductal gray (PAG), brainstem and thalamic nuclei, the superior colliculus, and the pulvinar (Kim et al., 2013; Penzo et al., 2015; Ray et al., 2020; Ren & Tao, 2020). These brain regions are involved in behaviours such as avoidance and increased orientation to and processing potentially adverse stimuli. As highlighted below these circuits are affected in Parkinson’s, leading to a higher risk of anxiety compared to people without Parkinson’s.

The metacognitive model of general psychopathology proposes that a person's thinking style is a generic causal factor (Wells, 1999, 2011). The process largely consists of perseveration through worry or rumination and arises from metacognition. Metacognition involves monitoring, regulating, and evaluating thinking processes (Flavell, 1979). Metacognitive processes involve knowledge, beliefs, mental regulation, and judgments. It influences and regulates the selection and execution of appraisals, attention, and memory (particularly recall) (Lebuda & Benedek, 2023).

The metacognitive model of generalised anxiety disorder (GAD) describes basic psychological factors and processes that are thought to underlie most types of anxiety disorder (Wells, 1995). The model is shown in Figure 1.3.

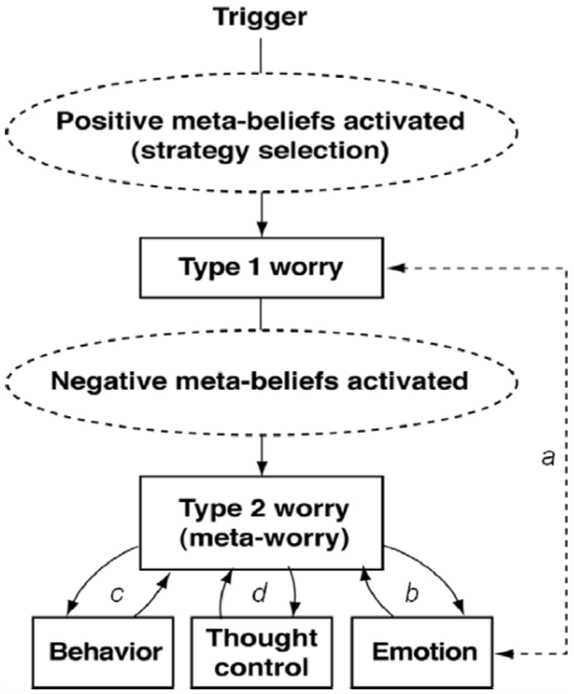


Figure 1.3: The metacognitive model of GAD with feedback labels added. Adapted from Bond and Dryden (2002).

A person with GAD worries in response to negative thoughts to anticipate problems, avoid them, or find solutions. This type of worry about oneself and the surrounding world is known as 'Type 1 worry'. Worrying can be an unconscious way of coping with stress, and it is associated with having positive beliefs about one's thinking process (positive metacognitive beliefs). Using the example, positive metacognitive beliefs could be:

"If I worry about harm in the future, I will be able to avoid it".

"Thinking about bad things that could happen means I will be prepared".

"Worrying helps me to cope".

It is common for people to experience occasional episodes of worry. The metacognitive model suggests that relying too much on worrying or being inflexible in response to negative thoughts may harm emotional self-regulation. Therefore, excessive worrying can contribute to a non-specific vulnerability to emotional symptoms. Regular (Type 1) worrying is not sufficient to cause GAD.

Generalised anxiety disorder develops from negative beliefs about worrying that can form from exposure to information or interpretations of internal events. For example, an individual may re-evaluate their tendency to worry about things after learning from a magazine that anxiety and stress could be harmful to the body and should be controlled. Negative beliefs can cause one to view worrying as uncontrollable and dangerous, leading to a negative appraisal of the situation. These negative appraisals or interpretations are called 'meta-worry' or type-2 worry.

Type-2 worrying can intensify anxiety by making the perceived threat appear more immediate. It can cause the person to feel more anxious and stressed about the situation, making it harder to cope. Negative beliefs about worrying erode confidence in coping and safety. Examples of negative metacognitions could be:

"I have no control over my worry."

"Worrying will cause me to have a mental breakdown."

"Worry can cause a heart attack."

Two factors that contribute to maintaining the problem are coping behaviours and thought control strategies. People living with GAD vacillate or have conflicting motivations to engage in worry or avoid/control the activity, preferring not to trigger worrying by trying to suppress initial thoughts concerned with worry-topics. This approach is seldom wholly effective and adds to the tendency to perseverate on a particular topic (Wegner et al., 1987; York et al., 1987). The failure of this approach reinforces the idea that our thoughts are beyond our control, thus leading to negative beliefs about our ability to regulate them. When effective, suppression prevents the person from determining that it is possible not to worry in response to a negative thought. When a person with GAD experiences an uncontrollable thought, they do not interrupt or stop the worrying process. This creates a metacognitive paradox in mental regulation, as increased thinking is used to reduce thinking. This failure to disengage from excessive, prolonged thinking deprives the person experiencing GAD of the opportunity to correct their misconceptions about the uncontrollability of worry.

In addition to patterns of thought control, overt behaviours contribute to problem maintenance (Conner & Norman, 2017). Efforts to prevent worrying often involve seeking reassurance or avoiding triggers. The issue with seeking reassurance is that it surrenders control of worrying to others, preventing individuals from realising their internal control. In certain situations, people may adopt an 'information search' approach as a strategy, trying to find facts that will ‘put their mind at rest.’ However, they often encounter negative information or generate further questions, triggering more worry (Rachman, 2012). In each instance, the person fails to employ the most suitable or efficient metacognitive control strategy (Wells, 2010). This is because people lack knowledge of alternative strategies and hold positive beliefs about the need to engage in sustained worrying, which is inconsistent with the concept of ‘letting thoughts go’. The model includes various feedback loops that function as maintenance mechanisms. These are labelled (a-d) in Figure 1.3. The way these loops function is as follows:

a) Type 1 worrying can increase anxiety as it heightens threat awareness. However, anxiety can decrease as worry generates ways to cope. Changes in anxiety and other emotional states may indicate the success of worrying and the need for sustained or reduced thinking.

b) Anxiety symptoms reinforce "worry about worry" (Type 2 worry) because the person negatively interprets symptoms of worry as a sign of mental or physical harm. In turn, Type 2 worry can increase the sense of current threat, leading to greater anxiety and sometimes even panic attacks.

c) Behaviours such as avoiding triggering situations, using alcohol, or seeking reassurance prevent individuals from discovering they have control over their worry and that it is harmless. Negative beliefs that support type 2 worry continue to persist.

d) Suppressing thoughts that trigger worry can backfire and worsen anxiety. Type 2 worries (negative appraisals) and beliefs concerning uncontrollability are both sustained. When strategies c and d limit worry, they prevent people from discovering that worrying is harmless, leading to the maintenance of negative beliefs about its possible danger.

In summary, the complexity of anxiety in neuroscience and psychology has been demonstrated. Negative metacognition has been shown to have a relationship with pathological worry.

1.2.3 Anxiety in Parkinson's

There are a range of NMS of Parkinson's. These can be classified as cognitive, neuropsychiatric, gastrointestinal, sleep-related and autonomic (Chaudhuri et al., 2005). Neurotransmitters of the dopaminergic, glutamatergic, cholinergic, serotonergic, and adrenergic systems are involved in causing these symptoms (Lim et al., 2009; Willis et al., 2012). These systems are impaired by the abnormal accumulation of alpha-synuclein aggregates within neurons (αSyn, a protein that regulates synaptic vesicle trafficking and neurotransmitter release), which causes neuronal damage (Alafuzoff & Hartikainen, 2017). Anxiety is a NMS that affects around 40-56% of people with Parkinson’s (Pontone & Mills, 2021). People with Parkinson’s are more likely to experience anxiety than the general population and those living with other neurological conditions, such as epilepsy and multiple sclerosis (Broen et al., 2016; Hanna & Cronin-Golomb, 2012). This suggests that the neurobiology of Parkinson’s is a key driver for increasing the risk of anxiety for this group. People with Parkinson's frequently experience anxiety associated with the time pressure of performing activities (Wressle et al., 2007). People with Parkinson’s are more likely to fall due to fear of falling, which is influenced by anxiety, compared to age-matched controls (Dissanayaka et al., 2014; Farombi et al., 2016).

Parkinson's-associated anxiety is related to changes in the structure of the amygdala and dysfunction of various neuronal types, resulting in an imbalance between excitation and inhibition (Flores-Cuadrado et al., 2017; Floresco & Tse, 2007; Torres et al., 2021). Post-mortem brains of people with Parkinson's show reduced amygdala volume and neuronal cell loss, which is associated with anxiety (Harding et al., 2002). In a recent functional imaging study of 110 people with early-stage Parkinson's, a smaller volume of the left amygdala was found to be associated with symptoms of anxiety (Vriend et al., 2016). The results of these studies align with earlier findings in individuals with anxiety but not Parkinson's (Flores-Cuadrado et al., 2015; Hayano et al., 2009; Milham et al., 2005; van Mierlo et al., 2015). It is interesting to note that people with idiopathic rapid eye movement sleep behaviour disorder (iRBD), which often leads to the development of Parkinson’s, have been found to exhibit reduced gray matter volume in the left amygdala area extending to the hippocampus. This is particularly true for people with iRBD who also have anxiety and not for healthy individuals or those with iRBD without anxiety (Bourgouin et al., 2019). This study showed that structural changes in limbic brain regions, such as the amygdala and hippocampus, are correlated with anxiety prior to the onset of Parkinson's. Importantly, people with Parkinson's have been observed to exhibit αSyn pathology in the amygdala (Flores-Cuadrado et al., 2017). This may represent the structural correlates of anxiety and contribute significantly to the pathophysiological mechanisms that drive anxiety in Parkinson's.

As well as abnormal amygdala size, activity, and connectivity, other neurodegenerative changes associated with different neurotransmitter systems (e.g. dopamine and serotonin) may be linked to anxiety in Parkinson's (Criaud et al., 2021). Dopamine reduction in the caudate putamen is a hallmark of Parkinson's and accounts for the cardinal motor symptoms. However, dysregulation of the dopaminergic system is also linked to NMS of Parkinson's. The exact impact of dopamine on the development of anxiety in Parkinson's is not well comprehended. Striatal dopamine transporter (DAT) reduction is associated with anxiety in people with Parkinson's (Erro et al., 2012; Weintraub et al., 2005). In experimental models, dopaminergic projections from the ventral tegmental area (VTA) to the BA (part of the amygdala) modulate fear and anxiety, potentially implicating the VTA in Parkinson's (Brandão & Coimbra, 2019; de Oliveira et al., 2011; Tang et al., 2020). Dopamine also modulates the inhibitory mechanisms that the medial prefrontal cortex exerts on the anxiogenic output of the amygdala, a brain structure involved in anxiety (Pontone & Mills, 2021; Zarrindast & Khakpai, 2015). Dopamine deficiency thus leads to neuronal hyper-excitability and amplified responses to perceived adverse threats (Hofmann et al., 2012; Kano et al., 2011; Kienast et al., 2008).

Disturbances in the serotonergic and cholinergic systems may also be involved in the NMS of Parkinson's (Ballanger et al., 2012; Maillet et al., 2016; Reisine et al., 1977). Serotonin (5-HT) is highly expressed in the amygdala and other limbic regions (Bocchio et al., 2016). People in the early stages of Parkinson's have been observed to have changes in their serotonergic system (Maillet et al., 2016). For example, significant alterations were observed in the putamen's cholinergic and serotonin receptors during post-mortem analysis (Reisine et al., 1977). Genetic variants in the promoter regions of the serotonin transporter (SERT) gene were identified, and people with Parkinson's who possess the short allele of the SERT promoter had a significantly higher score on anxiety measures (Menza et al., 1999). Further, people with Parkinson's who experience higher levels of anxiety have lower thalamic serotonin levels in positron emission tomography (PET) studies and people with Parkinson's may have lower levels of serotonin in their brains (Chen & Marsh, 2014). This suggests that serotonergic degeneration may contribute to anxiety symptoms in Parkinson's patients (Joling et al., 2018). Finally, alterations of gamma-aminobutyric acid (GABA) and norepinephrine (NE) systems have also been implicated in anxiety development in Parkinson’s (Simuni & Fernandez, 2013).

Neuroimaging analyses in recent years have identified structural and functional changes to interlinked functional networks within the brain that are associated with anxiety related to Parkinson's (Carey et al., 2021; Carey et al., 2020). Functional magnetic resonance imaging (MRI) studies have identified neuronal connectivity changes in multiple brain regions, such as decreased limbic-dorsolateral prefrontal cortex connectivity (Dan et al., 2017). People with Parkinson’s living with more impaired neuropsychiatric profiles show reduced functional connectivity in limbic cortico-striatal circuits and increased functional connectivity (the measure of how brain regions interact with one another) between the cerebellum and occipitotemporal regions (Tinaz et al., 2021). Magnetic resonance imaging studies of people in the early stages of Parkinson's also reveal a correlation between decreased structural covariance of left striatal seeds and contralateral caudate nucleus and increased severity of anxiety (Oosterwijk et al., 2018). In people with drug-naive Parkinson’s, such abnormal intrinsic connectivity between large-scale networks may represent a neural correlate of anxiety symptoms even without cognitive impairment (De Micco et al., 2021).

In summary, structural, neurochemical and functional activation alterations in large-scale brain networks, including the interconnected amygdala, hippocampus, caudate nucleus, anterior cingulate cortex and prefrontal cortex, are believed to underlie anxiety development in Parkinson's (Betrouni et al., 2022; Criaud et al., 2021; Vriend et al., 2016; Wang et al., 2021; Zhang et al., 2023).

To conclude, anxiety in people with Parkinson’s has traditionally been associated with the loss of quality of life and debilitating motor symptoms caused by the condition. However, it is now recognised as a NMS, especially in the early stages. This is due to the pathology in cortico-limbic systems and the corresponding neuro-circuitries and transmitter systems described above. In early disease pathogenesis, fear and anxiety may also be a pathological driver, causing αSyn upregulation in limbic regions or neuronal over-excitation. Further, living with Parkinson's, an incurable neurodegenerative condition, results in a combination of psychological stressors and physiological effects on the brain's neurotransmitter function and structure. As a result, individuals with Parkinson's have a higher risk of anxiety.

1.2.5 The cost of anxiety in Parkinson’s

Nonmotor symptoms are common and impact quality of life but are typically less well recognised and addressed by health professionals (Chaudhuri & Schapira, 2009; LeWitt & Chaudhuri, 2020; Shulman et al., 2002; Todorova et al., 2014). A ranked list of research priorities by people with direct and personal experience of Parkinson’s identified ‘effective stress and anxiety management’ as the second greatest research priority (Deane et al., 2014).

Anxiety substantially impacts a person with Parkinson's ability to fully engage in their desired daily activities (Duncan et al., 2014). The neurobiological and psychological stresses related to anxiety decrease energy and motivation for daily activity (Johansson et al., 2012). Poor functioning can persist after even partial recovery from anxiety due to the long-term impact of psychosocial impairment (Rodriguez et al., 2005). The impact of anxiety disorders on everyday life for people with Parkinson's is highlighted in their personal stories:

> *"Well I sort of, sweaty. And I feel, I feel I go starey. A bit like a rabbit in the headlights. Sometimes. And I just feel that I'm there but I'm not part of what's going on. I feel like I'm an outsider looking in, an observer of a situation rather than being part of it. . ."* (Lovegrove & Bannigan, 2021) page 8

Anxiety in Parkinson’s can have profound deleterious impacts on the person’s lifestyle and identity:

“It ruins a lot of things because I can look forward to something and then get there and it’s so awful, I have to leave […] it limits what I can do.” (Blundell et al., 2023) page 5

“You can’t help it and then it leaves you feeling as a man, are these things going to be haunting you forever more. Then you can have performance anxiety because of the Parkinson’s and not sleep right. Then you’ve got the business of how does your wife feel about that. You’ve got the problem of being able to walk with her and hold her hand or be able to lay your hand across her body or something without the hand shaking. And, it-it’s really unpleasant and that causes anxiety, definitely. Definitely. You just wish you could, you just wish you could go to sleep and wake up and you’re ok.” (Lovegrove & Bannigan, 2021) page 13

People with Parkinson's often describe anxiety as a constant and unpredictable presence that affects their daily lives, according to multiple research studies:

“It’s there in the background all of the time, and I was always fearful of it reoccurring, it was a very painful experience having anxiety to the extent that I did. It was, it was just an awful.” (Lovegrove et al., 2017) page 498

“And that’s an anxiety which is, it is always there but I would say up to now it’s background. Background noise. I can see depending on the way the condition goes I could be more and more anxious about me and those around me.” (Lovegrove & Bannigan, 2021) page 10

"I just feel it will always be with me." (Blundell et al., 2023) page 4

In the UK, households affected by Parkinson's lose, on average, £16,582 annually due to higher health and social care costs and reduced income (Parkinson's UK, 2017). There is a paucity of research highlighting the economic cost of anxiety in Parkinson's specifically. Estimates suggest that the average cost of admission to an acute hospital for a person with Parkinson's with anxiety is over £5,000 with an average length of stay of 10 days (HSJ Parkinson's UK Excellence Network, no date). In comparison, a person without Parkinson's receiving the lowest level of care and investigation at accident and emergency (A&E) costs £86 (The King's Fund, 2023). The cost of a more complex A&E admission starts at £418 (The King's Fund, 2023). The average length of inpatient hospital stay in the UK is six days (OECD, no date).

Living with anxiety and Parkinson's exacts a profound toll, both personally and economically. The weight of anxiety that comes with Parkinson's can drastically reduce quality of life and impede joy. Whilst scant evidence exists, the economic cost of anxiety in Parkinson's cannot be underestimated. Increased health and social care system utilisation creates an imposing financial burden and places strain on people with Parkinson's and their families. Moreover, the indirect costs, such as diminished work productivity and missed opportunities, further underscore the societal impact of these conditions. Reflecting on the intersection of anxiety and Parkinson's, it becomes increasingly evident that a holistic approach is imperative and a new intervention is warranted.

1.3 Current interventions

Anxiety is a highly prevalent NMS in Parkinson’s (Lintel et al., 2021). The recognition and treatment of anxiety in Parkinson’s can be complex due to diagnostic criteria overlapping with other Parkinson’s symptoms (Ho et al., 2021). The evidence for pharmacological treatments for anxiety in Parkinson’s is limited (Pontone & Mills, 2021). In non-Parkinson populations, several non-pharmacological interventions may be used to manage anxiety successfully (Parker et al., 2021). These interventions include psychological approaches such as cognitive behavioural therapy (CBT) and mindfulness, as well as biofeedback approaches such as applied relaxation (AR) or breathing retraining (BR). The effectiveness of these interventions in Parkinson’s is limited but rapidly emerging (Pontone & Mills, 2021). This section aims to provide an overview of some of these interventions and how they relate to anxiety in Parkinson’s.

Based on reviews, it appears that there are currently no pharmacological interventions that are effective in reducing anxiety among people with Parkinson's (Pontone & Mills, 2021). There is no specific medication for treating anxiety in people with Parkinson's. Benzodiazepines, GABA agonists commonly used as anxiolytics, may cause sedation, cognitive impairment, and increase the risk of falls. Buspirone is a partial serotonin (5-HT) agonist that is used in anxiety disorders. However, Buspirone can worsen motor symptoms in people with Parkinson's (Prediger et al., 2012).

In populations without Parkinson's, psychological treatments for anxiety recommended by NICE guidelines and the NHS Talking Therapies programmes (previously known as Improving Access to Psychological Therapies, or IAPTs) are cost-effective and provide long-term financial and health benefits (Heuzenroeder et al., 2004; National Collaborating Centre for

Mental Health, 2018; NICE, 2011). IAPT services vary across the UK due to a shortage of clinical psychologists (Clark, 2018; The King’s Fund, 2015). The NICE guidelines recommend mindfulness-based cognitive therapies and cognitive behavioural therapy (CBT) for anxiety as part of the IAPT program (National Collaborating Centre for Mental Health, 2018; NICE, 2011). The evidence base for using psychological therapy to help people with Parkinson's manage anxiety is limited. It has been suggested that theoretical models and interventions for anxiety should be expanded to address issues specific to people with Parkinson’s (Egan et al., 2015). In 2015, Egan et al. developed an augmented Cognitive Behavioural model for anxiety and depression in Parkinson's disease. This augmented CBT model is part of similar models in clinical neuropsychology and older peoples’ psychology (Broomfield et al., 2011; Gracey et al., 2016; Kishita & Laidlaw, 2017). The augmented model incorporates well-established predisposing and maintaining factors of anxiety and depression using CBT techniques. These factors include core beliefs (Beck, 2020), rumination (Ehring & Watkins, 2008), hypervigilance relating to physical symptoms (Clark, 1986), counterproductive behaviours (Salkovskis et al., 1999) and avoidance (Farchione et al., 2012). However, the approach is adapted to incorporate specific components of Parkinson's, including categories related to cognition, illness beliefs, and cohort beliefs about disability. The long-term sustainability of quality improvements following CBT has been questioned (Johnsen & Friborg, 2015). This is particularly relevant for people with Parkinson’s as cognitive impairment is a common NMS and may mean that the long-term effects of CBT for this group are reduced (Biundo et al., 2017; Biundo et al., 2016). People with Parkinson’s express a desire for interventions that address everyday problems rather than psychological therapy (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017). Stakeholders also reiterated this as part of this project's patient and public involvement and engagement (PPIE) consultation.

Mindfulness is the psychological process of bringing one’s attention to present experiences compassionately and non-judgmentally and has been incorporated into psychological therapies (Willekens et al., 2018). In a meta-analysis of mindfulness-based training for anxiety (not related to Parkinson’s), an average effect size of 0.67 (95%CI [0.47, 0.87]) in favour of mindfulness was found across 39 studies (n=1,570). In their meta-analysis, Hofmann et al. (2010) identified mindfulness as a promising intervention for treating anxiety. More recent studies suggest that mindfulness techniques may have overall positive effects on Parkinson’s with the the strongest results seen in anxiety and depression symptoms (van der Heide, Speckens, et al., 2021). Mindfulness interventions are also considered feasible and acceptable by people with Parkinson’s (Bogosian et al., 2022). Potential mechanisms underlying mindfulness are unclear but may include reducing neurodegeneration and enhancing cerebral mechanisms (Goltz et al., 2024; van der Heide, Meinders, et al., 2021). These results, though not definitive, suggest mindfulness as a promising anxiety intervention.

Applied relaxation (AR) focuses on relaxing the muscles in a particular way during situations that usually cause anxiety (Ost & Breitholtz, 2000). Hayes-Skelton et al. (2013) identify AR as a preferred and effective intervention for anxiety in the general population and recommend directions for future research. Methodological flaws reduce the robustness and reliability of their conclusions. For example, there is no description of the search process; thus, no transparency or rationale regarding study selection is provided. Hayes-Skelton et al. (2013) clearly state their bias towards AR in the introduction and conclusion yet fail to address this inherent bias in the methodology. Due to the identified issues, the findings have limited credibility and cannot be transferred to people with Parkinson’s. Likewise, a search of multiple databases yielded no results on AR's use and efficacy with people with Parkinson's.

Currently, there is insufficient evidence to support the use of AR as an effective treatment for anxiety in individuals with Parkinson's disease.

Breathing retraining (BR) focuses on gaining control over breathing to slow a person’s respiration rate and reduce physiological anxiety (Tweeddale et al., 1994). Breathing retraining has been suggested as an option to manage and reduce anxiety in people with GAD and can be delivered by various professionals with training (Tolin et al., 2020). A search of multiple databases as part of this PhD project yielded numerous results for BR’s use and efficacy with respiratory conditions such as chronic obstructive pulmonary disease (COPD) but no results for BR in people with Parkinson's. There is currently not enough evidence to support the effectiveness of BR as a treatment for anxiety in people with Parkinson's.

To summarise, psychological interventions recommended by the UK's NICE guidelines and NHS Talking Therapies (previously known as IAPTs) for non-Parkinsonian anxiety are cost-effective and offer long-term benefits for health and finances (Heuzenroeder et al., 2004; National Collaborating Centre for Mental Health, 2018; NICE, 2011). There is emerging evidence on the effectiveness of mindfulness and cognitive behavioural therapy approaches in people with Parkinson's (Biundo et al., 2016; Hofmann et al., 2010; Johnsen & Friborg, 2015; McLean et al., 2017). This section has identified a lack of credible evidence for the use of AR or BR in managing anxiety in Parkinson’s. Previous research has highlighted that people with Parkinson’s living with anxiety place less value on group work (the typical format for many anxiety treatments), with more importance being placed on participation in meaningful roles and activities (Lovegrove et al., 2017). Additional approaches are also warranted, given the shortage of clinical psychologists in the UK (The King’s Fund, 2015) and the central role of restricted participation in contributing to increased chronic anxiety

(Coventry et al., 2014; CSDH, 2008). Complex interventions, commonly used in health and social care services and other public health and economic policy areas where there are health consequences, could offer promising avenues for addressing these challenges.

1.4 Complex intervention development

Complex interventions are implemented and assessed across various individual and societal levels. An intervention could be classified as complex due to its various associated factors. These factors may include the number of components involved, the range of behaviours targeted, the expertise and skills needed by those delivering and receiving the intervention, the number of groups, settings, or levels targeted, or the level of flexibility of the intervention or its components. The Medical Research Council (MRC) have published a framework that outlines the process of developing, evaluating, and implementing complex interventions (Medical Research Council, 2008; Skivington et al., 2021). The framework comprises four main stages: development, feasibility/piloting, evaluation, and implementation. There are interactions between the phases that are not necessarily sequential, and each stage is not completely independent (Medical Research Council, 2008). Although the MRC framework is a well-cited and flexible approach to intervention development, other more prescriptive approaches are available. For example, there is a classification system for approaches to intervention development that identifies eight different categories of approach (O'Cathain et al., 2019). Alternative approaches to developing complex interventions are available, but the choice of approach should depend on the developer's context, needs, and values (Moore et al., 2019b; O'Cathain et al., 2019). Occupational therapy typically involves complexities not present in drug or medical trials (Nelson & Mathiowetz, 2004).

The aim of this thesis was considered with the guidance to ensure the application of the most appropriate research methods. This process involves identifying relevant existing evidence through a systematic review (Medical Research Council, 2008; Skivington et al., 2021). Figure 1.5 shows how the OBtAIN-PD research project relates to the MRC framework for developing complex interventions.

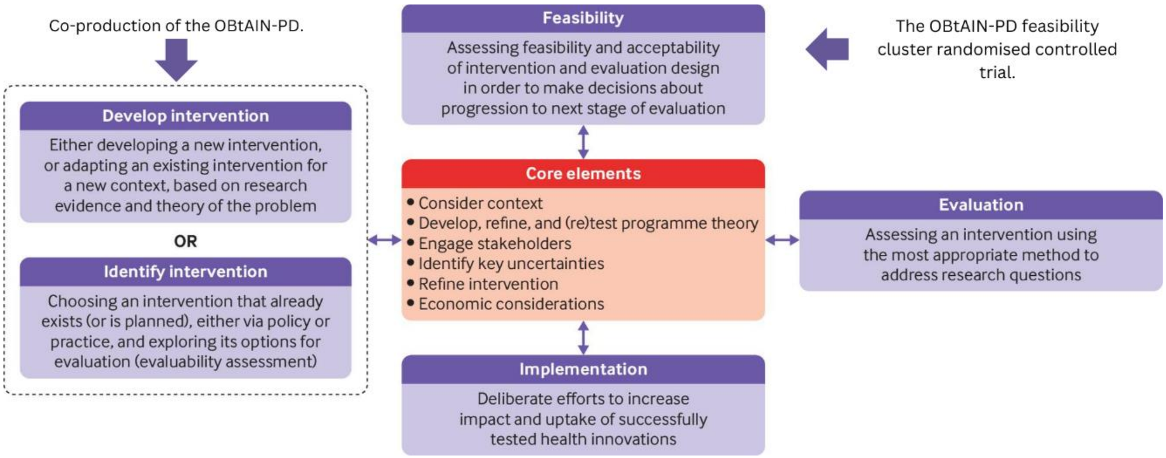


Figure 1.4: Developing an occupation-based complex intervention for living well with anxiety in Parkinson’s (OBtAIN-PD) study relating to the Medical Research Council Framework. Adapted from (Skivington et al., 2021).

1.5 Occupational Therapy in Parkinson’s

Occupational therapy was founded on the idea that humans require meaningful activity (occupation) to occupy their time (Yerxa, 1992). The power of occupation to transform the lives of people affected by illness and trauma is a core concept (Kielhofner, 2007). Adolf Meyer, a founder of the occupational therapy profession, stated in the 1920s that human health is promoted through occupation, i.e., work, play, rest, and sleep (Meyer, 1922). This idea that meaningful engagement in occupation is strongly related to human development, health, and wellbeing is one of the underpinning assumptions of occupational therapy (Jonsson, 2008; Meyer, 1922). The profession is rooted in medical, social-behavioural, psychological, psychosocial, and occupational sciences (World Federation of Occupational

Therapists, 2019). This foundation prepares occupational therapists to work collaboratively with people in various settings, including communities, groups, and individuals (World Federation of Occupational Therapists, 2019). Occupational therapy aims to help people improve their ability to participate in daily activities by addressing personal, environmental, or combined factors (World Federation of Occupational Therapists, 2019).

Fisher and Marterella (2019) define occupation as the tasks and activities a person wants, needs, or is expected to complete. Regarding occupational therapy, three fundamental beliefs form the philosophical foundation of the profession and guide the therapeutic process. Firstly, occupational therapists view people as beings who engage in various occupations and may face challenges related to these activities. Secondly, they acknowledge occupation's substantial role in people's lives. Finally, occupational therapists consider incorporating occupation in all phases of the therapeutic process to help their clients achieve optimal outcomes (Fisher & Marterella, 2019). It serves as a starting point for what occupational therapists do and a driver of implementing occupational therapy in clinical practice (Fisher & Marterella, 2019).

The ‘Do-Live-Well’ framework (Moll et al., 2015) illustrates occupational therapy’s focus on participation. ‘Do-Live-Well’ provides a structure for promoting wellbeing that reframes participation as ‘doing’ to reinforce the fundamental message that ‘what you do every day matters’ (Moll et al., 2015). It provides a health promotion tool centred on four interdependent concepts (Moll et al., 2015) (Figure 1.5), underpinned by theoretical and empirical evidence (Moll et al., 2015). Occupational therapists are experts in analysing and enabling people to optimise their occupational performance through engaging in meaningful occupations.

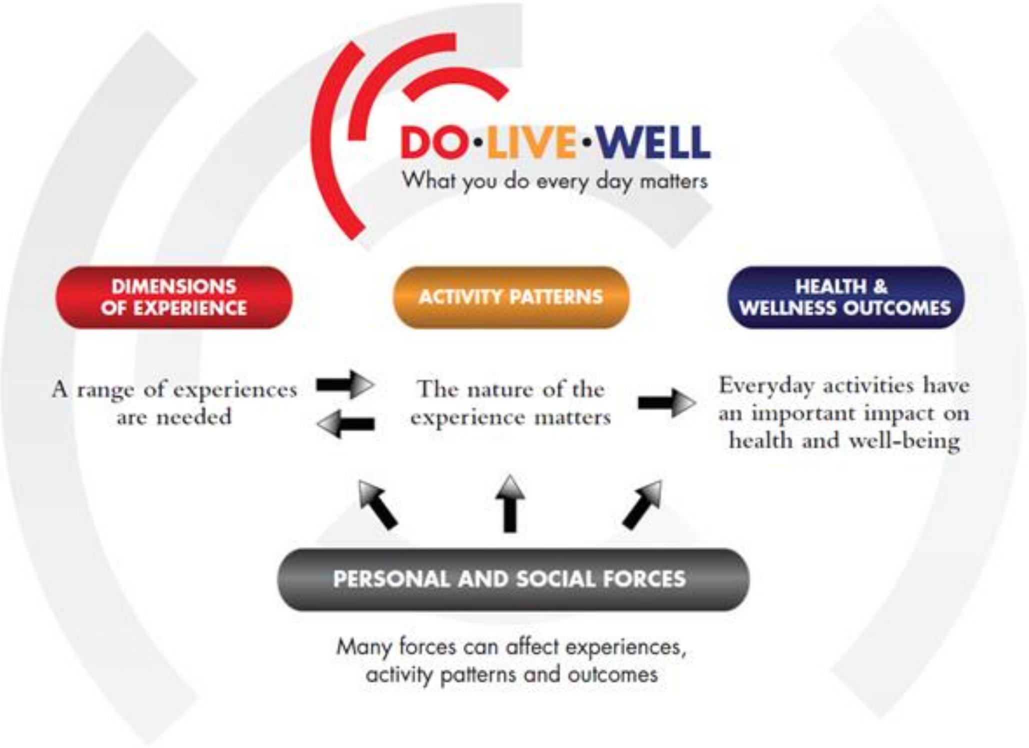


Figure 1.5: "Do-Live-Well". A Canadian framework for promoting occupational, health, and wellbeing.

The role of occupational therapy with people with Parkinson's is to enable the person to engage in meaningful roles, tasks, and activities at home and in the community (Royal College of Occupational Therapists, 2018; Wood et al., 2022). This engagement in activities and roles is called *occupational performance* (Baum & Law, 1997). Occupational therapy for Parkinson's involves enhancing occupational performance, safety, and efficiency in daily activities (Royal College of Occupational Therapists, 2018). In the early stages, it aims to help people with Parkinson's prevent giving up activities, while in later stages, it focuses on enabling adapted participation. Occupational therapy also supports care partners in assisting in daily activities while considering their well-being (Prado et al., 2020; Sturkenboom et al., 2014; Wood et al., 2022).

Occupational therapy is a mainstay of clinical guidelines for people with Parkinson’s (National Collaborating Centre for Chronic, 2006; NICE, 2018, 2022). Interventions delivered by occupational therapists that provide a space for self-rediscovery, identity formation, and community participation are often valued over acute, assessment-based psychological interventions in non-Parkinson populations (Wimpenny et al., 2014).

Occupational therapists can collaborate with people with Parkinson’s to evaluate and modify their activity planning and execution to minimise time constraints and enhance their self-efficacy (Creighton, 1992). The impact of these strategies on anxiety-related participation limitations has yet to be investigated. Occupational therapy interventions for people with Parkinson’s are described in professional guidelines (Royal College of Occupational Therapists, 2018; Sturkenboom et al., 2011; Wood et al., 2022). Limited, moderate-quality evidence exists within the occupational therapy literature for addressing anxiety symptoms in the general population as well as Parkinson’s, and the variety of interventions used and study methodologies means that the effectiveness of occupational therapy interventions for this population are not yet determined (Fox et al., 2019; Pisegna et al., 2022). Due to the specific needs of people with Parkinson’s, these interventions must be modified for this population (Bogosian et al., 2020; Mendorf et al., 2023). Interventions provided by occupational therapists can be occupation-based (using occupation as the foundation) or occupation-focused (focusing a person’s attention on occupation) (Fisher, 2013). The findings of previous research and the views of the PPIE stakeholders of this project reinforce the need for an occupation-based intervention for anxiety in Parkinson’s (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017). Occupational therapists, with their expertise in improving wellbeing through participation and training in physical and mental health, are well-positioned to support individuals with Parkinson's whose participation is impacted by anxiety (Christine, 1990).

1.6 Patient and Public Involvement and Engagement

Patient and public involvement and engagement (PPIE) in research positively benefits recruitment, design, dissemination, and implementation of findings (Boote et al., 2011; Renedo et al., 2015). This research project was completed as part of an NIHR Clinical Doctoral Research Fellowship (NIHR301565). A PPIE consultation was conducted with people with Parkinson’s (n=15) recruited through the charity Parkinson’s UK. This took the form of PPIE stakeholders reviewing the draft proposal with a follow-up one-to-one telephone discussion. The NIHR Involve Briefing Notes for Researchers: public involvement in NHS, public health and social care research (National Institute for Health Research, 2012) was used as a framework for the consultation process. Two focus groups were completed at the requests of the PPIE stakeholders as they had discussed the study proposal between themselves and thought a group discussion would be valuable. These groups were conducted as video calls on Zoom ("CYPH, INC. v. ZOOM VIDEO COMMUNICATIONS, INC," 2022). The point of the calls was to clarify and elaborate on any points or ideas within the proposal that the PPIE stakeholders had. The research topic was strongly endorsed as meaningful and relevant by the PPIE stakeholders, who commented:

> *“Thank you for taking on research into anxiety and Parkinson’s. It is a symptom that has dogged me for years, with no obvious interventions available.”*

> *“Yes, this is needed.”*

"Anxiety research is absolutely valuable."

"As a person living with Parkinson's, this research is important to me"

Furthermore, PPIE stakeholders stated that they felt the order of the study process was sensible, and it would be a study of interest to people with Parkinson's. Other stakeholder recommendations, such as making the language more accessible and being more transparent about the potential benefits to people with Parkinson's, have been integrated throughout the OBtAIN-PD project. The involvement of care partners in the group concept mapping study (chapter 3) was included. A separate small group of PPIE stakeholders composed of people with Parkinson's (n=5) reviewed the plain English summaries for each study and made recommendations to improve their readability.

Additionally, a PPIE consultation was conducted with occupational therapists (n=3) from a range of clinical backgrounds (including neurology, mental health, and inpatient services) who all have experience working with people with Parkinson's and/or anxiety. This consultation aimed to check that the proposed project's approach, aims, and objectives were meaningful and realistic for occupational therapists. All occupational therapists agreed that the project was meaningful and realistic.

The OBtAIN-PD acronym was co-produced and chosen by people with Parkinson's (n=5) and care partners (n=3). This consultation was conducted as an online focus group using video conferencing ("CYPH, INC. v. ZOOM VIDEO COMMUNICATIONS, INC," 2022). A list of computer-generated acronyms was presented to the group, who were also given the choice to bring their own ideas to the session. Following the discussion, the group chose the acronym OBtAIN-PD because they felt that the word 'obtain' had positive and empowering connotations. They believed it conveyed the idea of acquiring control over their anxiety and, consequently, their lives, through proactive effort and support.

The OBtAIN-PD logo (figure 1.6) was co-produced with the project’s Patient Advisory Group (PAG), which consisted of people with Parkinson’s (n=4) and care partners (n=2) in collaboration with a graphic designer at the University of Plymouth Design and Print Centre. As well as being easy to read, the PAG strongly felt that the logo should symbolise support and that OBtAIN-PD is inclusive of everyone. This is evoked by the ‘O’ which symbolises a group of people in a circle holding hands or with their arms around one another with a rainbow colourway that is symbolic of the LGBTQIA+ pride flag.

Figure 1.6: The final OBtAIN-PD logo.

Each study involved stakeholders, including people with Parkinson’s, care partners, and occupational therapists. The respective chapters detail their involvement.

1.7 Methodological orientation

Informed by the PPIE consultations described in section 1.6 and in line with the Medical Research Council guidance on developing and evaluating complex interventions (Skivington et al., 2021), it was evident that the use of one research method would not be effective in developing the content of the OBtAIN-PD and determining the feasibility of conducting a trial. Qualitative methods to achieve consensus would enable the development of the intervention and enable a deeper exploration of participants' experiences of participating in a trial. Consequently, a mixed-methods design comprising four phases, including a scoping review, group concept mapping, logic modelling, and a feasibility RCT with embedded qualitative study, would provide a more holistic view when integrating and interpreting findings. This would enable comprehensive conclusions to be drawn when evaluating complex healthcare interventions (Craig et al., 2008).

Plano Clark and Ivankova (2016) describe mixed-methods research as:

> *"…the intentional integration of qualitative and quantitative research methods to best address a problem".* (p. 4)

Since the 1980s, the combination of research methods has become increasingly accepted, although there are differing views on integrating quantitative and qualitative methods (Greene, 2008; Johnson et al., 2007). Greenhalgh and Papoutsi (2018) argue that many evaluation studies that test complex interventions fail to consider the intervention's complexity fully. They suggest that complex healthcare systems have unclear boundaries, where clinicians operate under internal rules and adapt and improve those systems iteratively. Randomised controlled trials alone cannot fully address questions as much real-life healthcare is uncontrollable (Subbiah, 2023). Therefore, more in-depth mixed-methods approaches are required to explore the dynamic nature of testing an intervention's feasibility and implementation. The Medical Research Council Framework for the development and testing of complex interventions (Skivington et al., 2021) emphasised that there is a need for more studies that use mixed methods and process-based approaches to explore the challenges of non-linearity and iterative local adaptations (Moore et al., 2015). The OBtAIN-PD project utilised mixed-methods research principles throughout the research process, adopting an integrated approach to conceptualising and interpreting the findings.

When it comes to research, using both quantitative and qualitative methods can be complicated because the underlying philosophies of these two approaches seem to contradict each other. Quantitative research is traditionally based on positivism, which asserts that scientific inquiry is the only way to establish reliable knowledge. This experimental method was first introduced by August Comte (1798-1857), who is considered the first philosopher of modern science (Crotty, 1998). In the early 19th century, philosophers like Karl Popper introduced post-positivism philosophy. It valued objectivity and recognised that researchers' values and backgrounds can influence their research. This influence can create a potential source of bias that should be acknowledged and managed (Popper, 1959). The post-positivist movement in the 1980s enabled the development of qualitative methodologies and mixed research methods (Giddings & Grant, 2007). Constructivist qualitative research aims to interpret meaning and context from multiple realities, including the researcher's experience (Lincoln & Guba, 1985).

According to some authors, there is no necessary connection between specific philosophies and research methods (Cook, 1979; Greene et al., 1989). Greenhalgh suggested a departure from traditional paradigms and challenged "prevailing assumptions and methodological rules" to advance the knowledge base (Greenhalgh, 2013, p. 92). Integrating research methods in mixed-methods research and their underlying conventions can be challenging for researchers. The researcher may attempt to combine differing paradigms within one study. Additionally, the investigator will operate within their personal and professional contexts, adding another complexity layer. However, this reflexivity is considered an essential and valued contribution to qualitative research ontology (Giddings & Grant, 2007).

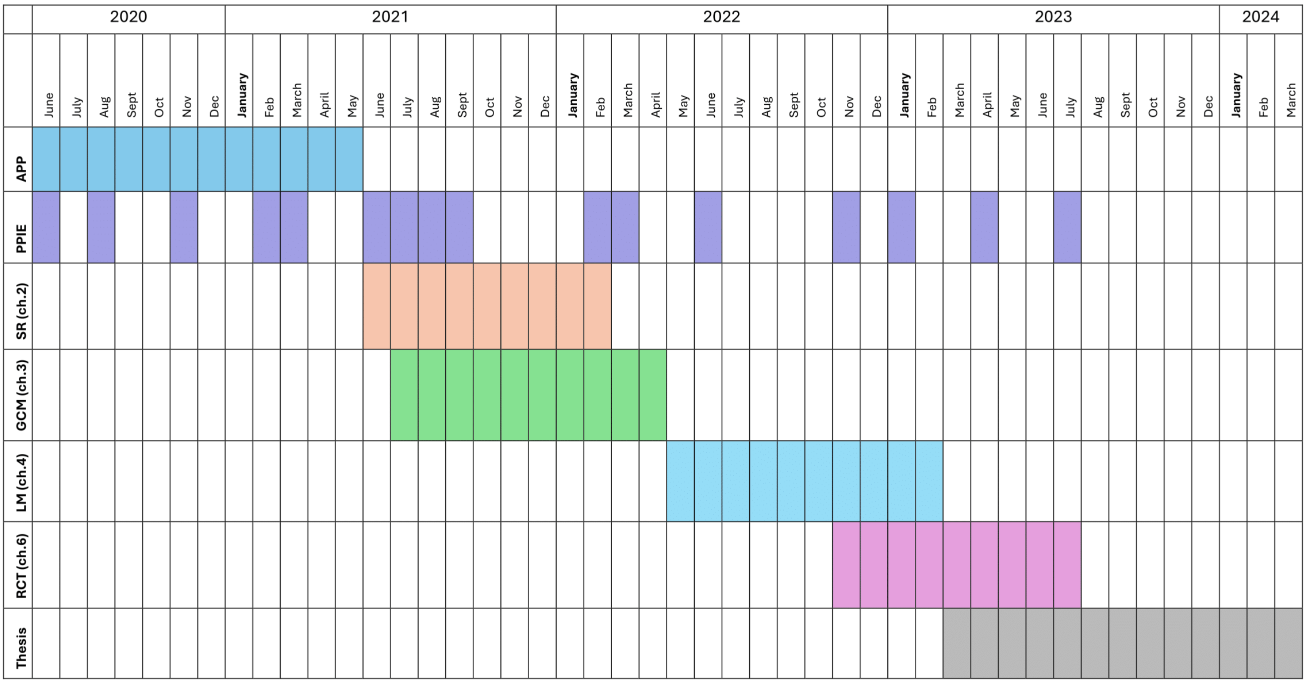
I am an occupational therapist who uses quantitative and qualitative research data to inform clinical practice. Quantitative data may provide a higher level of objectivity of results. On the other hand, qualitative data can offer an effective way of exploring attitudes, feelings, and behaviours in a more detailed and profound manner.

The OBtAIN-PD project was designed using a pragmatic approach to consider the practicality of a wide range of designs and their applicability to the complex healthcare evaluation field with awareness of the underlying ideologies. The design of the OBtAIN-PD project aimed to avoid conflicts between different methods. This approach avoids the domination of one method over others. If there is any difference in findings across methods, it provides an opportunity to refocus the research questions and original research assumptions. Lather (2006) suggests that disagreements between paradigms should not lead to conflict or require reconciliation; instead, there should be "disjunctive affirmation" (Lather, 2006, p. 52). This means that researchers accept that there are multiple valid ways of approaching research and that one methodology must be ‘false’ as the other is ‘true’.

1.8 Thesis Aim and Structure

This thesis aims to co-produce an occupation-based complex intervention for living well with anxiety and Parkinson’s (OBtAIN-PD). This will be achieved using a complex intervention development process consisting of a scoping review, group concept mapping, and logic modelling. As a researcher and practising occupational therapist, I intend to ensure that this research is clinically relevant and meaningful to people with Parkinson’s and their care partners. This thesis is derived from and informed by people with Parkinson’s, care partners, occupational therapists, academics, methodologists, and PPIE.

This chapter presents an introduction and background to the substantial burden of anxiety in Parkinson's. An overview of interventions used with people with Parkinson's living with anxiety is presented. An overview of Occupational Therapy is given, and its suitability in addressing the challenges presented by anxiety in Parkinson’s is established. The process of developing a complex intervention is discussed. The PPIE has been discussed, and the research philosophy underpinning the project has been outlined. Chapter two presents a scoping review protocol and the resulting review that identifies current occupational therapy interventions for community-dwelling adults with anxiety. Chapter three describes a study where people with Parkinson’s, care partners, and occupational therapists identify critical components for an occupation- and community-based intervention for people with Parkinson’s with anxiety. Chapter four details a logic modelling study in which people with Parkinson's, care partners, and occupational therapists worked together to develop OBtAIN-PD. This resultant intervention aims to help individuals with Parkinson's manage their anxiety and improve their quality of life. The specification of the OBtAIN-PD is given in chapter five. Chapter six presents a protocol for a feasibility cluster randomised controlled trial of the OBtAIN-PD. Chapter seven discusses the research project, while chapter eight provides recommendations and conclusions for future studies. An overview of the PhD timeline, indicating where research activities were conducted in parallel and how they flow together, is shown in Figure 1.7.



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PPIE		■	■			■					■	
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RCT (ch.6)			
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Key

APP- Application process to NIHR Clinical Doctoral Research Fellowship

PPIE- Patient and Public Involvement and Engagement

GCM- Group concept mapping study (chapter 2)

LM- Logic modelling study (chapter 4)

RCT- Randomised controlled trial protocol development and ethics application (chapter 6)

Figure 1.7: Overview of the PhD research activities.

Chapter 2: Scoping Review

In the previous chapter, the need for a new intervention to help people with Parkinson's live well with anxiety was outlined. The first step of the MRC's framework when developing and evaluating a complex intervention involves identifying the evidence base (Figure 1.5).

Identifying features of antecedent interventions is part of the development phase of the MRC framework (Skivington et al., 2021). This allows those features or characteristics to be adapted for a new intervention, such as the OBtAIN-PD (Skivington et al., 2021). This chapter presents a protocol followed by the subsequent scoping review (Lovegrove et al., 2023; Lovegrove, Marsden, et al., in press). Due to the paucity of evidence in the area of anxiety interventions used by occupational therapists to help people with Parkinson's with anxiety, it was decided to widen the search to the population of all adults with anxiety. Since there is still a lack of evidence in this area, it was considered valuable to identify specific characteristics and concepts in papers or studies and to map, report, and discuss these characteristics and concepts as potential components for the OBtAIN. In these cases, a scoping review is a better choice compared to a systematic review (Munn et al., 2018). Therefore, a scoping review was selected as the methodology for this study.

The scoping review findings informed the co-production of the OBtAIN-PD in the logic modelling study (Chapter 4). The scoping review data chart of the included studies is presented in Table 2.1. Articles that relate to the same study are colour-coded for clarity. This scoping review revealed that occupational interventions for anxiety often use outcome measures that are not specific to occupational therapy. The review indicates that future interventions and research should use occupational therapy outcome measures and appropriate impairment-based measures. This will demonstrate the success and effectiveness of occupational therapy services in improving the occupational performance and participation of individuals with anxiety. Most interventions were group-based, but individual occupational therapy sessions could offer unique benefits. Occupational therapy interventions for adults with anxiety should use goal setting and tailoring to enhance effectiveness and impact. Rigorously designed clinical trials are needed for occupational therapy interventions in adults with anxiety, including economic evaluations to demonstrate cost-effectiveness.

Reference	Brief name	Why	What	Procedures	Who provided	How	Where	When, how much	Tailoring	Modifications	Planned	Actual
Chugh-Gupta *et al.*, 2013	Yoga	Facilitate slower and deeper respiration, increase O2 consumption, reduce BP and HR, increase muscle tone and blood flow, positively influence GABA production, enhance strength and flexibility	Described in figure 3	Hatha yoga- physical postures, breathing, meditation Lyengar yoga- Alignment, equipment to achieve poses Tibetan yoga- specific routines Ashtanga yoga- physical postures	N=9 RCTs taught by expert or “trained” yoga instructors	N=14 RCTs, group sessions N=2 RCTs, individual sessions All non-RCTs included group sessions	N=1 non-RCT had home practice sessions. No others described location	No. of sessions: 1-60 (range) No. of weeks: 1-12 (range)	Not discussed	Not discussed	Not discussed	Not discussed
Eklund, 2013	Redesigning Daily Occupations (ReDO)	Reduce burdens and increase motivation and energy through balance of everyday occupations	No details provided	Three phases: 1. Five weeks, focus on self-analysis of everyday activity patterns. 2. Five weeks, goal setting and strategies to accomplish desired changes. 3. Six weeks, period of work placement at women's ordinary workplaces. Included three group support/mentoring sessions.	Each group led by two occupational therapists with specific training for leading the ReDO program	Group sessions and a work placement	Primary health care centres	6 weeks in three phases. Phases 1 and 2= two sessions per week, each lasting 2.5 hours Phase 3= three group sessions but unclear if they would be for the same length of time	Phase 3 delivered in workplace	Not discussed	Not discussed	Not discussed
Eklund and Erlandsson, 2013	Redesigning Daily Occupations-program (ReDO)	Achieve better balance between everyday occupations leading to better wellbeing and increased ability to return to work	Not discussed	Phase 1 focuses on occupational self-analysis (five weeks). Phase 2 focuses on goal setting and strategies for accomplishing change in patterns of everyday occupations (five weeks).	Two licensed occupational therapists who were specifically trained to lead the ReDO programme	Group sessions and a work placement	Sweden, two towns in selected district	Over 16 weeks, three phases. First five weeks phase 1, second five weeks phase 2, then 6 week work	Not discussed	Not discussed	Not discussed	Not discussed

				Phase 3; 6-week work placement, meet three times as a group				placement in phase 3 Two 2.5 hour sessions per week except phase 3 when group meets three times				
Eklund *et al.*, 2013	Redesigning Daily Occupations-program (ReDO)	Based on occupational therapy and occupational science principles. Focus on patterns of daily occupations and balance between them. Avoid detrimental occupations and engage in positive ones to increase motivation and energy.	Not discussed	Considered whether the woman would have the time and energy to engage in the ReDO programme. Reflecting on own occupational history. Identifying interests. Stresses and rewards Mapping how time is used. Becoming aware of value and meaning found in everyday occupations. Strengthening the women's own abilities to analyse their everyday occupations and find strategies to obtain balance is also emphasised.	Not discussed	Three phases. Phases one and two; group work. Phases three; work practice and groups.	Primary healthcare centres	16 weeks, 10 groups total. Phases one and two 5 weeks each. During this phases, group meets twice a week. Phase 3; 6 week work practice. Group meets three times to offer support.	Not discussed	Not discussed	Not discussed	Not discussed
Erlandsson, 2013	Redesigning Daily Occupations-program (ReDO)	Based on people's experiences, ability to return to work may depend on ability to re-adapt routines, lead to a lasting change in patterns of daily occupations,	Tools and exercises for self-analysis, book for personal reflection, 24-hour circle, fruit, music, scrapbooks,	1.1 Individual meeting with interview 1.2 Program intro 1.3 What is an occupation? Different time perspectives 1.4 Occupational balance	Two specially trained occupational therapists	Occupational therapy group treatment	Southwest of Sweden	6-8 participants per group, three phases over 16 weeks. Phases 1 & 2 are five weeks each.	Not discussed	Not discussed	Not discussed	Not discussed

		demonstrate increased work capacity, improve health	farewell party	1.5 Patterns of daily occupation 1 1.6 patterns of daily occupation 2 1.7 Stress, hassles, and uplifts in daily life 1.8 hassles and uplifts in day-to-day life 1.9 Goal setting 1 1.10 Goal setting 2 2.1 Sleep as a prerequisite for occupation and health 2.2 Work-occupational history 2.3 Evening seminar for selected relatives, colleagues, and/or employer 2.4 Occupational value 2.5 Preparations for job placement 2.6 Hassles at work 2.7 2.7 Occupational balance including work 1 2.8 occupational balance including work 2 2.9 conclusion of phases 1 and 2 2.10 Ending phases 1 and 2				Phase 3 (job placement) is six weeks. Two and half hours per group.				

				3. Work placement								
Fox *et al.*, 2019	Occupational therapy; led intervention, using cognitive-behavioural therapy, using health behaviour change theory, using skill-building theory, using occupation science theory, using neurological and sensory theories	Improving functioning and mental health outcomes. Improve anxiety symptoms. Target difficulties in completing ADLs.	Neurological and sensory interventions; cranial electrotherapy stimulation device administered by the participant themselves	Oversights only in keeping with article type	Intervention defined as occupational therapy, or led/designed/facilitated by an occupational therapist All interventions occupational therapy-led	Group, individual, and combination	Not discussed	Sessions range 3-18 Hours per session range 2-4 Weeks range 4-16	Not discussed	Not discussed	Not discussed	Not discussed
Fox *et al.*, 2021			Manual with session guidance, slides, worksheets, and additional reading. Worksheets given to participants.	Individual meeting with occupational therapist then group sessions: 1. Intro 2. Occupational history 3. Occupational balance 4. Patterns of daily occupations and time (1) 5. Patterns of daily occupations and time (2) 6. Hassles and uplifts in daily life 7. Goal setting 8. Occupational value 9. Evening seminar	Facilitators completed 3-day training course and certification. Facilitators were occupational therapists.	Pre-group individual sessions, then groups.	City-based primary care centre.	Group sessions over 10 weeks.	Some adaptations made by treating therapists but the intervention itself was not tailored, described as having a rigid manual.	Changing content order (fidelity maintained). Adapting occupation-based sessions. Homework done within session. Cut content reintroduced into ReDO-10.	Therapists completed a written reflection after each session on how closely they had adhered to the manual, any adjustments made and notes on their facilitation	Unclear if fidelity fully maintained.

				10. Goals and strategies 11. Concluding 12. Follow-up 1 (after 1 month)								
Gunnarsson *et al.,* 2006	The Tree Theme Method (TTM)	Creative activities like painting a tree may be used to stimulate occupational storytelling and making. Life story narrative to understand how one acts and actions. Promote self-image development and how person relates to the environment.	Sheets of 40x48cm paper, watercolours , and oil crayons.	Occupational therapist introduces theme and leads relaxation exercise. Questions to focus reflection. Painting intervention sessions: 1. Present life situation 2. Childhood 3. Teenage years 4. Future tree 5. Future tree 6. Follow-up interview three years later 7. Follow-up TTM 8. Follow-up TTM	Occupational therapist.	Individual sessions with occupational therapist.	Mental health care in different clinics in Sweden. Psychiatric outpatient clinic.	Five sessions, then a follow-up stage three years later (one interview and two TTM sessions) Unclear what time frame the first five sessions were delivered over	Not discussed	Not discussed	Not discussed	Not discussed
Gunnarsson *et al.,* 2015	The Tree Theme Method (TTM)	Based on activities to achieve a satisfying everyday life. Intervention that can be used to compliment CBT and pharmacological treatment. Based on art therapy and life storytelling. Increase ability to cope with everyday life by	Not discussed.	Paint pictures of trees that represent certain periods of life in five sessions. First four start with progressive relaxation and person paints a symbolic tree. Picture used as a starting point to discuss different points of life with focus on everyday ADLs. Theme of tree differs from one session to the next and each tree represents a particular period of life: the present, childhood, adolescence, adulthood.	Occupational therapists trained in TTM. Also training in study procedures.	Individual sessions.	Primary health care centres and general outpatient mental health care units in three counties in the south of Sweden	Five sessions of 60 mins each during 6-9 week period.	Not discussed	Not discussed	Fidelity forms completed after each session by treating occupational therapists in both groups	Not discussed

		developing strategies.		Fifth session focus is on story-making and shaping future plans. Patient and therapist decide on tasks for completion between sessions.								
Gunnarsson *et al.,* 2018	The Tree Theme Method (TTM)	Based on art therapy and life storytelling with a focus on activities in everyday life. Telling life story allows opportunity to reflect on how to act and explain why they act in a specific way in a specific situation and context.	Not discussed.	Sessions start with progressive relaxation. Reflective dialogue between person and therapist followed by painting tree representing different life periods: 1. Present life situation 2. Childhood 3. Adulthood 4. Not stated 5. Future tree Final session includes dialogue of how to incorporate change. New tree painted each session.	Occupational therapists specially trained in the specific frames and techniques of TTM.	Not made clear if individual or group	Primary health care centres and general outpatient mental healthcare units in three counties in Sweden	Five sessions. No indication of session length or frequency.	Not discussed	Not discussed	After each completed intervention the therapists reported the content in each session to assess adherence to the TTM procedures	Not discussed
Kitchiner *et al.,* 2009	Cognitive behavioural therapy adult education evening class (Stress Control), anxiety management group	As some individuals uncomfortable in a group setting, so a generic management strategy using stress control principles that could be delivered to up to 60 people at a time delivered	PowerPoint slide presentations, therapist /patient manual. Written materials for participants to take home	Stress control (SC)- anxiety education, self- assess techniques, techniques to control responses, discussion of personal problems. Anxiety management (AM)- more interactive with broad psycho-educational approach. CBT model used with emphasis on activity scheduling and planning. Training in a variety of applied relaxation techniques. Groups used to engender a self-help ethos in a safe environment.	SC courses delivered by two experienced mental health nurses with experience in using CBT. AM group facilitated by occupational therapists with 15-20 years of delivering anxiety	Group sessions presented as a taught course	University Hospital of Wales. Groups held in the late afternoon in a formal classroom setting.	Six two hour sessions held at weekly intervals	Not discussed	Not discussed	Random selection of three video or audio tapes for each condition assessed for fidelity by experts.	Judged to adhere closely to manuals.

					management groups. Trained to use the manual.							
Lambert *et al.*, 2007	Occupational therapy-led lifestyle approach.	Potential role of lifestyle in the prevention of mental health problems recognised. Modifying habitual lifestyle behaviours in a health protective direction will reduce the frequency and severity of anxiety and panic symptoms.	Lifestyle diaries.	Lifestyle review using self-report and lifestyle diaries. Education to increase awareness of the potential negative benefits of some lifestyle behaviours. Specific lifestyle changes negotiated. Monitoring and review of the agreed lifestyle changes and any changes in symptoms.	Occupational therapists.	Individual appointments.	Two primary care trusts in the east of England.	10 intervention sessions over a 16-week period. 3x1h at weekly intervals, 3x0.5h at weekly intervals, 3x0.5h at fortnightly intervals, 1x1h at monthly intervals. Delivered in four stages.	Not discussed	Not discussed	Not discussed	Not discussed
Lambert *et al.*, 2008	16-week occupational therapy-led lifestyle intervention.	Habitual lifestyle behaviours can affect health both negatively and positively. Modifiable lifestyle behaviours contribute to anxiety and depression, therefore influencing these may have beneficial effects.	Not discussed	1. Lifestyle review. 2. Education to increase awareness of behaviour health effects. 3. Specific lifestyle goals negotiated between therapist and person. 4. Monitoring and review of the agreed lifestyle changes and any consequent change in symptoms.	Occupational therapists.	Individual lifestyle intervention sessions.	GP practice, primary care.	10 lifestyle intervention sessions over a 16-week period. Three 60 minute appointments at weekly intervals, three 30 min appointments at weekly intervals, three 30 minute appointments at	Not discussed	Not discussed	Not discussed	Not discussed

								fortnightly intervals, and a final 60 minute appointment after a month.				
Lambert *et al.*, 2010	Occupational therapy-led lifestyle approach.	Lifestyle approach may be at least as effective as usual care when treating panic disorder.	Not discussed.	Lifestyle review using self-report diaries. Education to increase patient awareness of negative health effects of some behaviours. Specific lifestyle changes negotiated. Monitoring and review of agreed changes.	Trained research occupational therapist.	Not clear if individual or group sessions.	Primary care.	10 intervention sessions over a 16-week period.	Not discussed	Not discussed	Not discussed	Not discussed
Lork *et al.*, 2019	Work-directed rehabilitation provided by OTs and PTs to promote work capacity in CMDs	Efforts to increase work capacity need to be directed towards specific work context. Person-environment-occupation (PEO) model assumes occupational performance is an interaction between these factors.	Not discussed	First session- work-related resources and problems identified with occupational therapist to agree on more specific goals and tentative content to develop strategies. Occupational therapy module- vocational behavioural strategies inspired by ReDO aiming at increasing balance in everyday life by changing activity patterns.	Occupational therapist (n=1) and/or a PT (n=2) specialised in treating patients with mental health problems, 5-20 years' experience in this field. Two seminars prior to study with PI to discuss and learn more about the approach	Not discussed.	Swedish primary care, rehabilitation centre.	Intervention period of 8 weeks with 4-16 visits.	Tailored with participant and adapted top their needs. Patients chose OT module, PT module, or both.	Not discussed	Not discussed	Not discussed
Prior, 1998a.	Short-term anxiety management course.	Cognitive behavioural group using stress management and assertiveness techniques. Detailed	Handouts.		Not discussed	Group sessions	Mental health day hospital.	Six sessions over six weeks.	Not discussed	Not discussed	Not discussed	Not discussed

		education on anxiety, stress reduction techniques, progressive relaxation, and problem solving.										
Prior, 1998b.	Short-term anxiety management course.	Not discussed	Not dicsussed	Not discussed	Not discussed	Not discussed	Mental health day hospital in West London	Not discussed	Not discussed	Not discussed	Not discussed	Not discussed
Rosier *et al.*, 1998	Anxiety management groups	Anxiety management group developed by occupational therapists based on cognitive behavioural approach. Objectives were to recognise personal symptoms, identify triggers, identify lifestyle factors, understand management techniques, share personal experience, facilitate movement to other appropriate treatments following extended assessment.	Homework forms.	Week 1- introduction, identification of somatic symptoms and coping strategies, relaxation techniques. Homework; anxiety symptoms & frequency checklist. Week 2- Review homework, anxiety spiral, nervous system education, lifestyle factors and assessment, goal formulation, relaxation techniques. Homework; how I use my time. Week 3- review homework and goals, negative thinking patterns. Guided imagery relaxation techniques. Homework; recording negative thoughts. Week 4- review homework and goals, challenging ‘thinking errors’. Guided imagery relaxation techniques. Homework; negative thought patterns. Week 5- review homework and goals, panic attacks and hyperventilation. Musical	Facilitators who receive weekly supervision.	Group sessions, in person. Maximum 10 people per group and two facilitators. Facilitators have weekly supervision with a psychodynamic therapist.	Community mental health team.	Seven weekly 1.5 hours sessions.	Week 6- people can choose own relaxation technique.	Not discussed	Not discussed	Not discussed

				relaxation techniques. Homework; advise on case study. Week 6- review case study homework and goals, relaxation techniques of choice. Week 7- review goals, complete evaluation form, arrange follow-up. Followed-up 5-6 weeks later, invited to group reunion.								

Table 2.1: Scoping review data chart. Articles relating to the same study are matching colour-code

The scoping review protocol presented in this chapter is the Word version accepted for publication in *JMIR Research Protocols* (Lovegrove et al., 2023). The scoping review is the accepted Word version submitted for publication in *JMIR Aging* (Lovegrove, Marsden, et al., in press). In both articles, the authors are referred to intext with initials when delineating their role in the review. The authors are Christopher Lovegrove (CL), Ingrid Sturkenboom (IS), Mary Smith (MS, information specialist, Exeter Health Library), Jonathan Marsden (JM) and Katrina Bannigan (KB). The full list of references for both articles paper is included in the main thesis bibliography to improve readability.

2.1 Characteristics of Occupational Therapy Interventions for Community-Dwelling Adults With Anxiety: Protocol for a Scoping Review

Background: Anxiety is linked to decreased life quality and well-being. Living with an anxiety disorder results in higher personal and societal financial expenditure. Occupational therapists work with people living with anxiety in a variety of settings. A preliminary database search was conducted, and no current or underway systematic or scoping reviews on the topic were identified. Developing an overview of studies of occupational therapy interventions for people with anxiety is a necessary first step to understanding the existing knowledge and to increase the impact of future interventions. This scoping review will build on the findings of a previously conducted systematic review.

Objective: This scoping review will identify the following: (1) what occupational therapy interventions exist for adults with anxiety and (2) the intervention characteristics including outcomes used and impact observed.

Methods: This protocol was reviewed by an occupational therapist as part of a patient and public involvement consultation. The review will consider all studies and publications of occupational therapy that include community-dwelling adults with a diagnosis of anxiety who are aged 18 years and older and diagnosed with an anxiety disorder (Diagnostic and Statistical Manual of Mental Disorders [DSM-5-TR] criteria). Databases to be searched are MEDLINE, CINAHL, Cochrane Library, Science Direct, PsycArticles, Psychology & Behavioural Sciences Collection, Embase, PubMed, TRIP, Proquest, Social Care Online, JBI EBP database, OpenGrey, and OALster. Titles and abstracts will be screened against the inclusion criteria using Rayyan Qatar Computing Research Institute. Potentially relevant studies will be retrieved in full and assessed against the inclusion criteria. Articles published in English will be included. No date limiters will be used. Study selection will be completed by 2 independent reviewers. Data will be extracted using a data extraction tool.

Results: Data will be charted using the Template for Intervention Description and Replication (TIDieR) checklist in alignment with the review objectives. The scoping review will be reported in accordance with the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols statement.

Conclusions: This scoping review will produce valuable information about community-based interventions used to improve participation, life quality, and well-being for adults with anxiety to support the development of occupational therapy interventions. The findings will be disseminated through professional and National Health Service bodies, employer organizations, conferences, and research articles. The findings will be of value to health care professionals and researchers working to improve the lives of people living with anxiety.

Trial registration: Open Science Framework DOI 10.17605/OSF.IO/JS549; https://osf.io/js549/.

International registered report identifier (irrid): DERR1-10.2196/41230.

Keywords: activities of daily living; adult; anxiety; community; development; health; intervention; life quality; occupational therapy; quality of life; research; support; therapy; well-being.

Background

Anxiety and stress-related disorders, conditions that involve excessive fear or worry about a current or anticipated future event, are the ninth-highest global cause of disability (Vos et al., 2015). Anxiety disorders are highly persistent over a person's lifetime and are associated with elevated levels of disability, reduced quality of life, and decreased participation (Kessler et al., 2007). Living with an anxiety disorder results in higher personal and societal financial expenditure. For example, in the United Kingdom, the mean annual care costs for people living with anxiety are £71 million (US $84.2 million) (Parkinson's UK, 2017). In the United States, this figure is approximately US $52 billion (Yang et al., 2019).

Anxiety disorders, no matter the type or origin of the disorder, have a profound influence on an individual's ability to participate in their chosen activities in daily life to a level with which they are satisfied (Duncan et al., 2014). The stress associated with anxiety disorders reduces energy and the motivation to complete activities of daily living (Johansson et al., 2012) and is linked to both resilience and occupational adaptivity, that is, any adjustment or behavior change in response to the demands of living (Lopez, 2011). Focusing on the biochemical or cognitive aspects of anxiety as part of a health intervention may not necessarily contribute to an improvement in an individual's participation in life activities. Additionally, poor functioning can continue after full or partial recovery from an anxiety disorder due to the longitudinal impact of psychosocial impairment, suggesting that participation in daily life appears to be independent of symptoms of anxiety (Rodriguez et al., 2005). It is also known that participation and functioning are a greater predictor of health care usage and cost than the severity of either anxiety or depressive symptoms (Twomey et al., 2017). These findings point to a need to identify the characteristics of interventions that focus on how individuals with anxiety participate in daily activities, as this will contribute to the development of more targeted and effective interventions in the future. Furthermore, interventions that are targeted more appropriately may potentially be more cost-effective (Laxminarayan et al., 2006).

The stories of those living with anxiety disorders emphasizes the impact that this condition has on people's everyday lives. This includes the effect that anxiety has on social relationships and feelings of shame and embarrassment:

> *I go to the bathroom and when I come back he says "where have you been?" I've been to the toilet. "You have been a long time." So trying to hide… (the attacks). He thinks it's stupid. It makes you feel ashamed.* (Kadam et al., 2001)

The experience of anxiety is a complex phenomenon that affects people across cultures. In a study of adults living with anxiety in Iran, the participants explained the experience as "*it is like I am in a cage*" and fearing being both rejected or neglected by others, such as being mocked or losing popularity (Kadam et al., 2001). In the United Kingdom, some have explained the experience of anxiety and its impact as "*My head says I'm under attack and physically I feel like I'm under attack"* and "*it has prevented me from doing a lot of things*" (Mohammadi et al., 2019). This range of experiences further reinforces the need to explore the characteristics of interventions for people.

Occupational therapists have historically worked with people experiencing anxiety in a variety of settings. In a systematic review and narrative synthesis of occupational therapy interventions for people with anxiety disorders, Fox et al. (2019) were unable to make a judgment on overall clinical effectiveness due to the heterogeneity of the identified studies. As it was an effectiveness review, the authors highlighted the potential for replicability of the interventions in future research and as treatments, the characteristics of the identified studies, and their interventions were not charted in detail. It is also unclear if the authors adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement for reporting a systematic review, which the limits replicability and transparency of their review. In their conclusion, (Fox et al., 2019) highlight that future research should report on the impact of occupational therapy interventions for people living with anxiety. The proposed scoping review seeks to further the authors' findings (Fox et al., 2019) by updating the search and exploring and understanding the current landscape of intervention characteristics of the interventions identified to aid the development of future interventions and research. A search of the CINAHL database has identified that studies have been conducted since 2019 that would add to the data.

The identification of potential intervention characteristics is crucial to the development of new complex interventions (those interventions with several interacting components) (O'Cathain et al., 2019). If too little time is spent on identifying characteristics in the early stage of the complex intervention development cycle, this may result in a flawed intervention that is lacking in clinical and cost-effectiveness (O'Cathain et al., 2019). Furthermore, identifying the characteristics of previous occupational therapy studies will benefit the design and future evaluation of new interventions by examining how the research is conducted and identifying knowledge gaps (O'Cathain et al., 2019; Skivington et al., 2021). This approach aligns with the development stage of the "development-evaluation-implementation process" for complex interventions as outlined by the Medical Research Council (O'Cathain et al., 2019; Skivington et al., 2021). Adopting this approach will help to ensure that future interventions have a better chance of being effective when evaluated and of implementation, that is, being adopted in real-world settings (O'Cathain et al., 2019).

A preliminary search of MEDLINE, the Cochrane Database of Systematic Reviews, and *JBI Evidence Synthesis* was conducted, and no current or underway systematic reviews or scoping reviews on the topic were identified. Thus, the objective of this scoping review is to examine the range and characteristics of occupational therapy interventions that have been reported to improve the participation, quality of life, and well-being of community-dwelling adults living with anxiety. This scoping review will create a map of community-based interventions used to improve participation, quality of life, and well-being for adults with anxiety. It is hoped that the findings of the review will support the development of occupational therapy interventions to empower people to live well with their condition by improving their quality of life, mood, and participation in meaningful occupations.

Review Questions

What Occupational Therapy Interventions Exist Globally for Adults with Anxiety? Specifically, this review will collect and chart data to address the following subquestions: (1) what are the characteristics of the occupational therapy interventions identified? (2) What are the outcome measures used to evaluate the occupational therapy interventions identified? (3) What was the reported impact of occupational therapy interventions for adults with anxiety? (4) What are the implications for practice and future research of the occupational therapy interventions identified?

Methods

Study Design

The proposed scoping review will be conducted in accordance with the Joanna Briggs Institute (JBI) methodology for scoping reviews (Peters, Godrey, et al., 2020). This scoping review protocol is registered on the Open Science Framework (Lovegrove, 2021) and will be reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) statement (Moher et al., 2015). This scoping review protocol will be conducted using the JBI guidelines for scoping reviews to ensure a systematic methodology that can be replicated (Peters, Godrey, et al., 2020). The planned review will be reported in line with the PRISMA Extension for scoping reviews (Tricco et al., 2018).

Eligibility Criteria

Participants

The review will consider studies of occupational therapy that (1) include adults with a diagnosis of anxiety who are aged 18 years and older and are resident in their own home or a care setting and (2) include diagnoses such as generalized anxiety disorder, panic disorder, and anxiety disorder not otherwise specified as defined by DSM-5-TR (or earlier versions) criteria. Studies for exclusion will be those with people without a confirmed diagnosis of an anxiety disorder, those concerning pharmacological interventions, researches focused on diagnostics, researches focused on stress or stress-related disorders.

Concept

The concept being mapped within this scoping review will be occupational therapy interventions used to support the participation, well-being, and quality of life of people living with anxiety. The terms anxiety and stress are often used interchangeably in research. As a result, these terms require clarification. Bystritsky and Kronemyer (2014) explain that stress tends to be an external stimulus arising from the environment. Alternatively, Hallion and Ruscio (2013) describe anxiety as a persistent internal feeling of fear and worry that is intrusive in daily life. Clarifying these definitions suggests that it is more appropriate to focus solely on anxiety in this scoping review, rather than a combination of terms.

Occupation is viewed as the performance of chosen daily life tasks that provide desirable levels of pleasure, productivity, and restoration (Fisher, 2013). Examples of meaningful occupations may include (but is not exclusive to) walking in nature, interacting with the community (eg, leisure groups), or going to work (paid and unpaid). Occupational therapy interventions can be characterized as occupation based or occupation focused (Fisher, 2013). Occupation-based interventions therapeutically use the individual's participation in a chosen meaningful occupation in the context as it would unfold in that person's everyday life, for example, running, working, cooking, and as the method for evaluation. Occupation-focused interventions focus on training the specific skills required for the successful performance of an individual's chosen occupation, for example, the provision of compensatory or adaptive equipment or teaching alternative strategies during a personal care occupation such as toileting (Fisher, 2013). Interventions that are focused on changing a person's basal physiology are neither occupation based nor occupation focused.

The specific items of interest are the characteristics, outcome measures, impact, and implications for the practice of the identified interventions. Participation can be defined as the ability of a person to meaningfully engage and be satisfied with their activities of daily life and has been identified by the World Health Organization as essential to health (CSDH, 2008; Larsson-Lund & Nyman, 2017). For the purposes of this review, all types of occupational therapy interventions that support participation in meaningful occupation as the method for evaluation and intervention will be included. All modes of delivery will be incorporated, and any dosage or frequency of intervention will be considered. Examples of types of interventions include self-management, social support, and psychosocial interventions and their variants, and examples of modes of delivery include support groups, one-to-one sessions, telehealth, and digital delivery models.

Context

This scoping review will consider studies that specifically include community-based occupational therapy interventions in all countries for adults living with anxiety. This could include people with anxiety living in their own homes or other care settings.

Types of Sources

This scoping review will consider both experimental and quasi-experimental study designs including randomized controlled trials, nonrandomized controlled trials, before and after studies, and interrupted time-series studies. In addition, analytical observational studies including prospective and retrospective cohort studies, case-control studies, and analytical cross-sectional studies will be considered for inclusion. This review will also consider descriptive observational study designs including case series, individual case reports, and descriptive cross-sectional studies for inclusion.

Qualitative studies will also be considered that focus on qualitative data including, but not limited to, designs such as phenomenology, grounded theory, ethnography, qualitative description, action research, and feminist research. In addition, systematic reviews that meet the inclusion criteria will also be considered, depending on the research question. Text and opinion papers will also be considered for inclusion in this scoping review.

Review Team

The review is being conducted by a team comprised of a National Institute for Health and Care Research Clinical Doctoral Research Fellow (CL), academics (KB, IS, and JM), and an information specialist (MS).

Patient and Public Involvement

The scoping review protocol has been reviewed by an occupational therapist (AP) with experience of working in a community setting.

Search Strategy

The search strategy will aim to locate both published and unpublished studies. An initial limited search of MEDLINE, CINAHL, and PsycINFO was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles were used to develop a full search strategy for PubMed, MEDLINE, CINAHL, JBI EBP database, PLOS, Social Care Online, The Cochrane Library, Science Direct, Embase, PsycArticles, Psychology & Behavioural Sciences Collection, TRIP database, OpenGrey, OALster, and ProQuest Dissertations & Theses (Appendix 1). The search strategy, including all identified keywords and index terms, will be adapted for each included database and information source. The reference list of all included sources of evidence will be screened for additional studies. The searches will be conducted by MS and CL.

Studies published in English will be included, as the resources for translation are not available, and no date limiters will be used.

Study or Source of Evidence Selection

Following the search, all identified citations will be collated and uploaded into the bibliographic citation management system, EndNote 20.2.1 (Clarivate Analytics), and duplicates removed (The EndNote Team, 2013). The citations will be transferred to Rayyan Qatar Computing Research Institute to manage the screening process (Ouzzani et al., 2016). Following a pilot test, titles and abstracts will then be screened by two or more independent reviewers (CL and KB) for assessment against the inclusion criteria for the review. Potentially relevant sources will be retrieved in full, and their citation details imported into the JBI System for the Unified Management, Assessment, and Review of Information (Munn et al., 2019). The full text of selected citations will be assessed in detail against the inclusion criteria by 2 independent reviewers (CL and KB). The reasons for the exclusion of sources of evidence at full text that do not meet the inclusion criteria will be recorded and reported in the scoping review. Any disagreements that arise between the reviewers at each stage of the selection process will be resolved through discussion, or with an additional reviewer (JM or IS). The results of the search and the study inclusion process will be reported in full in the final scoping review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping review (PRISMA-ScR) flow diagram (Tricco et al., 2018).

Data Extraction

A data extraction form is provided (Appendix 2). The Template for Intervention Description and Replication (TIDieR) checklist will be used for data extraction (Hoffmann et al., 2014). This internationally recognized checklist for describing interventions will enable a systematic description of the interventions and their characteristics in sufficient detail to allow future replication (if required). Data will be extracted from papers included in the scoping review by 1 reviewer (CL) using the TIDieR checklist. A second reviewer (KB) will check the extracted data. The data extraction process will first be piloted by the 2 reviewers initially on 3 papers to ensure that TIDieR checklist is used consistently. The data extracted, in line with the TIDieR checklist items, will include specific details about the intervention rationale, materials, procedures, provider, delivery mode, location, dosage, modifications, and fidelity. Any disagreements that arise between the reviewers will be resolved through discussion, or with an additional reviewer. If appropriate, the authors of papers will be contacted to request missing or additional data, where required.

Ethical Considerations

Since the scoping review methodology consists of reviewing and collecting data from publicly accessible material, this study does not require ethical approval.

Results

The extracted data will be charted in tabular form using the TIDieR checklist (Hoffmann et al., 2014). A narrative summary will accompany the charted results and will describe how the results relate to the review's objective and question. The results will be presented following the TIDieR format and the main conceptual categories used in the extraction too, as well as gaps in the literature. These will be presented in relation to the question of this scoping review.

Discussion

This scoping review will produce a map of the current body of research and community-based occupational therapy interventions that are used to improve participation, quality of life, and well-being of adults living with anxiety by building on the findings of a previously published systematic review (Fox et al., 2019).

To the best of our knowledge, this is the first scoping review to map the characteristics of community-based occupational therapy interventions for community-dwelling adults living with anxiety. The comprehensive information about the characteristics of such interventions, such as the outcome measures used and impact, will make an important contribution to the development of new occupational therapy interventions and future research. Identifying the characteristics and components of currently used interventions and published research is useful in optimizing the clinical and cost-effectiveness of future treatments and studies (O'Cathain et al., 2019). As anxiety is a global health issue, these findings will be of interest not only to clinicians and researchers in the United Kingdom but also to those in the international community working in this area.

As with any review, there are several limitations to conducting the proposed scoping review. While a rigorous identification and inclusion strategy has been outlined, there remains a risk that some data which may have provided further insights are inadvertently omitted. This risk is enhanced by the challenges of searching gray literature. In addition, as scoping reviews explore the breadth of a topic and not the depth, the reviewers cannot comment on the quality of the studies included in the scoping review. The proposed scoping review will synthesize the study limitations and findings as reported by the included literature. A methodological appraisal of the included studies will not be performed. Thus, the limitations and findings reported in the proposed review are not necessarily exhaustive or interrogated beyond the peer-review process of the published article. Finally, restricting the search strategy to articles only published in English means that articles that would be eligible for inclusion have the potential to be missed.

The review authors will use the findings of this scoping review to contribute to the co-production of a new complex intervention to help people with Parkinson to live well with anxiety, embedded within the UK National Health Service. Similarly, these findings will be of value to a wider audience of health care professionals and researchers involved in service development or research projects that aim to improve the lives of people living with anxiety.

2.2 Characteristics of occupational therapy interventions for community-dwelling adults with anxiety: a scoping review

ABSTRACT

Background: Anxiety is a global health issue associated with reduced life quality and wellbeing. Developing an overview of studies of occupational therapy interventions for people with anxiety is an essential first step to understanding the existing knowledge. This will increase the impact of future interventions.

Objective: This scoping review will identify: i) what occupational therapy interventions exist for adults with anxiety; ii) the intervention characteristics, including outcomes used and impact observed.

Methods: We considered all studies and publications of occupational therapy that include community-dwelling adults with a diagnosis of anxiety who are 18 years and older and diagnosed with an anxiety disorder (DSM criteria). Databases searched were PubMed, MEDLINE, CINAHL, JBI EBP database, PLoS, Social Care Online, The Cochrane Library, Science Direct, Embase, PsycArticles, Psychology & Behavioural Sciences Collection, TRIP database, OpenGrey, OAIster, and ProQuest Dissertations & Theses. Titles and abstracts were screened against the inclusion criteria using Rayyan QCRI. Potentially relevant studies were fully retrieved and assessed against the inclusion criteria. Two independent reviewers completed the study selection. Data were extracted using a data extraction tool. Data were charted using the Template for Intervention Description and Replication (TIDieR) checklist in alignment with the review objectives.

Findings: Eighteen studies were included in the review. Articles were published in the northern hemisphere and were equally split between occupational therapy-specific and non-specific journals. Two RCTs (n=2, 11%) were included with the remainder being quasi-experimental, non-RCT designs (n=16, 89%). Articles reported multiple interventions and data collection methods in various practice settings. Eight interventions with a range of characteristics were identified. Thirty-one different outcomes were reported. Twenty-four individual impacts were observed.

Interpretation: Future research should report on the impact of occupational therapy interventions in activity as a key outcome of interest, as opposed to impairment-based outcome measures. This scoping review reinforces previous research findings and highlights the need for further high-quality research into occupation-based or occupation-focused interventions for community-welling adults living with anxiety.

Funding: The National Institute for Health and Care Research (NIHR), grant number NIHR301565, supported this work.

Systematic review registration: Open Science Framework (osf.io/js549).

KEYWORDS

Occupational Therapy; Anxiety; Adult; Health; Activities of Daily Living

INTRODUCTION

Anxiety and stress-related disorders are the ninth-highest global cause of disability (Vos et al., 2015). These disorders comprise excessive fear or worry about a current or anticipated future event (Vos et al., 2015). Anxiety disorders are highly persistent over an individual's life course, associated with higher levels of disability, reduced quality of life, and decreased participation in meaningful activity (Kessler et al., 2007). Living with an anxiety disorder leads to higher personal and societal financial expenditure. The mean annual care costs for people with anxiety in the UK is £71m (Parkinson's UK, 2017). This figure is around $52 billion in the US (Yang et al., 2019). Global financial expenditure related to anxiety disorders (combined with depression) is estimated to be approximately USD 1 trillion and is forecast to reach USD 16 trillion by 2030 (Patel et al., 2018).

Anxiety disorders profoundly influence a person's ability to participate in their chosen activities in daily life to a level with which they are satisfied, no matter the type of disorder or its origin (Duncan et al., 2014). The neurobiological and psychological stresses associated with anxiety disorders reduce both energy and motivation to complete activities of daily living (Johansson et al., 2012). This is linked to resilience and occupational adaptivity, i.e., any behaviour adjustments in response to the demands of living (Lopez, 2011). Focusing on anxiety's biochemical or cognitive aspects as part of a health intervention may not necessarily improve a person's participation in life activities. Additionally, poor functioning can continue after full or partial recovery from an anxiety disorder due to the longitudinal impact of psychosocial impairment (Rodriguez et al., 2005). The continuation of poor functioning post-recovery suggests that participation in daily life is independent of anxiety symptoms (Rodriguez et al., 2005). Participation and functioning are also stronger predictors of healthcare usage and cost than the severity of anxiety or depressive symptoms (Twomey et al., 2017). These findings highlight a need to identify the characteristics of interventions that focus on how individuals with anxiety participate in daily activities. Identifying such features will contribute to developing more targeted and effective future interventions. Furthermore, interventions targeted more appropriately may be more cost-effective (Laxminarayan et al., 2006).

The stories of those living with anxiety disorders accentuate the impact of anxiety disorders on their everyday lives. The experience of anxiety is a complex phenomenon that affects people across cultures. In a study of adults with anxiety in Iran, participants describe the experience as *"it is like I am in a cage"* and fearing rejection or neglect by others, such as mocked or losing popularity (Mohammadi et al., 2019). In the UK, the experience of anxiety and its impact has been described as:

> *"My head says I'm under attack and physically I feel like I'm under attack"* and *"it has prevented me from doing a lot of things."* (Mental Health Foundation, 2014) pg.19 & 29

The impact of anxiety disorders on social relationships and feelings of shame and embarrassment was shared by participants in a qualitative study of GP patients experiencing anxiety, depression, or both:

> *'I go to the bathroom and when I come back he says "where have you been?" I've been to the toilet. "You have been a long time." So trying to hide… (the attacks). He thinks it's stupid. It makes you feel ashamed.'* (Kadam et al., 2001) pg.378

Other long-term conditions do not prevent a person from developing an anxiety disorder. Anxiety is a common experience that negatively affects wellbeing in various long-term conditions, including Parkinson's disease, Multiple Sclerosis, and Chronic Obstructive Pulmonary Disease (Naylor et al., 2012). For example, in qualitative studies of anxiety in people with Parkinson's participants shared the following:

> *"Well I sort of, sweaty. And I feel, I feel I go starey. A bit like a rabbit in the headlights. Sometimes. And I just feel that I'm there but I'm not part of what's going on. I feel like I'm an outsider looking in, an observer of a situation rather than being part of it. . ."* (Lovegrove & Bannigan, 2021) pg.8

These experiences, ranging from the ubiquitous nature of anxiety to the negative impacts on daily life, reinforce the necessity of exploring the characteristics of interventions for people living with anxiety to inform intervention development.

Occupational therapists have historically worked with people experiencing anxiety in various settings, including (but not limited to) acute hospitals, outpatient clinics, and community settings (Bryant, 2022). In a systematic review and narrative synthesis of occupational therapy interventions for people with anxiety disorders, Fox, Erlandsson, and Shiel (2019) could not judge overall clinical effectiveness due to the heterogeneity of the identified studies. The authors highlighted the potential for replicability of the interventions in future research and as treatments. The identified studies and intervention characteristics were not charted in detail, as the review's primary aims focused on effectiveness. It is unclear if the authors adhered to the PRISMA statement for reporting a systematic review, thus limiting the review's replicability and transparency. In conclusion, Fox, Erlandsson, and Shiel (2019) highlight that future research should report on occupational therapy interventions' impact on people living with anxiety. This scoping review seeks to build on Fox, Erlandsson, and Shiel (2019) findings by updating the search and exploring and understanding the intervention characteristics. The findings of this review will aid the development of future interventions and research.

Identifying potential intervention characteristics is critical to developing new complex interventions, i.e. those with several interacting components (Skivington et al., 2021). Spending too little time on identifying attributes in the early stage of the complex intervention development cycle may lead to a flawed intervention that is lacking in clinical and cost-effectiveness (Skivington et al., 2021). Likewise, identifying the characteristics of previous occupational therapy studies will benefit the design and evaluation of new interventions by identifying knowledge gaps (Peters, Godrey, et al., 2020; Skivington et al., 2021). This approach aligns with the development stage of the “development-evaluation-implementation process” for complex interventions outlined by the Medical Research Council (Skivington et al., 2021). This approach will help ensure that future interventions are more effective when evaluated and adopted in real-world settings (Skivington et al., 2021).

A preliminary search of MEDLINE, the Cochrane Database of Systematic Reviews and *JBI Evidence Synthesis* was conducted. No current or underway systematic or scoping reviews on the topic were identified. This scoping review aims to examine and map the range and characteristics of occupational therapy interventions that have been reported to improve the participation, quality of life, and wellbeing of community-dwelling adults living with anxiety. The review findings will support the development of occupational therapy interventions to empower people to live well with their condition by improving participation in meaningful occupation, thus improving quality of life.

Review Questions

This review aims to answer the question: what occupational therapy interventions exist globally for adults with anxiety?

Specifically, this review collects and charts data to address the following sub-questions:

i) What are the characteristics of occupational therapy interventions identified?

ii) What outcome measures are used to evaluate identified occupational therapy interventions?

iii) What was the reported impact of occupational therapy interventions for adults with anxiety?

iv) What are the implications for practice and future research of the occupational therapy interventions identified?

METHODS

This scoping review followed the JBI methodology for scoping reviews (Peters, Godrey, et al., 2020). It is registered on the Open Science Framework (Lovegrove, 2021). In line with best practice, review reporting used the updated Preferred Reporting Items Systematic Reviews and Meta-Analyses Extension for Scoping Reviews checklist (PRISMA-ScR) (Appendix 3) (Skivington et al., 2021). The review followed an a priori protocol (Lovegrove et al., 2023). Any deviations from the protocol are reported and justified.

Eligibility Criteria

Participants

The review considered studies of occupational therapy that include:

- Adults with a diagnosis of anxiety who are aged 18 years and older and are resident in their own home or a care setting;
- diagnoses such as generalised anxiety disorder (GAD), panic disorder, and anxiety disorder not otherwise specified as defined by DSM criteria.

Studies for exclusion were:

- those with people without a confirmed diagnosis of an anxiety disorder;
- those concerning pharmacological interventions;
- research focused on diagnostics;
- research focused on stress or stress-related disorders.

Concept

The concept mapped within this scoping review is occupational therapy interventions used to support the participation, wellbeing, and quality of life of people with anxiety. The terms anxiety and stress have been used interchangeably in research. Consequently, these terms require clarification. Stress tends to be an external stimulus arising from the environment, whereas anxiety is a persistent internal feeling of fear and worry that is intrusive in daily life (Hallion & Ruscio, 2013). Clarifying these definitions suggests that focusing solely on anxiety in this scoping review rather than a combination of terms was more appropriate.

Occupation is regarded as performing chosen daily life tasks that provide desirable pleasure, productivity, and restoration (Larsson-Lund & Nyman, 2017). Examples of meaningful occupations may include (but not exclusively) walking in nature, interacting with the community (e.g., leisure groups), or working (paid and unpaid). Occupational therapy interventions can be occupation-based or occupation-focused (Fisher, 2013). Occupation-based interventions therapeutically use the person's participation in a chosen meaningful occupation (e.g., learning, gardening, cooking) in the context as it would unfold in their everyday life and as the method for evaluation. Occupation-focused interventions focus on training the specific skills required for the successful performance of a chosen occupation (Fisher, 2013). Examples of such interventions could be providing compensatory or adaptive equipment, teaching alternative strategies during showering, or providing fatigue management education. Interventions focused on changing a person's underlying physiology are neither occupation-based nor occupation-focused.

This review included all types of occupational therapy interventions that support participation in meaningful occupation, such as the evaluation method, intervention method, or both. All modes of delivery were included. The specific items of interest were the characteristics, outcome measures, impact, and implications for the practice of the identified interventions. Any intervention dosage or frequency was considered.

Context

This scoping review considers studies that specifically include community-based occupational therapy interventions for adults living with anxiety in all countries. These studies could have included people with anxiety residing in their own homes or other care settings.

Types of Sources

This scoping review considered both experimental and quasi-experimental study designs. These include randomised controlled trials, non-randomised controlled trials, before and after studies, and interrupted time-series studies. Analytical observational studies included prospective and retrospective cohort studies, case-control studies, and analytical cross-sectional studies. This review also included descriptive observational study designs such as case series, individual case reports, and descriptive cross-sectional studies.

This review considered studies focusing on qualitative data including, but not limited to, designs such as phenomenology, grounded theory, ethnography, qualitative description, action research, and feminist research. Text and opinion papers were considered for inclusion in this scoping review if they contributed to answering the research question.

Review team

The review team comprised of an NIHR Clinical Doctoral Research Fellow (CL), academics (KB, IS, JM), and an information specialist (MS).

An occupational therapist (AP) with experience working in a community setting reviewed the a priori protocol (Lovegrove et al., 2023). Their input aided in shaping the review aims, objectives, and inclusion criteria.

Search strategy

An information specialist (MS) was involved in designing and implementing the search strategy to support its accuracy. The search strategy aimed to locate published and unpublished primary studies, reviews, and text and opinion pieces. Two research team members (CL, MS) completed an initial limited search of MEDLINE, CINAHL, and PsycINFO to identify articles on the topic. A complete search strategy was developed using the text words in the titles and abstracts of relevant articles and their index terms. Databases searched were PubMed, MEDLINE, CINAHL, JBI EBP database, PLoS, Social Care Online, The Cochrane Library, Science Direct, Embase, PsycArticles, Psychology & Behavioural Sciences Collection, TRIP database, OpenGrey, OALster, and ProQuest Dissertations & Theses (Appendix 4). The search strategy, including all identified keywords and index terms, was adapted for each included database and information source. One team member (CL) screened the reference list of all included sources of evidence for additional studies. Two research team members completed the searches (CL, MS). Searches were completed in 2022 and repeated in 2023.

This review only includes studies published in English, as the translation resources were unavailable. The search did not use data limiters.

Study/Source of Evidence selection

Following search completion, all identified citations were collated and uploaded into the bibliographic citation management system, EndNote 20.2.1 (Clarivate Analytics, PA, USA) (The EndNote Team, 2013). Duplicates were removed. The research team made the decision not to use the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI; Adelaide, Australia) as JBI SUMARI does not offer modifiable data extraction templates, which was needed for this review (Munn et al., 2019). Citations were transferred to Rayyan QCRI (Qatar Computing Research Institute [Data Analytics], Doha, Qatar), a systematic review web application to manage the independent relevance checking process (Ouzzani et al., 2016).

Two reviewers (CL, KB) piloted a screening tool on a sample of studies. Minor adjustments were made until a consensus was reached to enhance clarity before continuing the screening process. The screening tool ensured that reviewers consistently applied the inclusion criteria and that all decisions were recorded on Rayyan QCRI. Two reviewers (CL, KB) screened the title and abstracts against the inclusion criteria. Potentially relevant papers were retrieved in full and assessed in detail against the inclusion criteria by the same two independent reviewers. Full-text studies that did not meet the inclusion criteria were excluded. All exclusion reasons were recorded. No disagreements that required discussion with the independent third reviewer (IS) arose. Per scoping review guidance (Peters, Godrey, et al., 2020), studies were not quality assessed, as this scoping review aimed to map available evidence rather than understanding methodological quality.

Data Extraction

Alongside data about impact and outcomes, data about intervention characteristics were extracted using The Template for Intervention Description and Replication (TIDieR) checklist (Appendix 2) (Hoffmann et al., 2014). This internationally recognised checklist for describing interventions enabled a systematic description of the interventions and their characteristics in sufficient detail to allow future replication (if required). Two independent reviewers (CL, KB) piloted the TIDieR on a sample of three articles to ensure its consistent use. One reviewer (CL) extracted data from papers included in the scoping review using the TIDieR checklist. A second reviewer (KB) checked the extracted data. Discrepancies were addressed and clarified without involving the third reviewer (IS). In line with the TIDieR checklist items, the extracted data includes specific details about the intervention rationale, materials, procedures, provider, delivery mode, location, dosage, modifications, and fidelity. One reviewer (CL) contacted the authors of papers to request missing or additional data where required.

Data Presentation

As specified in the protocol and recommended in the JBI scoping review guidance (Lovegrove et al., 2023; Peters, Godrey, et al., 2020), the extracted data is presented in diagrammatic and tabular form. A PRISMA flow diagram was generated using an online tool (Haddaway et al., 2022). The extracted data is charted in tabular form using the TIDieR checklist (Hoffmann et al., 2014). A narrative summary accompanies the charted results and describes how the results relate to the review objectives and questions. A mapping approach to analysis was used as the scoping review's objective is to collate the range of existing evidence and describe the methodological characteristics of existing research rather than synthesising or appraising the evidence. The results are presented following the TIDieR format, the main conceptual categories used in the extraction, and gaps in the literature.

FINDINGS

Database and secondary searching returned 9,913 records (Figure 2.1). Due to the number and range of databases searched, a high number of duplicates were identified. After removing duplicates, 2,058 underwent title and abstract screening with 2,037 articles excluded. Full-text screening led to the exclusion of a further three articles. Most studies were excluded due to not having an occupational therapy focus or for including anxiety as a secondary outcome. A final total of 18 records were included in the review (Chugh-Gupta et al., 2013; Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021; Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018; Kitchiner et al., 2009; Lambert et al., 2008; Lambert et al., 2007; Lambert et al., 2010; Lork et al., 2021; Prior, 1998a, 1998b; Rosier et al., 1998). Full charting of the included articles is included as a supplementary file (Appendix 5). The characteristics of the included studies are presented in Table 2.1. Across the 18 included studies, articles were published predominantly in northern hemisphere countries (n=16/18, 89%) with the remainder not stated (Table 2.1). Articles were published equally in occupational therapy-specific and non-specific journals (n=9/18; 50%). Most studies adopted a non-RCT/quasi-experimental design (n=6/18; 33%); studies reporting RCTs were also highly represented (n=5/18; 28%) (Table 2.2). Studies took place in a variety of practice settings and have used multiple interventions and multiple data collection methods, including interviews and observation and multiple types of outcome data. The included articles will now be mapped to answer each question of this review.

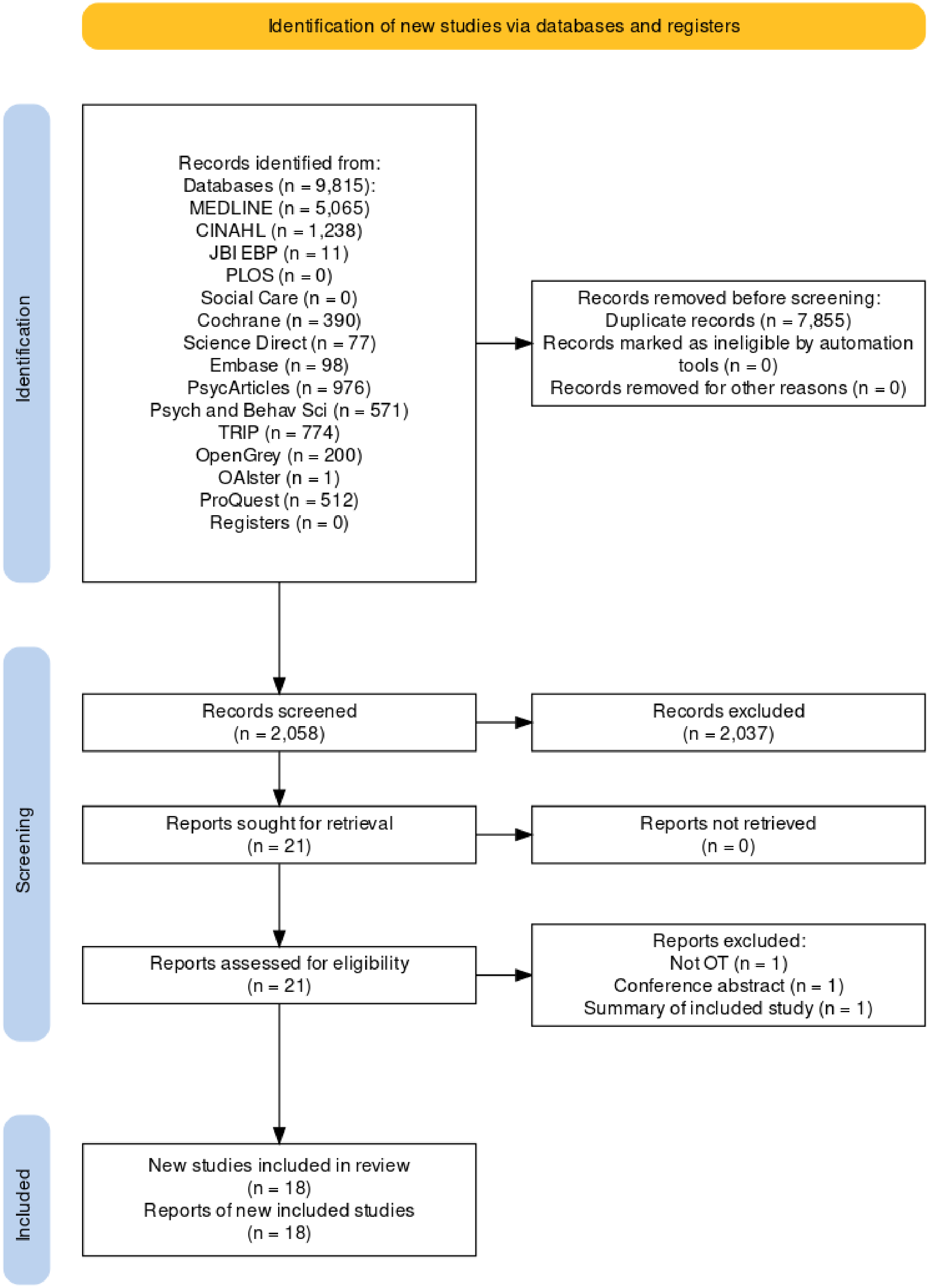


Figure 2.1: Search results and study selection and inclusion process (30, 48)

Article Characteristics	Empirical (n=18)
Publication year	
1998	3
2006	2
2008	1
2009	1
2010	1
2013	4
2014	1
2015	1
2018	1
2019	2
2021	1
Publication type	
Journal article	18
Methodology	
RCT	5 (1 report)
Non-RCT/ quasi-experimental	6
Systematic review	2
Case study research	1
Economic evaluation	1
Intervention development	1
Intervention description	1
Mixed method	0
Qualitative	1
Intervention Agreed	
Lifestyle	9
Psychological anxiety management	4
Art	3
Exercise	1
Not specified (systematic review)	1
Geographical context	
Sweden	8
England	6
Ireland	1
Wales	1
Not stated (but author locations stated)	2
Setting	
Participant's home	0
Primary healthcare centre	9
Mental healthcare centre (inc. Community team)	3
Dual primary and mental healthcare	0
Outpatients	1
Secondary healthcare	0
University	1
Not explicitly stated	4

Table 2.2: Characteristics of included articles.

What are the characteristics of occupational therapy interventions identified?

There was a range of characteristics across the studies (Table 2.3). Eight interventions were identified across the 18 studies. These were Yoga, Redesigning Daily Occupations (ReDO), The Tree Theme Method (TTM), anxiety management group (psycho-educational), occupational therapy-led lifestyle approach, work-directed rehabilitation, short-term anxiety management course, and an anxiety management group (community mental health). Studies were collated and analysed together if they used the same intervention protocol, such as the ReDO programme. Group work was the predominant delivery method (n=5/8 interventions, 63%) (Chugh-Gupta et al., 2013; Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021; Kitchiner et al., 2009; Lambert et al., 2008; Lambert et al., 2007; Lambert et al., 2010; Prior, 1998a, 1998b; Rosier et al., 1998). Three interventions were delivered 1:1 (n=3/8 interventions, 25%) (Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018; Lork et al., 2021). One intervention used both groups and 1:1 sessions (n=1/8 interventions, 12%) (Chugh-Gupta et al., 2013). Seven of the interventions were delivered by an occupational therapist (n=7/8 interventions, 88%) (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021; Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018; Kitchiner et al., 2009; Lambert et al., 2008; Lambert et al., 2007; Lambert et al., 2010; Lork et al., 2021; Prior, 1998a, 1998b), with the remainder by trained instructors (n=1/8, 12%) (Chugh-Gupta et al., 2013). Seven interventions used a structured approach (n=7/8 interventions, 88%) (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021; Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018; Kitchiner et al., 2009; Lambert et al., 2008; Lambert et al., 2007; Lambert et al., 2010; Lork et al., 2021;

Prior, 1998a, 1998b). Goal setting was used in four interventions (n=4/8 interventions, 50%) (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021; Lork et al., 2021; Prior, 1998a, 1998b; Rosier et al., 1998). Tailoring, where the intervention content is adapted for an individual, was used in two interventions (n=2/8 interventions, 25%) (Lork et al., 2021; Rosier et al., 1998). Two of the interventions used follow-ups (n=2/8 interventions, 25%) (Lork et al., 2021; Rosier et al., 1998). Cognitive behavioural therapy (CBT) was used in three interventions (n=3/8 interventions, 38%) (Fox et al., 2019; Kitchiner et al., 2009; Prior, 1998a, 1998b; Rosier et al., 1998). Lifestyle redesign® or management approaches were used in three interventions (n=3/8 interventions, 38%) (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021). Modifications and the involvement of family, loved ones, or carers were each used in one intervention (n=1/8 interventions, 12%) (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013).

Source	Characteristics											
	Name of intervention	Delivered by an occupational therapist	Group	1:1	Structured	Goal setting	Tailoring	Modifications	Family/ loved ones/ carers involved?	Follow-up	Cognitive behavioural therapy	Lifestyle redesign®/ management
Chugh- Gupta *et al.,* 2013	Yoga		X	X								
Eklund and Erlandsson, 2013; Eklund *et al.* 2013; Erlandsson, 2013; Eklund, 2014; Fox *et al.,* 2019; Fox *et al.,* 2021)	Redesigning Daily Occupations (ReDO)	X	X		X	X		X	X			X
Gunnarsson *et al.,* 2006; 2015; 2018	The Tree Theme Method (TTM)	X		X	X							
Kitchiner *et al.,* 2009; Fox *et al.* 2019	Anxiety management group	X	X		X						X	
Lambert *et al.,* 2007; 2008; 2010; Fox *et al.,* 2019	Occupational therapy-led lifestyle approach	X	X		X							X
Lork *et al., 2019*	Work-directed rehabilitation provided by OTs and PTs to promote work capacity in CMDs	X		X	X	X	X			X		X
Prior 1998a.; 1998b.; Fox *et al.,* 2019	Short-term anxiety management course	X	X		X	X					X	
Rosier *et al.,* 1998	Anxiety management groups	X	X		X	X	X			X	X	

Table 2.3. Characteristics of the identified interventions.

What outcome measures are used to evaluate identified occupational therapy interventions?

Thirty-one different outcomes were identified (Table 2.4). Two interventions did not report outcome measures reported (n=2/8 interventions, 25%). Four outcomes were occupational therapy-specific measures (n=4/31, 13%; Canadian Occupational Performance Measure, COPM; Occupational value assessment with predefined items, Oval-pd; Satisfation with

Daily Occupations, SDO; Occupational Balance Questionairre, OBQ) and were used in one of the eight interventions (n=1/8 interventions, 12%) (Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018). Most measures were specifically used to measure anxiety (n=9/31, 29%) and were used in five interventions (n=5/8 interventions, 63%) (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021; Kitchiner et al., 2009; Lambert et al., 2008; Lambert et al., 2007; Lambert et al., 2010; Prior, 1998a, 1998b). These were the Positive and Negative Affect Schedule (PANAS), State-Trait Anxiety Inventory (STAI), Depression Anxiety Stress Scale (DASS), Hospital Anxiety and Depression Scale (HADS), Anxiety Disorders Interview Schedule (ADIS-IV), Beck Anxiety Inventory (BAI), Fear Questionnaire, and Performance Anxiety Questionnaire. Three quality of life measures were used (n=3/31 measures, 10%) in three interventions (n=3/8 interventions, 38%) (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021; Lambert et al., 2008; Lambert et al., 2007; Lambert et al., 2010). These were the 36-Item Short Form Survey (SF-36), Manchester Short Assessment of Quality of Life (MANSA), the EuroQol-5D (EQ-5D), and the EuroQol visual analogue scale (EQ-VAS). Three work-specific outcome measures (n=3/31, measures 10%) were used in three interventions (n=3/8 interventions, 38%) (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021; Kitchiner et al., 2009). These were the Work and Social Adjustment Scale (WSAS), Work Readiness Scale (WRS), and the Work Environment Impact Scale- Self Rating (WEIS-SR). Two life satisfaction measures (n=2/31 measures, 6%), the Client Satisfaction Questionnaire (CSQ) and the Sense of Coherence Scale (SOC), and were used in three interventions (n=3/8 interventions, 38%) (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018; Prior, 1998a, 1998b). Two measures, the Beck's

Depression Inventory (BDI-II) and Montgomery-Åsberg Depression Rating Scale- Self report (MADRS-S), were used to specifically measure depression (n=2/31 measures, 6%) and were used in three interventions (n=3/8 interventions, 38%) (Kitchiner et al., 2009; Lambert et al., 2008; Lambert et al., 2007; Lambert et al., 2010). A stress-specific measure (Perceived Stress Scale, PSS) was used in two interventions (n=2/8 interventions, 25%) (Chugh-Gupta et al., 2013; Eklund, 2013). Measures used to assess economic (quality-adjusted life years, QALYs; Incremental Cost-Effectiveness Ratios, ICERs), physiological, psychopathology (Symptom Checklist-90-Revised, SCL-90-r), therapeutic relationships (Health assessment questionnaire-II, Haq-II), disability (WHO Disability Assessment Schedule, WHODAS 2.0), mastery (Pearlin Mastery Scale, PMS), and general health (General Health Questionnaire- 28, GHQ-28) were used once each (n=1/31 measures, 3%; total n=8/31 measures, 26%), and were used across five interventions (n=5/8, interventions 63%) (Chugh-Gupta et al., 2013; Fox et al., 2021; Gunnarsson et al., 2015; Gunnarsson et al., 2018; Kitchiner et al., 2009; Lambert et al., 2010).

Intervention	Outcome measures used in the included studies																														
	PANAS	STAI	HADS	PSS	MANSA	PMS	CSQ	WRS	WEIS-SR	GHQ-28	COPM	DASS	WHODAS 2.0	OVal-pd	PMS	EQ-5D-5L/ EQ-	BAI	ADIS-IV	SF-36	BDI-II	QALYs/ ICERs	SCL-90-r	MADRS-S	SDO	OBQ	SOC	HAq-II	Life and Social Adjustment Scale (WSAS)	Fear Questionnaire	Performance Anxiety Questionnaire	Physiological
Yoga	X	X	X	X																										X	X
Redesigning Daily Occupations			X	X	X	X	X	X	X			X	X	X	X	X															
The Tree Theme Method (TTM)					X		X				X												X	X	X	X					
Anxiety management group										X										X								X	X		
Occupational therapy-led lifestyle approach																X	X	X	X	X	X	X							X		
Work-directed rehabilitation provided by OTs and PTs to promote work capacity in CMDs																															
Short-term anxiety management course			X				X																					X	X		
Anxiety management groups																															

Table 2.4. Outcome measures used in the interventions.

What was the reported impact of occupational therapy interventions for adults with anxiety?

Twenty-four individual impacts were observed across the eight interventions (Table 2.5). Impacts were defined as any identifiable positive or negative influence for the person's health or functioning, service delivery, or costs (Cruz Rivera et al., 2017). Anxiety reduction was most common across seven interventions (n=7/8 interventions, 86%) (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Kitchiner et al., 2009; Lambert et al., 2008; Lambert et al., 2007; Lambert et al., 2010; Lork et al., 2021; Prior, 1998a, 1998b; Rosier et al., 1998). Greater behaviour awareness was an observed impact in five interventions (n=5/8 interventions, 63%) (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021; Kitchiner et al., 2009; Lambert et al., 2008; Lambert et al., 2007; Lork et al., 2021; Rosier et al., 1998). Other observed impacts were at the process level. Intervention satisfaction (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Fox et al., 2019; Fox et al., 2021; *International handbook of occupational therapy interventions*, 2015; Prior, 1998a, 1998b; Rosier et al., 1998), acceptability (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018; Prior, 1998a, 1998b), delivered as intended (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021; Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018), and increased understanding (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018; Lambert et al., 2008; Lambert et al., 2007) were each observed three times (n=3/8 interventions, 38%). Increased quality of life (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Fox et al., 2019; Fox et al., 2021; Lambert et al., 2008; Lambert et al., 2007; Lambert et al., 2010), enhanced satisfaction (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Fox et al., 2019; Fox et al., 2021; Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018; Rosier et al., 1998), improved coping (Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018; Rosier et al., 1998), general health improvement (Chugh-Gupta et al., 2013; Lambert et al., 2008; Lambert et al., 2007), extra workload (Fox et al., 2021; Rosier et al., 1998), depression reduction (Eklund, 2013; Kitchiner et al., 2009), time-consuming (Lambert et al., 2008; Lambert et al., 2007; Prior, 1998a, 1998b), and follow-ups (Prior, 1998a, 1998b; Rosier et al., 1998) were observed twice each (n=2/8 interventions, 25%). The remaining impacts were observed once each (12%) (Eklund, 2013; Eklund &

Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021; Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018; Lambert et al., 2008; Lambert et al., 2007; Prior, 1998a). The need for further research on impact was identified across six interventions (n=6/8 interventions, 75%) (Chugh-Gupta et al., 2013; Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021; Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018; Kitchiner et al., 2009; Lork et al., 2021; Prior, 1998a, 1998b).

Regarding individual interventions, the Redesigning Daily Occupations (ReDO) programme had the most observed impacts at fourteen (n=14/24, 58%) (Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2019; Fox et al., 2021). The Tree Theme Method (TTM), occupational therapy-led lifestyle approaches, and short-term anxiety management course had seven observed impacts (n=7/24, 29%) (Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018; Lambert et al., 2008; Lambert et al., 2007; Lambert et al., 2010; Prior, 1998a; Prior & Campbell, 2018). The community anxiety management groups observed six impacts (n=6/24, 25%) (Rosier et al., 1998). The taught anxiety management group had five observed impacts (n=5/24, 21%) (Kitchiner et al., 2009). Finally, work-directed rehabilitation and yoga had three observed impacts (n=3/24, 13%) (Chugh-Gupta et al., 2013; Lork et al., 2021).

Intervention	Impact observed																							
	Anxiety reduction	Improved quality of life	Enhanced satisfaction	Improved coping	General health improvement	Long term effects	Intervention satisfaction	Increased paid work engagement/ reduced sick leave	Acceptable	Extra workload	Delivered as intended	Value for money	Research needed	Self-Mastery	Depression reduction	Increased understanding	Helps assist client to tell life story	Panic reduction	Lifestyle review	Reduced fear	Greater behaviours awareness	Time-consuming	Followed up	Redesigning daily occupations
Yoga (Chugh-Gupta *et al.,* 2013)	**X**				**X**								**X**											
Redesigning Daily Occupations (ReDO) (Eklund and Erlandsson, 2013; Eklund *et al.* 2013; Erlandsson, 2013; Eklund, 2014; Fox *et al.,* 2019; 2021)	**X**	**X**	**X**				**X**	**X**	**X**	**X**	**X**		**X**	**X**	**X**	**X**					**X**			**X**
The Tree Theme Method (TTM) (Gunnarsson *et al.,* 2006; 2015; 2018)			**X**	**X**					**X**		**X**		**X**			**X**	**X**							
Anxiety management group (Kitchiner *et al.,* 2009; Fox *et al.* 2019)	**X**										**X**		**X**		**X**						**X**			
Occupational therapy-led lifestyle approach (Lambert *et al.,* 2007; 2008; 2010; Fox *et al.,* 2019)	**X**	**X**			**X**							**X**				**X**			**X**	**X**	**X**	**X**		
Work-directed rehabilitation provided by OTs and PTs to promote work capacity in CMDs (Lork *et al., 2019)*	**X**												**X**								**X**			
Short-term anxiety management course (Prior 1998a.; 1998b.; Fox *et al.,* 2019)	**X**					**X**	**X**		**X**				**X**									**X**	**X**	
Anxiety management groups (Rosier *et al.,* 1998)	**X**			**X**			**X**			**X**											**X**		**X**	

Table 2.5. Observed impacts of the interventions.

DISCUSSION

This scoping review explored what occupational therapy interventions exist globally for community-dwelling adults with anxiety. It extends previous research (Fox et al., 2019) to identify the characteristics of these interventions, the outcome measures used to evaluate them, and their reported impact. Eighteen articles were identified that report on eight interventions with a range of characteristics, outcomes, and impacts reported. Interventions were delivered in a variety of settings using different methods.

Group therapy was the main method of delivering interventions to adults living with anxiety (n=5/8 interventions, 63%). Group therapy is associated with various beneficial therapeutic factors, such as universality, cohesiveness, and service-level benefits (Lambert et al., 2010; Malhotra & Baker, 2023). Participants often find groups acceptable, finding it helpful to share experiences and provide peer support, which can be instrumental in supporting change (Fox et al., 2019; Fox et al., 2021; Lambert et al., 2008; Lambert et al., 2007). Whilst group work generally involves additional workload, occupational therapists in one study found this acceptable, and there are benefits in treating more people at a time (Fox et al., 2021). Despite the seemingly overwhelming benefits, group therapy has potential disadvantages that need consideration. Group delivery can mean that there is less opportunity for clinicians to spend time with a person and to tailor interventions to their individual needs (Whitfield, 2010). When discussing intimate experiences such as anxiety, groups may seem intimidating, and there may be a preference to do this on an individual basis (Lovegrove et al., 2017). Other interventions (n=3/8 interventions) reported positive impacts from 1:1 individual therapy with similar reports of acceptability (Chugh-Gupta et al., 2013; Gunnarsson et al., 2006; Gunnarsson et al., 2015; Gunnarsson et al., 2018). Most interventions reported using a structured approach (n=7/8). This is not surprising as structured interventions that account for context and complexity are both effective and recommended (Hawe, 2015; Skivington et al., 2021). Future occupational therapy research and interventions should be vigilant in exploring the best way of addressing people's needs and not assume that this will automatically be via group therapy work.

Goal setting was used in four interventions (n=4/8 interventions, 50%). This is not surprising given the evidence for using goal setting in occupational therapy (Arbesman & Logsdon, 2011; Hand et al., 2011; Scobbie et al., 2011). In anxiety interventions, goal setting is effective via mechanisms such as open communication, collaboration, and hope (Jacob et al., 2022; Richardson, 2023). Goal setting is often used to tailor interventions to a person's specific needs, yet tailoring (n=2/8 interventions, 25%) and modification (n=1/8 interventions, 12%) were not routinely used in the reported interventions. This seems at odds with the person-centred ethos of occupational therapy and the focus on meaningful activity, particularly considering the effectiveness of tailored interventions and their impact on reducing health disparities (Baker et al., 2015; Campbell & Quintiliani, 2006). This finding underscores the importance of using a checklist such as the TIDieR so that aspects that likely contribute to the mechanisms of change are not missed. Research using methodologies such as realist evaluation is needed to enhance understanding of such working mechanisms (Lemire et al., 2020).

The involvement of family, loved ones, or carers was only reported in one intervention (n=1/8 interventions, 12%) (Eklund & Erlandsson, 2013; Eklund et al., 2013; Erlandsson, 2013; Fox et al., 2021). This was unexpected considering that the want for said involvement has been clearly expressed by various patient groups (Dijkman et al., 2022; Lovegrove et al., 2017; Prior & Campbell, 2018). Future occupational therapy and interventions should utilise goal setting and intervention tailoring to enhance effectiveness where feasible.

Outcome measures are important to determine the effectiveness of an intervention and are used widely in healthcare, including occupational therapy (Laver Fawcett, 2014). The ReDO programmes described the most observed impacts (n=14/24, 58%). This is perhaps to be expected as the studies evaluating this intervention also reported the most outcome measures (n=12/27, 44%) and thus had the most data from which to report. Because the interventions were designed to address anxiety, it is not surprising that anxiety-specific measures were widely used. Fortunately, anxiety reduction was also the most observed impact (n=7/8 interventions, 86%). Quality of life measures were also used for similar reasons (Barbalat et al., 2019; Mercieca-Bebber et al., 2018), despite only being used in three interventions (n=3/8 interventions, 37%). Only one intervention (n=1/8 interventions, 12%) reported using occupational therapy-specific outcome measures(Eklund, 2013; Eklund & Erlandsson, 2013; Eklund et al., 2013; Fox et al., 2021). Therefore, it could be argued that the impact of occupational therapy on occupational performance in meaningful activity is only measured in one of the reviewed interventions.

Despite the growing need for health professions to demonstrate cost-effectiveness in an increasingly financially constrained climate, only one intervention was economically evaluated (Lambert et al., 2010). This finding reflects the current low number of health-economic evaluations of occupational therapy interventions, which will be important to address as global financial challenges continue (Green & Lambert, 2017). Future research studies and interventions should include validated occupational therapy outcomes and economic evaluations to document and evaluate their contribution to a person’s health outcomes (Leland et al., 2015).

What are the implications for practice and future research of the occupational therapy interventions identified?

Future research should report on the impact of occupational therapy interventions on activity as a key outcome of interest, as in conjunction with select impairment-based outcome measures. Participation or function was not reported as an outcome in seven interventions included in this review, including in two randomised controlled trials (n=7/8 interventions, 86%) (Kitchiner et al., 2009; Lambert et al., 2007). We recommended that functioning and participation in meaningful occupations be measured as core outcomes of occupational therapy interventions for anxiety in future clinical trials. These should be included alongside impairment-based measures to facilitate more comprehensive measurement of people’s health.

The need for further research was noted in six interventions (n=6/8 interventions, 75%). The structure of the interventions is not clearly described in all the reported interventions, which makes replication difficult (Klein et al., 2000). Rigorous, well-powered studies need to be conducted to test occupational therapy interventions for adults living with anxiety. The studies included in this review demonstrate that it is possible to complete RCTs and quasi-experimental studies in this clinical area. The need for more high-quality research in occupational therapy, particularly in mental health, has been well documented in the literature (Bannigan et al., 2008; Kirsh et al., 2019). This review reinforces previous research and highlights the need for high-quality research into occupation-based or occupation-focused interventions for community-welling adults living with anxiety that include economic evaluations (Fox et al., 2019; Mackenzie et al., 2017).

Strengths and limitations

This review searched published and grey literature to conduct a comprehensive review. It followed a peer-reviewed protocol with systematic and transparent processes (Lovegrove et al., 2023). JBI methodology for conducting scoping reviews was followed (Peters, Godrey, et al., 2020; Peters, Marnie, et al., 2020). Bibliographic software (Endnote) and systematic review software (Rayyan) was used to robustly manage citations and the screening process (Ouzzani et al., 2016; The EndNote Team, 2013).

Fifteen databases were searched. No further relevant articles were identified through websites or citation searching, confirming that a thorough search was conducted. The research team made some decisions to balance a comprehensive search with available resources that may have affected the inclusivity of this review. English language limits and Western-dominant databases were used because of translation resource availability within the research team. All included articles originate from Northern Hemisphere countries, which may reflect this (Table 2.1). Thus, the research team may have missed articles published in other languages and eligible for inclusion, which means we may have missed valuable insights.

Scoping reviews explore the breadth of a topic and not the depth. As such, the research team cannot comment on the quality of the included studies. Methodological appraisal of the included studies was not performed. Consequently, the limitations and findings reported in the proposed review are not exhaustive or examined beyond the peer-review process of the published article.

CONCLUSION

Anxiety is a common global cause of disability (Vos et al., 2015). Occupational therapists work to enable people to participate in everyday life activities to a level they are satisfied with (World Federation of Occupational Therapists, 2019). This scoping review aimed to determine what occupational therapy interventions exist globally for adults with anxiety. Eighteen studies were included in the review, which report on eight different interventions for this group of people. A range of outcome measures were used but only one intervention employed occupational therapy-specific measures. Future interventions and research should be vigilant to use occupational therapy outcome measures alongside appropriate impairment-based measures. This will allow proper evaluation of the effectiveness of occupational therapy services that aim to improve occupational performance and participation of people living with anxiety. The majority of interventions were delivered in groups, but both the potential benefits of individual occupational therapy sessions should not be ignored. Goal setting and tailoring should be used to enhance the effectiveness and impact of occupational therapy interventions for adults living with anxiety. Rigorously designed clinical trials of occupational therapy interventions for adults living with anxiety are needed; these should include economic evaluations to demonstrate cost-effectiveness.

Acknowledgements

The authors thank Anna Paisey (AP) for contributing to developing this scoping review's protocol. A list of abbreviations is provided in Appendix 6.

Chapter 3: Group Concept Mapping Study

The scoping review contributed to the thesis by identifying the evidence; part of the 'development' stage of the MRC complex intervention framework (Skivington et al., 2021). The next component of this stage is identifying and developing theory (Figure 1.5). A consensus study using group concept mapping was conducted to identify the key components required for the co-production of the OBtAIN-PD. This chapter presents the peer-reviewed article of this study. This novel participatory study highlighted priority components that provide starting points for future development of an occupation- and community-based intervention for people with PD-related anxiety.

Understanding and addressing the priorities of relevant stakeholders is crucial in healthcare decision-making, especially in situations with limited evidence or resources (Arakawa & Bader, 2022; Carter et al., 2023). Consensus methods help prioritise research questions, trial outcomes, clinical guidelines, medical education topics, and resource allocation (Arakawa & Bader, 2022; Carter et al., 2023). They also play a key role in complex intervention development by combining evidence with expert opinion to prioritise components for inclusion (Farquhar et al., 2013; Johnston et al., 2020). Common features of consensus methods include standardised materials, moderated interactions, private polling, and iterative feedback from the group (Arakawa & Bader, 2022).

Andre Delbecq and Andrew Van de Ven developed nominal group testing (NGT) in the late 1960s to generate ideas and reach consensus (Van de Ven & Delbecq, 1972). The process involves four steps: brainstorming, idea reduction, idea prioritisation, and consensus building. Participants generate ideas, then reduce the list, rank the remaining ideas, and work together to reach a consensus.

Nominal Group Testing is effective for idea generation, especially when many stakeholders have diverse opinions, or when the topic is sensitive and people are reluctant to share their views publicly (Maguire et al., 2022; Vahedian-Shahroodi et al., 2023). However, it may not be suitable for complex problems that require critical thinking and analysis (Vahedian-Shahroodi et al., 2023).

One risk of the NGT process is that opinions may not converge in the voting process, making the process more time-consuming for participants and necessitating additional rounds (Maguire et al., 2022; McMillan et al., 2016). This may make NGT more difficult for those managing complex long-term health conditions, such as Parkinson's. Additionally, due to the structure of NGT, there is a risk that the cross-fertilization of ideas may be reduced or lost, potentially resulting in the loss of innovative ideas (Manera et al., 2019; McMillan et al., 2014).

The Delphi method, also known as the Delphi process or Delphi technique, is a communication method used to obtain a group consensus from panels of experts. It involves using one or more rounds of questionnaires shared anonymously with participants, with controlled feedback following each round (Khodyakov, Grant, Kroger, & Bauman, 2023). This method ensures that decision-making is based on the convergence of expert opinion. It was originally developed by the RAND Corporation in the 1950s to survey expert opinion, gather information, and forecast the impact of new technologies on future defence policy (Khodyakov, Grant, Kroger, & Bauman, 2023). More recently, the Delphi consensus method has been a popular way to gain controlled feedback and group opinion and to define best practices in various fields, including healthcare (Niederberger et al., 2021).

The Delphi method has numerous strengths. First, it allows experts to communicate through a mediator (a researcher), facilitating rational academic debate by eliminating obstacles (Ismail & Taliep, 2023). Therefore, this method prevents direct confrontations among experts and connects existing knowledge and areas of agreement/disagreement. The Delphi method enables anonymity, promoting creativity, honesty, and balanced consideration of ideas while reducing the risk of negative group dynamics affecting outcomes (Ismail & Taliep, 2023). It has been argued that downsides associated with group dynamics, such as manipulation or coercion to conform to a certain viewpoint, can be minimized (Ismail & Taliep, 2023). This reduces the effect of noise, which distorts data and focuses on group and/or individual interests rather than problem-solving (Naisola-Ruiter, 2022). Lastly, the Delphi method enables group communication without geographical constraints, saving time and money by reducing travel costs (Naisola-Ruiter, 2022; Niederberger et al., 2021).

The Delphi method lacks clear guidance and agreed-upon standards for interpreting and analyzing results, as well as universally accepted definitions of consensus and criteria for selecting participants (Khodyakov, Grant, Kroger, Gadwah-Meaden, et al., 2023; Niederberger et al., 2021). This can make the process time-consuming and laborious for both researchers and participants, leading to drop-outs. Factors contributing to drop-outs include long-term commitment, distractions between rounds, and participant dissatisfaction with the process (Donohoe & Needham, 2009). The use of monetary payments or moral persuasion to convince participants may introduce bias into the results (Iqbal & Pipon-Young, 2009; Ismail & Taliep, 2023).

While the Delphi method's anonymity has its strengths, it can also lead to less ownership of ideas (Iqbal & Pipon-Young, 2009). Methodological limitations include challenges in generalizing results to a wider population due to sample size, varying response rates among invited experts, limited perspectives, uneven distribution of expertise among participants, and participants' specific agendas or geographic/cultural locations (Hsu & Sandford, 2007; Ismail & Taliep, 2023; Nambisan et al., 1999; Niederman et al., 1991).

A potential weakness of the Delphi method is the considerable discretion given to researchers in its application. As the quality of feedback determines the procedure's success, thorough analysis of responses becomes a significant responsibility for the researcher (Cuhls, 2023; Ismail & Taliep, 2023). Furthermore, it can be challenging to define what constitutes sufficient consensus in the Delphi procedure (Donohoe & Needham, 2009). The independence of experts' responses in the Delphi process may be compromised, especially when the experts are in contact with one another (Devaney & Henchion, 2018; Taylor, 2020).

Group concept mapping is a consensus method that helps a group organise their ideas on any topic and represent them visually in interconnected maps (Kane & Trochim, 2007). It combines qualitative and quantitative data collection and analysis approaches, making it an integrative mixed method (Kane & Trochim, 2007; Trochim & McLinden, 2017). This process allows for collaboration among groups of any size and with diverse participants. It combines the ideas of diverse participants to show what the group thinks and values in relation to the specific topic of interest. It is a structured conceptualization used by groups to develop a conceptual framework, often to help guide evaluation and planning efforts (Kane & Trochim, 2007). Group concept mapping is participatory in nature, allowing participants to have an equal voice and to contribute through various methods. As participants can see the statements of other stakeholders in the sorting and rating stage, the cross-fertilization of ideas is enabled (Napier-Raman et al., 2023). For these reasons, group concept mapping was selected over other consensus methods for the development of the OBtAIN-PD.

A group concept map visually represents all of a group's ideas and how they relate to each other. Depending on the scale, it shows which ideas are more relevant, important, or feasible (Rosas, 2017). Group concept mapping has been widely used in various fields, such as community and public health, social work, health care, human services, biomedical research and evaluation, and complex intervention development (Rosas, 2020).

Group concept mapping is a structured multi-step process. It includes brainstorming, sorting and rating, multidimensional scaling, cluster analysis, and the generation and interpretation of multiple maps (Kane & Trochim, 2007; Rosas, 2017). The first step requires participants to brainstorm a large set of statements relevant to the topic of interest, usually in response to a focus prompt. Participants are then asked to individually sort those statements into categories based on their perceived similarity and rate each statement on one or more scales, such as importance or feasibility.

The data is analyzed using ‘Groupwisdom™’ software (*The Concept System® groupwisdom™*, 2020). This software creates a series of interrelated maps by using multidimensional scaling of the sort data, hierarchical clustering of the multidimensional scaling coordinates applying Ward's method (Ward, 1963), and calculating average ratings for each statement and cluster of statements. The resulting maps display the individual statements in a two-dimensional space. Statements that are more similar are located closer to each other, and the statements are grouped into clusters that partition the space on the map. The ‘Groupwisdom™’software also generates other maps that show the statements in each cluster rated on one or more scales, and absolute or relative cluster ratings between two cluster sets. Lastly, participants go through a structured interpretation session to better understand and label all the maps.

The article in this chapter is the Word version accepted for publication in *Journal of Parkinson’s Disease* (Lovegrove et al., 2024). The main thesis bibliography includes the full list of references for the article to improve readability. The article uses language in keeping with the journal’s style, including US English and terms such as “Parkinson’s disease”.

3.1 Concept mapping to define components for an occupation-based intervention for Parkinson's & Anxiety

Abstract

Background: Anxiety, a common symptom of Parkinson’s disease (PD), results in reduced life quality, reduced participation in meaningful roles and daily activities, and increased health burden. There are no evidence-based interventions to reduce the impact of anxiety in PD on participation.

Objectives: This study aimed to identify the key components required for the co-production of an occupation- and community-based intervention for people with PD-related anxiety.

Methods: A participatory mixed-methods research study was conducted using online Group Concept Mapping methodology that included five stages: brainstorming, idea synthesis, sorting activity, rating activity, and analysis. A cluster map, pattern match, and ‘go-zone’ charts were created through multivariate statistical analysis based on participants' responses. The stages were guided by questions generated by the research team working with stakeholders.

Results: Eighty-three people participated, with 64 taking part in more than one activity. Participants included people with PD (n=72), care partners (n=6), and occupational therapists (n=5). The final map contained 119 statements with eight clusters (stress value 0.252): exercise, lifestyle changes, self-help, coping, access to information, professional help, peers and groups, support from others. Significant agreement existed between the importance and feasibility rating activities (*r* = -0.07). ‘Go-zone’ charts highlighted the priority statements for intervention development.

Conclusions: This novel participatory study highlighted priority components that provide starting points for future development of an occupation- and community-based intervention for people with PD-related anxiety.

Introduction

Parkinson’s disease (PD) is the second-most common neurodegenerative condition in the UK, affecting approximately 145,000 people (Parkinson’s UK, 2014). In addition to the cardinal motor symptoms of bradykinesia, rigidity, and tremor, PD also results in a wide range of sensory, cognitive, and psychological non-motor symptoms (Kalia & Lang, 2015). These can cause significant disability, interfere with participation in everyday roles and activities, and reduce quality of life (Duncan et al., 2014; Kalia & Lang, 2015).

Anxiety is a non-motor symptom that affects around 40-56% of people with PD (Pontone & Mills, 2021). People with PD fall more than age-matched controls, and risk factors for falling include fear of falling, which is influenced by anxiety (Dissanayaka et al., 2014; Farombi et al., 2016). Reviews indicate no effective pharmacological interventions to reduce anxiety in people with PD (Pontone & Mills, 2021). Psychological interventions for anxiety in non-Parkinsonian populations, recommended in the UK as part of NICE guidelines and the Improving Access to Psychological Therapies (IAPTs) programme (National Collaborating Centre for Mental Health, 2018; NICE, 2011), are cost-effective and have long-term financial and health benefits (Heuzenroeder et al., 2004). However, evidence for the effectiveness of mindfulness and cognitive behavioural therapy approaches is limited and inconclusive in people with PD (Biundo et al., 2016; Hofmann et al., 2010; Johnsen & Friborg, 2015; McLean et al., 2017). Additional approaches are also warranted, given the shortage of clinical psychologists in the UK (The King's Fund, 2015) and the central role of restricted participation in contributing to increased chronic anxiety (Coventry et al., 2014; CSDH, 2008)[15, 16].

People with PD have expressed a desire for an intervention aimed at living well with the complex experience of anxiety with PD, focused on 'doing' (i.e., participation in meaningful occupation) as both a means and a goal of intervention rather than only talking about thoughts and feelings (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017). With their dual training in physical and mental health and expertise in improving wellbeing through participation, occupational therapists are in an ideal position to support people with PD experiencing anxiety (Christine, 1990).

Occupational therapy focuses primarily on enabling participation in a person's chosen meaningful roles and activities, such as getting dressed, cooking a family dinner, or playing the piano in a jazz band (World Federation of Occupational Therapists, 2019). Access to occupational therapy is recommended in clinical guidelines to support symptom management, promote independence, and reduce hospital admissions. Research suggests that occupational therapy focused on the person's prioritized meaningful goals in activities in daily living and participation, is an effective intervention for people with PD (Radder et al., 2016; Sturkenboom et al., 2014). No identified best-practice occupational therapy intervention exists for people with PD with anxiety-related participation problems.

With a high prevalence of anxiety in people with PD, but little research into its management, it is essential to establish a sound scientific basis for developing an intervention based on the Medical Research Council's guidance for complex interventions (Skivington et al., 2021). As a first step in intervention development, this study involved all stakeholders as a precursor to a logic modeling process. It aimed to identify the components needed to co-produce a new occupation-based intervention to help people with PD live well with anxiety.

Methods

Study design

Consensus methods, such as nominal group technique and the Delphi methodology, are commonly used to generate and/or validate the components of a health intervention (Cantrill et al., 1996). However, these approaches struggle to engage diverse groups, particularly rarely heard groups (Cook & Bergeron, 2019). In contrast, Group Concept Mapping (GCM)

> "(1) generates group wisdom by creating consensus on key ideas and supports systems thinking by eliciting individual experiences to identify group conceptualization of an issue; (2) equalizes or lessens power differentials among participants; (3) engages patients as both study participants and collaborative decision makers throughout the research process; and (4) includes the availability of specific web-based software to engage participants, provide project management, and generate concept maps" (Cook & Bergeron, 2019) [page 2]

Therefore, GCM was used to identify the components needed for a new occupation-based complex intervention. It involved qualitative and quantitative methods in a structured, sequential process to organize the ideas of a group about a topic—people with PD living well with anxiety—and involved brainstorming, sorting, and rating (qualitative processes) combined with multivariate statistical analysis (quantitative) (Kane & Trochim, 2007). These ideas are then visually represented using two-dimensional concept maps (Kane & Trochim, 2007). This versatile method can be implemented in paper form or using a secure online platform called 'Groupwisdom™' (*The Concept System® groupwisdom™*, 2020), enabling participants to contribute at their convenience (Cook & Bergeron, 2019).

Ethical approval was secured from the University of Plymouth Faculty of Health Staff Research Ethics and Integrity Committee (Reference 2473).

Participants and Recruitment

Sample size in GCM studies varies depending on the question and data collection method (Nielsen et al., 2018). The recruitment target of n=40 was based on previous studies that have reported attrition of 10% between the GCM stages and reaching data saturation in stage 5 (Nielsen et al., 2018; Sjodahl Hammarlund et al., 2014; Trochim & McLinden, 2017). The sample was divided into three groups— people with PD, care partners, and occupational therapists (13-14 participants per group)— to avoid potential power differences between group participants. Occupational therapists were included based on feedback from patient and public involvement (PPI) stakeholders who contributed to the study design and felt that it was important to include therapists' perspectives. Twelve weeks were allocated for recruitment.

Purposive sampling was used and was targeted to ensure a diverse range of respondents—recruitment materials targeted age (for all groups) and diagnosis duration (for people with

PD). Inclusion criteria for our target sample were people with PD with a formal diagnosis of PD with self-reported Parkinson's-related anxiety, any care partner of a person with PD-related anxiety, and occupational therapists working with people with PD or with expertise in working with people with anxiety. Formal assessment of anxiety status was not used to avoid missing rich experiential data.

People with PD and care partners were recruited via the Parkinson's UK Research Support Network and the Peninsula Parkinson's Research Interest Group (PenPRIG). Occupational therapists were recruited via the Royal College of Occupational Therapists specialist sections for neurological practice (SSNP) and mental health (SSMH). A member of each organisation acted as a gatekeeper and sent out email advertisements to their distribution lists. The gatekeeper protected the autonomy of prospective participants and allowed them to decide freely whether they wished to participate. The email invitations included a copy of the participant information sheet and the lead researcher's (CL) contact details. Interested participants contacted the lead researcher, who answered any questions presented and then sent a weblink to 'Groupwisdom™', which required participants to complete an informed consent form.

Participants were asked to engage in three out of five stages of the GCM: brainstorming, sorting, and rating (see below). Each stage was open for two to four weeks; an invitation and two email reminders were sent to participants at each stage.

Data collection

There were five specific stages: *brainstorming* ideas in response to the focus prompt, using open text (stage 1), *idea synthesis* by the research team (stage 2), participants *sorting* the brainstormed statements into groups that made sense to them (stage 3), participants *rating* each statement on its importance and feasibility (stage 4), and data analysis (stage 5) (Kane & Trochim, 2007; Trochim & McLinden, 2017). Participants could access 'Groupwisdom™' at a convenient time and place during each stage and contribute as much data as they wished; no data limiters were used. Participants initially provided demographic information, including their role in the research (i.e., if they were a person with PD, care partner, or occupational therapist), gender, age, and how long they had been diagnosed with PD (if appropriate).

Stage 1: Brainstorming

Participants were asked to generate statements based on their thoughts and experiences in response to the focus prompt *"one thing that would help a person with Parkinson's to live well with anxiety might be…"*. There was a two-week window for participants to complete the brainstorming stage.

Stage 2: Idea Synthesis

The list of the participants' raw statements was exported to a spreadsheet, interrogated, and edited for grammar and readability without changing the wording. Statements expressing multiple ideas were split into single-idea statements; these were the only edits performed. All statements were assigned a keyword generated from the participants' language to express their meaning. Statements with similar keywords were scrutinised together, and duplicates were removed. The result was a final set of refined, unique statements for use in the later stages (Kane & Trochim, 2007).

Stage 3: Sorting Activity

Each statement in the final set was assigned a number and listed in random order on the 'Groupwisdom™' software. Each participant was asked to sort statements into groups that were meaningful to them by dragging and dropping them onto a blank workspace in the software. Participants were also asked to give each group a relevant name. For the data to be approved for further analysis, participants must have sorted ≥75% of the statements into meaningful themes (Kane & Trochim, 2007).

Stage 4: Rating Activity

Stage 4 ran simultaneously with stage 3 to reduce participant time burden. They were asked to rate each idea on a five-point ordinal scale for importance and feasibility to facilitate the identification of priority items. Importance ranged from 1 (*'not at all important')* to 5 (*'very important'),* and feasibility from 1 (*'not realistic at all'*) to 5 (*'very realistic')*. Participants were asked to rate each statement with all the others to ensure that the full range of the scale was used. Similar rating questions have been used in other GCM studies (Murray-Mendes et al., 2021). Both activities were closed after three weeks.

Stage 5: Analysis

Qualitative and quantitative techniques were used to analyse the data. The 'Groupwisdom™' software combined the sorted data into a similarity matrix, showing each statement as a position on an X-Y axis indicating how participants sorted statements. The similarity matrix produced a two-dimensional point map using a multidimensional scaling process. The closer points represented statements that were more often grouped together because the participants thought they were conceptually similar (Kane & Trochim, 2007)[27]. The software generated a stress value that indicated the degree to which the distances between each point on the map were representative of the sorting data. Lower stress values suggest greater stability and goodness-of-fit. Stress values below 0.365 are desirable for GCM research studies (Kane & Trochim, 2007; Trochim & McLinden, 2017).

Hierarchical cluster analysis was applied to the data using Ward's method to group statements with similar meanings into clusters representing how participants grouped their ideas (Ward, 1963). This statistical technique was performed in the 'Groupwisdom$^{\text{TM}}$' software and involves drawing boundaries onto the point map to produce a cluster map. Clusters are successively merged, resulting in several viable cluster maps. A final cluster 'solution' is then selected through qualitative interpretative analysis (Kane & Trochim, 2007). In this research study, the first author (CL) consulted with the rest of the research team (KB, JM, IS) to evaluate maps of six to nine clusters to determine the final cluster solution. This process involved checking whether the statements within each cluster represented the overall theme and comparing the cluster maps to each other to check for similarities and discrepancies between cluster statements and titles.

Cluster labels were suggested by the software for the final cluster solution based on the verbatim statements made by the participants during the sorting activity. The research team refined the cluster labels for grammar and readability, but the wording was unchanged.

The rated data were then organized into a pattern match as a visual representation of the data. This allowed comparison of each cluster's mean importance and feasibility (Kane & Trochim, 2007) and helped highlight priority themes for future intervention development. Individual go-zone graphs were created for each cluster, indicating which statements within the cluster were the most important and feasible. Go-zones are bivariate graphs divided into four quadrants by the mean scores generated for importance and feasibility (Kane &

Trochim, 2007). The upper right quadrant contained the statements that scored above the mean for importance and feasibility. Statements in the 'go-zone' were considered priority statements for intervention development (Appendix 7). These visual representations of the data are intended to aid in the appraisal and subsequent use of the results in a future intervention development study.

Rigor and Validity

The participatory approach of the GCM methodology promoted both the credibility and real-world applicability of the findings by ensuring that the results directly represented the participants' experiences and ideas. A senior researcher (KB) peer reviewed the cluster map to ensure that the headings represented the participants' language.

Data Sharing

The data supporting the results of this study are available from the corresponding author upon reasonable request.

Results

Study population

The final sample consisted of 83 who participated in at least one activity and 64 who participated in more than one activity. The final sample was predominantly female. The recruitment target for people with PD was exceeded (n=72). The care partner (n=6) and occupational therapist (n=5) groups were under-recruited. There was attrition between the study phases (Figure 1) with 38% (n=27) of people with PD, 33% (n=2) of care partners, and 80% (n=4) participating in the final phase.

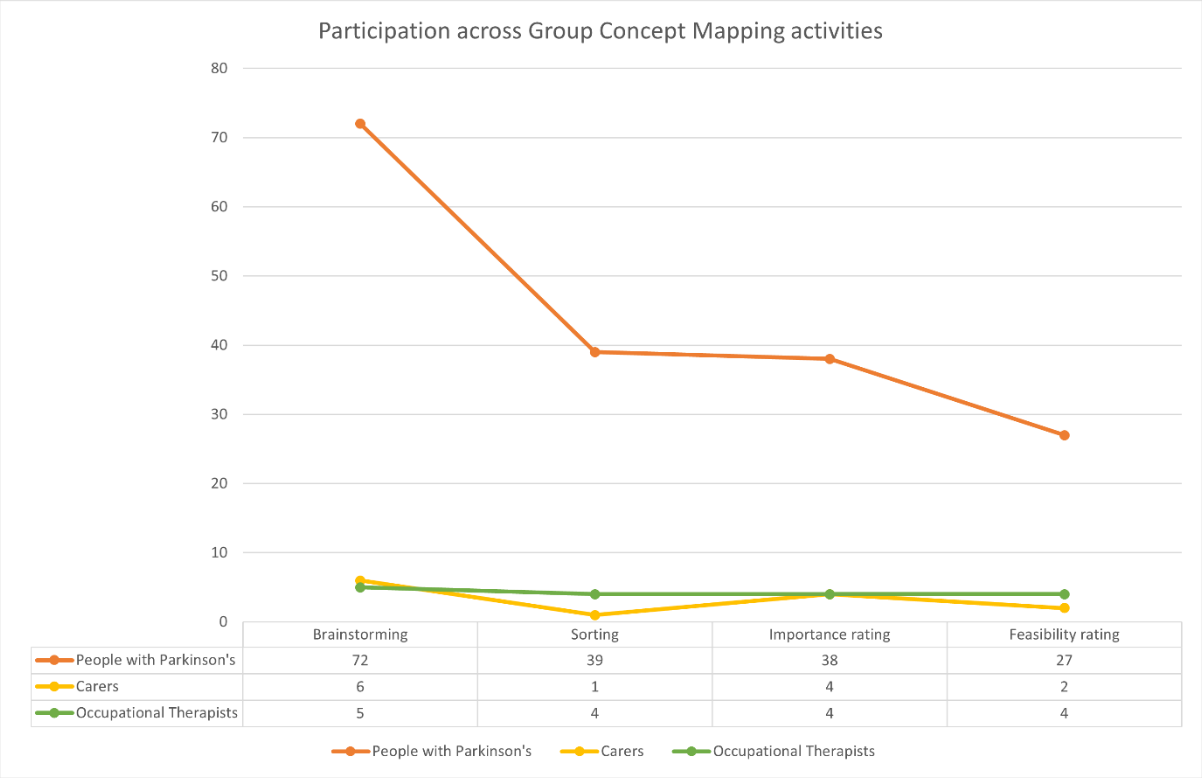
Figure 3.1 shows how many participants from each sample group took part in each activity. During brainstorming, participants provided 198 ideas in response to the focus prompt which were synthesized into a list of 119 unique statements (Appendix 7). One participant's sorting data was rejected because less than 75% of statements were sorted. Forty-four data sets from the sorting activity were approved for analysis. From the rating activity, one participant's feasibility rating data set was rejected due to rating less than 75% of the statements, with 33 approved for analysis.

Because the participants used the 'Groupwisdom$^{\mathrm{TM}}$' software at different times for the activities open for specified periods, some participants skipped, did not have the opportunity, or chose not to answer the demographic questions (n=12). Participant characteristics of respondents to demographic questions are shown in Table 3.1.

Table 3.1: Participant characteristics of respondents to demographic questions.

	Characteristic	**All participants (n=83)**	**People with Parkinson's (n=72)**	**Care Partners (n=6)**	**Occupational Therapists (n=5)**
Gender	Male	34 (41%)	32 (44%)	1 (17%)	1 (20%)
	Female	46 (55%)	37 (52%)	5 (83%)	4 (80%)
	Other (including transgender)	3 (4%)	3 (4%)	0	0
	35-44* years	3 (4%)	1 (1%)	0	2 (40%)
	45-64 years	34 (41%)	28 (39%)	3 (50%)	3 (60%)
	65-74 years	34 (41%)	33 (46%)	1 (17%)	0
	75 years and above	12 (14%)	10 (14%)	2 (33%)	0
	Median years PD diagnosis duration (range)	n/a	5 (1.0-21.0)	n/a	n/a

*No participants younger than this were involved in the study



	Brainstorming	Sorting	Importance rating	Feasibility rating
People with Parkinson's	72	39	38	27
Carers	6	1	4	2
Occupational Therapists	5	4	4	4

Figure 3.1: Line graph summarising participation across each GCM activity.

Concept Map

Multidimensional scaling of the data from all participant groups resulted in a point map with a stress value of 0.252. This score indicates the goodness of fit of the sorting data, i.e., the sample data are likely to represent the data that would be expected in the actual population (Maydeu-Olivares & Garcia-Forero, 2010). After the hierarchical cluster analysis, several cluster maps were generated and reviewed by the research team and a patient and public involvement (PPI) representative. Consensus was reached on an eight-cluster solution with the following cluster names taken directly from the participants' contributions: Access to information, Professional help, Peers and groups, Support from others, Coping, Self-help, Lifestyle changes, and Exercise. The cluster map is shown in Figure 3.2. A point on the map represents each numbered statement (see Appendix 7).

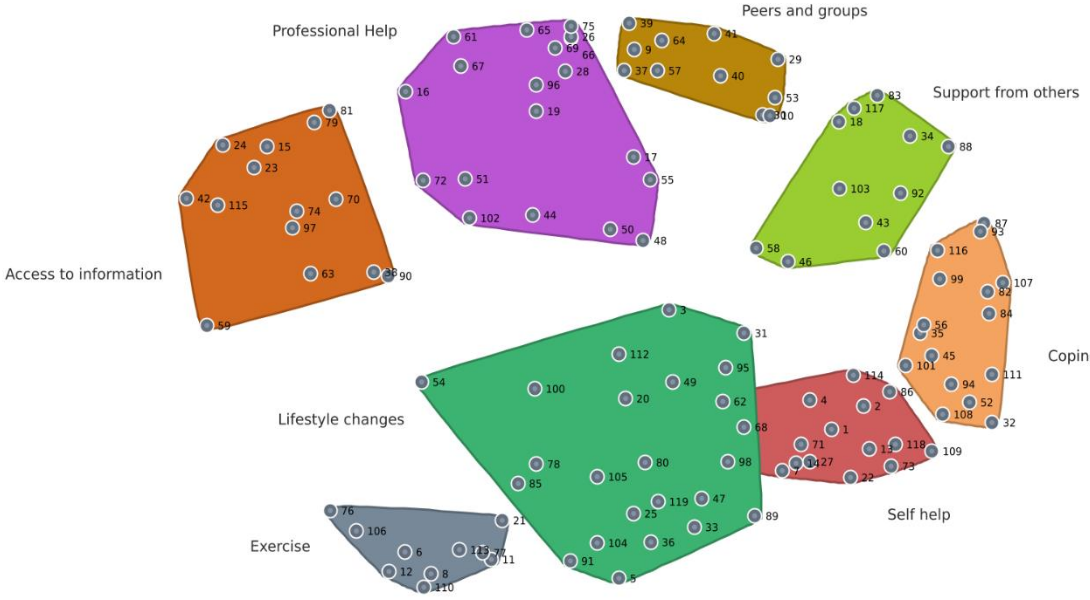


Figure 3.2: Cluster map showing eight priority themes for intervention development. The map shows the distribution of each statement as a numbered point.

Pattern Match

A pattern match compares the eight clusters' mean rating scores for importance and feasibility (Figure 3.3). The clusters are ranked along the vertical lines representing importance (left) and feasibility (right). The pattern match shows that three clusters were rated higher for importance than feasibility (*Professional Help, Peers and groups, Support from others*). The remaining clusters were rated higher for feasibility than importance (*Self-help, Lifestyle changes, Access to information, Coping, Exercise*). The overall correlation between the two rating patterns shows no to negligible relationship between importance and feasibility ratings across clusters (*r* = -0.07).

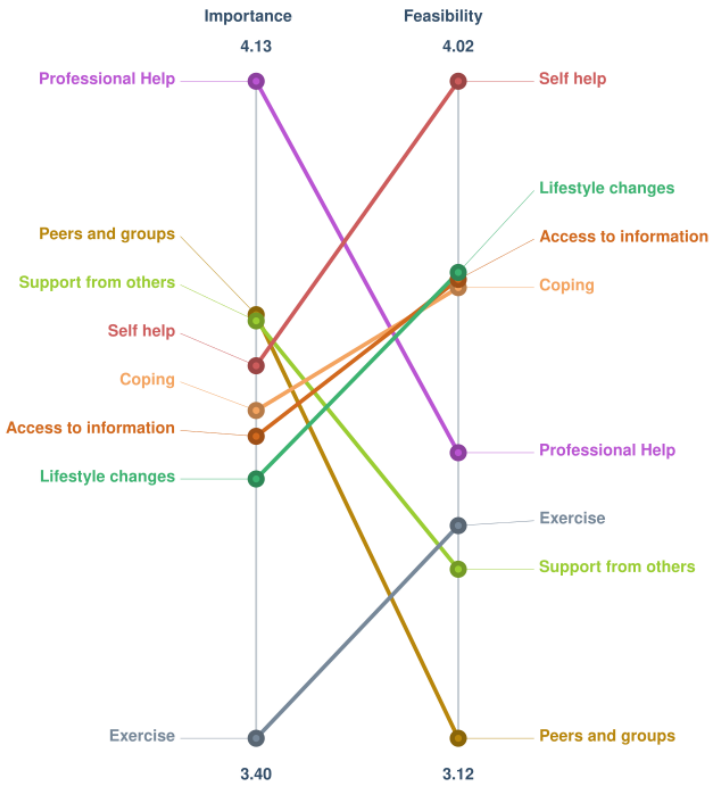


Figure 3.3: Pattern match comparing the mean importance and feasibility rating scores at the cluster level (upper limit= 5). Higher mean scores are closer to the pattern match's top (*r* = -0.07). Importance (n=46); feasibility (n=33).

Go-Zone Graphs and Statements

Go-zone graphs that were generated for each cluster are presented in Figure 3.4. Statements in the go-zones are identified as actionable priorities. Those with high importance and high feasibility were of particular interest, as they are considered priority themes for intervention development. Those with high importance but slightly lower feasibility are areas for future intervention development but are not immediate priorities.

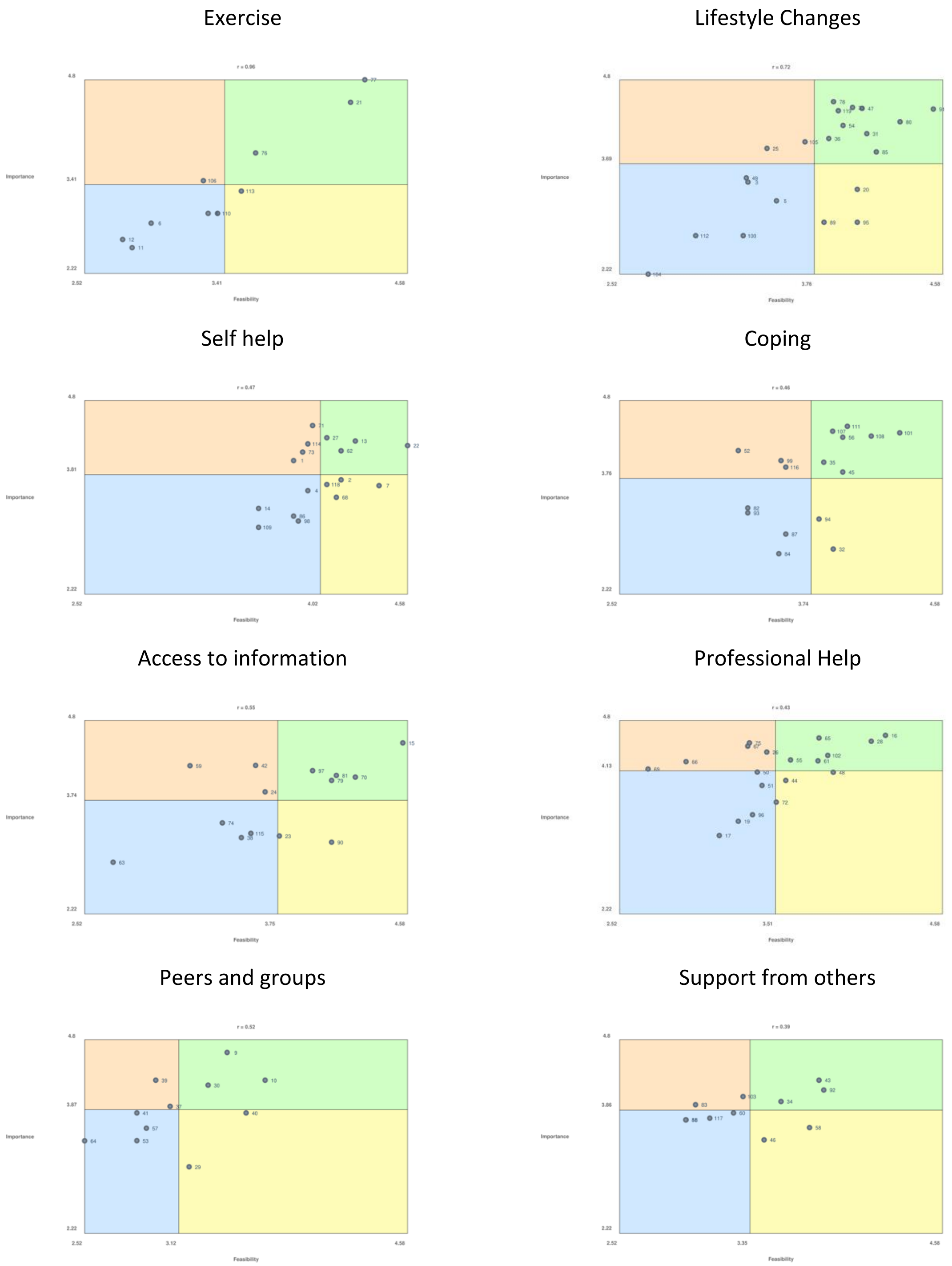


Figure 3.4: Go-zone plots for each of the eight clusters. Statements are shown as numbered points (see appendix 7). The upper right quadrant of each plot represents statements considered priorities for intervention development. The upper left quadrant represents areas for future development. Importance (n=46); feasibility (n=33).

The eight clusters represent a common understanding among participants of the key components for future intervention development.

“Professional Help”

This cluster was rated as the most important (Figure 3.3). There are 18 statements in this cluster. A common theme within this cluster is increasing clinicians' condition-specific knowledge, such as:

> *“Understanding how PD anxiety is different from other anxiety.”* (Statement 102)

Participants felt it was important and feasible for clinicians to understand anxiety in PD, consistent with previous research on clinical expertise in care teams and observational data (Talebi et al., 2023).

“Peers and groups”

This cluster was ranked second for importance but last for feasibility (Figure 3.3) and consists of 11 statements. Access to people and groups with experience of PD-related anxiety was a common theme:

> *“A matched and paired “Buddy” to discuss developments with”* (Statement 57)

> *“Having a structured support network with a list of who is responsible for what.”* (Statement 40)

“Support from others”

While superficially like the previous cluster, the 11 statements in this cluster highlight the specific qualities that people with PD would like to see people, in their social context, exhibit to support them in their anxiety:

"Encouragement to share anxiety with partners and close friends." (Statement 92)

"One to one support to improve self-confidence." (Statement 18)

The participants identified this cluster as important and feasible (Figure 3.3) which suggests that educating people in their social context about people with PD living with anxiety should be a core component of the intervention.

"Self help"

The 17 statements in this cluster relate to ways in which people with PD can help themselves to manage their anxiety so that they can live well with anxiety and PD. This cluster was rated fourth in importance and first in feasibility (Figure 3.3), suggesting that the intervention should include a substantial self-help component in order to:

"To simplify your life." (Statement 1)

"Exploring different ways to relax." (Statement 13)

Relaxation techniques that are easy and quick to implement were identified in the go-zone. These findings suggest that relaxation techniques commonly used for anxiety (e.g., box breathing exercises) should be central to the new intervention (Manzoni et al., 2008).

"Coping"

The concept of coping as a strategy for reducing the unpleasant feelings associated with anxiety is embodied in this cluster. The 16 statements in this cluster focused on coping with the emotional impact of anxiety, for example:

"Finding out what triggers your anxiety." (Statement 107)

"Accepting my condition rather than being frustrated by what I can't do." (Statement 111)

Addressing these pressures may provide a viable method of coping with anxiety for people with PD. Several statements in this cluster (statements 45, 108, 111) highlight learning to accept living with a long-term incurable illness as an important and feasible component of the proposed intervention (Figure 3.3).

"Access to information"

Statements in this cluster relate to people with PD not only having access to information about their condition when they need it but also being educated about the condition that they are living with, for example:

"Access to up to date research." (Statement 79)

"Better information and support regarding the later stages of Parkinson's Disease." (Statement 81)

Statements in this cluster suggest the provision of written information as important and feasible (Figure 3.4).

“Lifestyle changes”

This cluster ranked seventh in importance and second in feasibility (Figure 3.3) and contains 21 statements. The importance of engaging in meaningful activities coupled with lifestyle adjustments (such as improving diet and increasing physical activity) to manage anxiety is woven throughout the cluster, for example:

> *“Maintaining social interests e.g. sports.”* (Statement 78)

> *“Having a balanced diet.”* (Statement 80)

“Exercise”

The 10 statements in this cluster relate to physical exercise such as dancing (statement 6), yoga (statement 113), and tai chi (statement 8). However, exercise was rated the least important and sixth most feasible for an intervention to support people with PD s with anxiety (Figure 3.3).

Discussion

It could be argued that all clusters generated in this study are essential components of the new intervention, as no clusters or individual statements were rated lower than 3 (slightly important) on importance. The inclusion of feasibility ratings, therefore, highlighted clusters that should be targeted as a priority. Participation in meaningful roles and activities is included in several clusters (*“Exercise”, “Lifestyle changes”, “Self help”*) but not in clusters such as “*Coping”* and “*Support from others”*. These clusters highlight broader individual and social factors that support participation in meaningful occupation and will need to be considered in intervention development.

“*Professional Help”* was rated as the most important cluster by participants. People with PD identify a lack of understanding among professionals about PD and PD-related anxiety as a barrier to quality healthcare, which has been reflected in national campaigns in the UK (Parkinson’s UK, 2014; Read et al., 2019). This reinforces the notion that there is still much work to be done in this area and that clinician training in PD will be critical to the success of the new intervention. Improving clinicians’ understanding of PD-related anxiety would likely strengthen a positive therapeutic relationship (Horton et al., 2021). Establishing positive relationships with healthcare providers, in this case occupational therapists, can support maintaining a degree of normality and identity for people with PD (Read et al., 2019). This improvement in the relationship with healthcare providers may also reduce the ‘treatment burden’ for people with PD by optimizing treatment to work toward individual goals and minimize disruptions (Tan et al., 2023). This is consistent with research exploring patient-centered management of people with PD (Bloem et al., 2020).

The cluster *“Peers and groups”* highlights that participants consider timely access to peer support important, consistent with research exploring patient-centered management of PD (Bloem et al., 2020). Peer support can enhance social connectedness and help people with PD lead meaningful and satisfying lives. This is reflected in research exploring the lived experience of anxiety in PD and will be an important consideration for the next stage of intervention development (Lovegrove & Bannigan, 2021). Other research has identified that people with PD value support from people who understand what triggers their problems (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017). Fostering a ‘partnership’ between people with PD and their peers will help to create a safe environment for people with PD to share their experiences (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017). This partnership approach has been used in other interventions for long-term conditions (Apostol et al., 2021).

Peer support offers unique benefits from shared lived experiences (Gerritzen et al., 2022). Nevertheless, several potential barriers exist to accessing peer support (Gerritzen et al., 2022). This is possibly reflected in the participant's low feasibility rating of the cluster. Similar findings were highlighted in the *"Support from others"* cluster. This cluster focuses on fostering partnerships with people without PD who understand the triggers of people with PD, which is consistent with studies highlighting the need for emotional support (Uebelacker et al., 2014). It will be important to explore how such barriers to accessing peer support and support from others can be mitigated for individuals developing a new intervention.

"Self help" and *"Coping"* were identified as separate clusters by participants but are closely related. This is evidenced by the physical proximity and similar size of the clusters on the map (Figure 3.2) and similar importance ratings (Figure 3.3). Both clusters include self-management statements. Self-management strategies are effective in PD, but many focus primarily on motor symptoms (Milne-Ives et al., 2022). Although this may not seem applicable to a new intervention focusing on anxiety, several studies report that motor symptoms are closely related to anxiety in people with PD (Blundell et al., 2023; Lovegrove & Bannigan, 2021). Time pressure has been associated with increased anxiety, increased motor symptoms such as freezing of gait, and decreased quality of life in PD (Duncan et al., 2014; Lovegrove & Bannigan, 2021). Self-management techniques can provide a sense of empowerment through mechanisms such as participation in decision-making (Kang et al., 2022). Including self-management techniques addressing anxiety related to motor

symptoms, and vice versa, in a new intervention may be valuable. While people with PD have expressed that they do not want another psychological therapy, a new intervention based on a collaborative relationship with a healthcare professional may include psychological therapy concepts (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017). Acceptance and commitment therapy is a form of psychotherapy that enables people to focus on the present moment and accept their thoughts and feelings without judgment; it can be included under the umbrella term ‘talking therapies’ (Graham et al., 2016). This therapy has promising evidence of initial effectiveness in the self-management of long-term conditions including PD and provides an underlying concept for intervention development (Graham et al., 2016).

People with PD use fewer coping strategies than people with other long-term conditions (Costa et al., 2016; Pusswald et al., 2012). Many tend to use “self-control” (Costa et al., 2016; Pusswald et al., 2012). Women with PD tend to have more problem-focused coping strategies than men, but people with PD generally use both problem-focused and emotion-focused coping strategies (Anzaldi & Shifren, 2019). In addition, cognitive impairments, common in PD, are associated with decreased use of task-related coping (Fang et al., 2020; Hurt et al., 2012). Feelings of shame related to having PD can negatively affect coping and self-management and exacerbate anxiety symptoms (Angulo et al., 2019). Any new intervention will need to incorporate tailoring and individualization of treatment to account for these variations in coping strategies and the impact of cognitive impairment and emotional state (Ambrosio et al., 2014).

Participants rated having “*Access to information”* as a feasible component to include in the new intervention. This is consistent with previous research highlighting this need for education (McLaughlin et al., 2011; Uebelacker et al., 2014). Disease-specific education interventions have evidenced improvement in people with PD quality of life, potentially through patient empowerment (Rajan et al., 2020). Ensuring that patient education is delivered in a way that is both culturally and individually specific will be crucial to the successful delivery of the intervention and will likely involve a range of media (Friedman et al., 2011). Any information provided in a new intervention will need to be concise, approachable, and non-threatening to promote engagement, particularly as people with PD report “wanting to know but not wanting to know” (Read et al., 2022).

“*Lifestyle changes”* were similarly highlighted as feasible by participants, including maintaining social interests, engaging with hobbies, and integrating daily exercise and physical activity (Figure 3.4). The value of using preventative lifestyle programmes has been demonstrated to be a cost-effective way to improve health and wellbeing in myriad studies, including occupational therapy and provides a concept for future intervention (Clark et al., 2012). Similar concepts have been used in other lifestyle management interventions (Forsyth et al., 2015; Piotrowski et al., 2021). Participants also reported that maintaining a healthy diet is both important and feasible for living well with anxiety, which was also reported in other studies (Piotrowski et al., 2021; Pyatak et al., 2022). This links closely with the cluster “*Exercise*”.

Exercise was rated the least important and sixth most feasible for an intervention supporting people with anxiety with PD (Figure 3.3). As previously discussed, this may reflect a lack of understanding and education about PD. Exercise is an evidence-based intervention in PD that has demonstrated benefits on the motor symptoms of PD, but there is only emerging evidence on the effect on non-motor symptoms such as anxiety (Ng et al., 2021). Exercise has been shown to decrease anxiety in people with PD and is not restricted to a specific type of exercise (Ferreira et al., 2018; Kwok et al., 2019). Despite this, many barriers prevent sustained engagement in exercise and physical activity despite people with PD recognising its importance (Ellis et al., 2013; Hunter et al., 2019). Given the benefits of exercise on quality of life and anxiety in non-Parkinsonian populations, incorporating regular exercise into the daily routine may be a helpful component of the new intervention (Kandola & Stubbs, 2020). The new intervention will likely need to integrate these wider lifestyle components to promote sustained engagement in meaningful roles and activities to promote living well with anxiety.

In the next stage of intervention development, we will consider to what extent and in what way the key components can be included in a community- and occupation-based occupational therapy intervention. This will require a suitable method to meaningfully involve stakeholders (people with PD, care partners, and occupational therapists) in a co-production process.

Strengths and Limitations

A strength of the GCM methodology is its structured and systematic procedure to data collection that places the voice of the participants, most of whom were people with PD with anxiety, at the center. The eight clusters portray what the participants feel is important to include in a new intervention to help people with PD to live well with anxiety. In addition, the large number of statements suggests a range of thoughts among the participants, not just those of dominant group members. Online delivery using the 'Groupwisdom^{TM}' platform allowed participants to contribute to the study at their convenience, thus facilitating participation.

This study is not without limitations. The sample size exceeded our target (n=40) and was heavily weighted towards people with PD (n=72). Attrition occurred despite the research team's efforts to maintain study participation, such as automated email and text message reminders when requested by participants. This likely resulted in additional attrition bias that skewed the results and compromised the study's external validity.

Anxiety tends to occur earlier in PD and may be an early symptom of neurodegeneration (Seritan et al., 2019). This is reflected in the average disease duration of the participants (median 5 years). Evidence suggests that people living with young-onset PD (YOPD, diagnosed before 50 years) are more likely to experience anxiety than people with a late-onset of the disease (Dissanayaka et al., 2010). It would be reasonable to expect this to be reflected in the characteristics of the participants. However, we can only be confident that 1% of participants with PD meet the YOPD criterion (Table 3.1). The next age group (45-64) accounted for 39% of the sample. As these age groups are based on the UK census, we cannot determine how many participants would be considered YOPD. Although our sample would still represent those aged 65 and above (60%), it would be helpful to use adjusted age groups in future research to distinguish between early and late-onset PD.

Small numbers of care partners and occupational therapists participated compared to people with PD. Thus, we cannot be confident that our findings represent all the groups included in this GCM study as they are likely weighted towards the views and experiences of people with PD. The under-recruitment in both care partner and occupational therapist groups may partly be attributed to the COVID-19 pandemic, which has had a noted impact on non-COVID-19 research due to increased service demands (Bratan et al., 2021; Park et al., 2021). Our sample was predominantly female, including for the group of people with PD. This finding was unexpected, particularly as PD tends to be more prevalent in men and men are over-represented in most research (Baldereschi et al., 2000). Resultantly, our findings may not fully represent the views of male people with PD, care partners, or occupational therapists. Future research will likely need to change its recruitment strategy and sampling frame to address this imbalance.

Moreover, GCM does not claim to be a definitive methodology, so studies using different methods may be needed. Although accounted for in the design of this study and the GCM methodology, the loss of participants between stages means that potential data was lost. Finally, we only collected basic demographic data to identify gender, age, and diagnosis duration (if applicable). As we lack data on areas such as cultural background and socioeconomic status, we cannot be confident any one group was not over-represented, limiting the external validity of this study to the UK population, including those from seldom-heard groups.

While digital delivery provided a convenient means of conducting this research, the impact on potential participant engagement in this study cannot be ignored, as it is likely that those who are less digitally literate will not have participated (Office for National Statistics, 2019).

Future research directions

The findings highlight eight priority components, presented as clusters, for consideration in the future intervention. Individual ideas from within the clusters rated highly on importance and feasibility, are suggested as starting points for future intervention development. Clusters, such as “*Coping”* and “*Support from others”* highlight broader individual and social factors that support participation in meaningful roles and activities and need to be considered in intervention development. The ability to access timely support from peers and the development of individual coping strategies will be important considerations for the next stage of intervention development (Lovegrove & Bannigan, 2021). Future research, such as co-producing the intervention with stakeholders, is needed to integrate the components identified in this study into a new intervention to help people with PD to live well with anxiety. Future studies should seek to remove barriers to research participation for care partners and occupational therapists, as providing convenient data collection is unlikely to be sufficient.

Conclusion

This novel participatory study used an online GCM methodology to ask people with PD, care partners, and occupational therapists to highlight priority components that provide starting points for the future development of an occupation- and community-based intervention for people with PD-related anxiety. The eight clusters identified in the findings are exercise, lifestyle changes, self-help, coping, access to information, professional help, peers and groups, and support from others. Statements in each cluster rated highly on importance and feasibility will be prioritized in intervention development. We plan to use these findings to co-produce an occupation-based intervention for living well with anxiety in PD.

Chapter 4: Logic Modelling Study

The scoping review (Chapter 2) and group concept mapping study (Chapter 3) both contribute to the ‘development’ stage of the MRC framework (Figure 1.3). Before moving on to the feasibility phase, the final step is modelling processes and outcomes (Skivington et al., 2021). This chapter presents the findings of a logic modelling study where the findings of the previous chapters (and pre-PhD research) are used as ‘inputs’ for the systematic co-production of the OBtAIN-PD. This provides the basis for the next study in which this intervention will be tested for feasibility.

The article in this chapter is the Word version submitted for publication in *BMJ Open* (Lovegrove, Bannigan, Marsden, et al., in press). To improve readability, the full list of references is included in the main thesis bibliography. The article uses language in keeping with the journal’s style, such as the terms “Parkinson’s disease” and the abbreviation “PD.”

4.1 Developing an occupation-based complex intervention for living well with anxiety and Parkinson’s (OBtAIN-PD) using logic modelling

Background: Anxiety is a common non-motor symptom of Parkinson’s disease (PD). There is no specific pharmacological intervention for people with PD who experience anxiety. Current non-pharmacological treatments have mixed or inconclusive results. Based on the contemporary published literature, there does not appear to be a non-pharmacological intervention for people with PD and anxiety that focuses on activity and participation.

Objective: To co-produce an occupation-focused complex intervention suitable for delivery by occupational therapists to help people with PD live well with anxiety.

Design: Six-stage complex intervention development using logic modelling and a participatory approach to organise the new intervention's key inputs, processes, and outcomes.

Participants: 34 participants were recruited (People with PD n=14, care partners n=9, occupational therapists n=11) for the online logic modelling sessions.

Key Results: Resources to support the new intervention (‘Inputs’) include adequate resourcing, education for professionals and people with PD, flexibility of delivery methods, and goal setting. The intervention's actions to produce outcomes (‘Processes’) should include 1:1 support, lifestyle management, providing meaningful information, collaborative goal setting, therapeutic use of everyday activities, and involvement of friends and families. The intended results (‘Outcomes’) should include reductions in anxiety symptoms, people with PD enjoying more meaningful activities, increased understanding of anxiety and PD, improvement in clinical outcomes, and improvement of service level outcomes. These key aspects were incorporated into an intervention manual, educational material, and training video.

Conclusion: We have systematically co-produced a new occupation-focused complex intervention to help people with PD to live well with anxiety. This provides the basis for the next project in which this intervention will be tested for feasibility.

Keywords: Parkinson’s disease; health care stakeholder engagement, knowledge co-production

- **What is already known on this topic:** Anxiety is a common non-motor symptom of Parkinson’s disease. Current pharmacological and non-pharmacological interventions for this symptom have inconclusive or mixed results on anxiety for people living with Parkinson’s disease.
- **What this study adds:** A novel complex intervention has been developed that is focused on activity and participation to help people with Parkinson’s disease live well with anxiety. This study involves people with Parkinson’s, care partners, and occupational therapists in a multistakeholder co-production.
- **How this study might affect research, practice or policy:** This new intervention provides the basis for a feasibility randomised controlled trial, leading to new insights into this intervention's acceptability and potential impact for this population.

Introduction

Parkinson's disease (PD) is the second most common neurodegenerative condition worldwide (de Lau & Breteler, 2006). Globally, the prevalence of PD has doubled in the past 25 years and now affects more than 10 million (Dorsey, Sherer, et al., 2018). Recent estimates suggest that PD resulted in 5.8 million disability adjusted life years (DALYs) in 2019 (G.B.D. Neurology Collaborators, 2019). Most people with PD (98.6%) live with non-motor symptoms (Barone et al., 2009; Pontone et al., 2019). Between 43-56% of PWPs experience anxiety (Barone et al., 2009; Pontone et al., 2019). Reviews have found a higher prevalence of anxiety in PWPs compared to the general population (Walsh & Bennett, 2001). People with Parkinson's who experience anxiety have a greater risk of falling, live with greater health burden, and have reduced quality of life, independence, and social roles (Dissanayaka et al., 2014; Fineberg et al., 2013). Heightened anxiety in PWPs leads to increased fluctuations in motor symptom presentation (Ehgoetz Martens et al., 2014; Fernie et al., 2019; Pontone et al., 2019).

Anxiety is a continual internal feeling of worry and fear that intrudes on everyday life (Hallion & Ruscio, 2013). People with PD experience more anxiety than those with other neurodegenerative conditions and fear negative public perceptions (Walsh & Bennett, 2001). People with PD may be more at risk of anxiety than those with other long-term conditions due to the dopamine deficiency that is characteristic of PD (Kienast et al., 2008). Dopamine modulates the inhibitory mechanisms that the medial prefrontal cortex exerts on the anxiogenic output of the amygdala, a brain structure involved in anxiety (Pontone & Mills, 2021; Zarrindast & Khakpai, 2015). Dopamine deficiency leads to neuronal hyper-excitability and amplified responses to perceived adverse threats (Hofmann et al., 2012; Kano et al., 2011; Kienast et al., 2008). Dopamine-replacement medication is a primary intervention in PD, but people with PD in the later stages can experience a notable increase in symptoms when the medication effects wear between doses (Richard et al., 2004). Psychological stressors associated with long-term conditions experienced by people with PD may increase anxiety further (Delgadillo et al., 2017). This contributes to the maintenance of the hyper-excited neuronal anxiety circuit (Hofmann et al., 2012; Kano et al., 2011). This suggests that people with PD experience anxiety differently from other populations because of the neurobiology specific to PD combined with the psychological stressors of living with an incurable long-term condition. This is important for clinicians and researchers to consider when developing complex interventions, especially as there is no specific pharmacological intervention for PWPs experiencing anxiety (Pontone & Mills, 2021; Skivington et al., 2021).

The presence of anxiety in PD has a negative effect on PD motor symptoms. Anxiety has been shown to increase the freezing of gait (FOG) episodes in 'freezers' and higher motor symptom severity when compared to 'non-freezers', implying that anxiety is an important mechanism underpinning FOG (Ehgoetz Martens et al., 2014). This means that if people with PD are anxious, this will affect their functional mobility in daily life and consequently reduce their quality of life (Ehgoetz Martens et al., 2014; Hanna & Cronin-Golomb, 2012; Pontone et al., 2019). Cognitive impairment associated with anxiety impacts quality of life (Dissanayaka et al., 2017; Hanna & Cronin-Golomb, 2012). Other potential sources of stress that contribute to anxiety for all people, not just people with PD, include (but are not limited to) health, family, finances, and work, all of which can change over the life course (Kessler et al., 2007). Research suggests that anxiety is not experienced in isolation but as a set of complex multi-dimensional interactions with the world that may require a bespoke intervention (Blundell et al., 2023; Lovegrove & Bannigan, 2021).

The charity Parkinson's UK identifies anxiety as a research priority (Deane et al., 2014). Previous studies have contributed to understanding the experience of anxiety for people with PD and what sorts of concepts may be included in a new complex intervention (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017; Lovegrove et al., 2023; Lovegrove, Sturkenboom, et al., in press). People with PD have stated that they want an intervention aimed at living well with the complex experience of anxiety with PD, focused on 'doing' (i.e., participation in meaningful occupation) as the means and goal of intervention rather than only talking about their thoughts and feelings (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017).

Occupational therapy focuses on enabling people with PD to participate in their chosen meaningful roles and activities (World Federation of Occupational Therapists, 2019). Access to occupational therapy is recommended in clinical guidelines to support symptom management, promote independence, and reduce hospital admissions (NICE, 2018). Research suggests that occupational therapy focused on the person's prioritised meaningful goals in activities in daily living and participation is an effective intervention for people with PD (Radder et al., 2016; Sturkenboom et al., 2014) There is no occupational therapy intervention specific for people with PD with anxiety-related participation problems.

This study aimed to systematically co-produce an intervention that occupational therapists can deliver to help people with PD live well with anxiety.

Materials and method

We used the Medical Research Council's guidance for developing and evaluating complex interventions as a framework (Skivington et al., 2021). This study focused on the development stage. We used the method of logic modelling and a participatory approach to organise the new intervention's key inputs, processes, and outcomes for intervention development.

A logic model is a hypothesised description of the chain of causes and effects that result in an outcome of interest. In this research, the end outcome is enabling people with PD to live well with anxiety by increasing their participation in meaningful activities. Logic modelling can involve representative stakeholders in a structured process to support complex interventions' design, planning, communication, and evaluation (Moore et al., 2019a). There were six stages in developing the occupation-based complex intervention for living well with anxiety and Parkinson’s disease (OBtAIN-PD) using the logic model (Sermeus, 2015).

Stage 1: Installing a project team and formulating key objectives

The core project team consisted of the research team (CL, KB, JM, IS) and a patient & public involvement (PPI) representative (NC).

Stages 2 and 3: Component consensus and clustering of clinical activities into a process flow

Clinical activities, characteristics, and group consensus identified in previous research were used as input for modelling (Lovegrove & Bannigan, 2021; Lovegrove et al., 2023; Lovegrove, Sturkenboom, et al., in press). Participants were given an electronic or printed information pack (depending on participant choice) to inform their thinking. The information pack contained summaries of the findings of previously completed studies by the research team (Lovegrove & Bannigan, 2021; Lovegrove et al., 2023; Lovegrove et al., 2024) (Appendix 8). The information pack had been refined in collaboration with PPI representatives.

Stages 2 and 3 co-occurred within the same session to reduce the time burden on participants attending multiple sessions. A researcher (CL) facilitated the logic modelling process, starting with long-term outcomes and moving backward towards inputs. During the sessions, the participants were invited to group clinical activities based on their coherence (stage 2). The participant’s ideas were mapped directly into a process flow diagram to illustrate the interdependency of the individual components by participants (stage 3). Participants were allowed to complete sessions in person or via an online platform (Zoom) ("CYPH, INC. v. ZOOM VIDEO COMMUNICATIONS, INC," 2022). Sessions were recorded as it was likely that the planned outputs (logic models) produced by the groups would have variations requiring further analysis by the research team. Individual logic models were completed at each group session and then combined into an overarching model by the research team with PPI involvement (Schell et al., 2013; Sermeus, 2015; Skivington et al., 2021). The blank logic model that was used with participants in each session is shown in Figure 4.1.

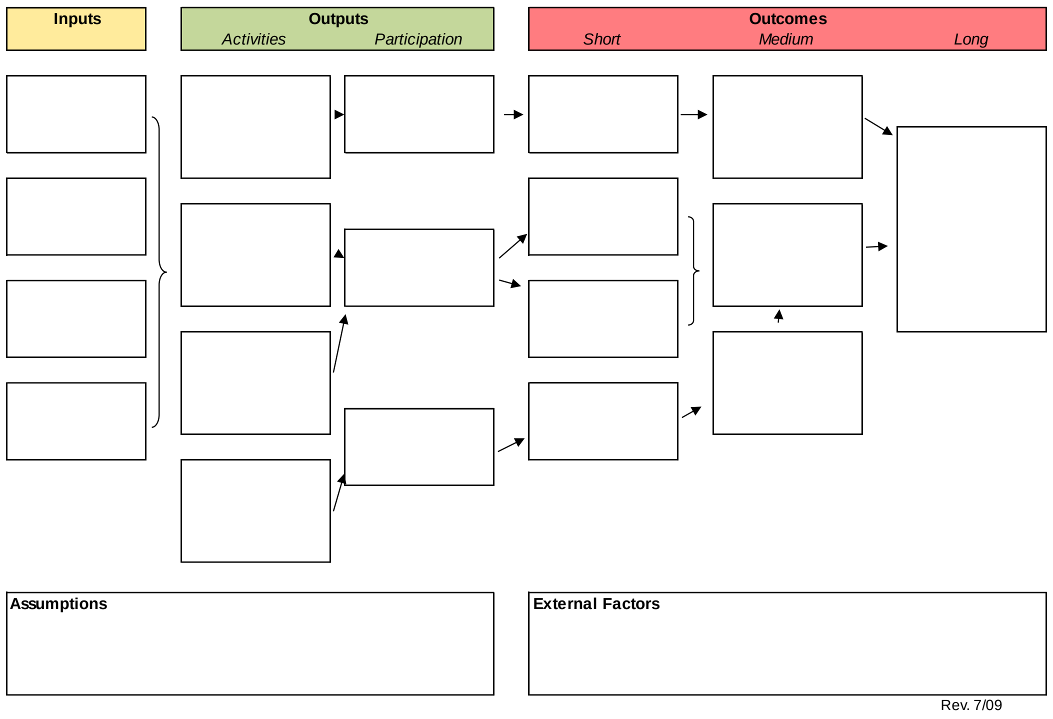


Figure 4.1: The blank logic model used with participants to co-produce the OBtAIN-PD.

Participants who felt unable to participate in a group session were offered a one-to-one session. All sessions were completed at a time, date, and in a setting convenient for the participants. The people with PD, care partners, and occupational therapists met separately to avoid potential bias caused by power dynamics (Robinson, 2014). There was no set order for the different participant sessions to be completed, as each session produced an individual logic model.

Stage 4: Process organisation

Stage 3 resulted in fourteen separate logic models. These logic models were aggregated to create a unified, more robust model. Three focus groups, one for each participant group, were conducted by the lead researcher (CL) to review the existing models to identify common elements and differences (Mills et al., 2019) through discussion of each component (i.e. the inputs, outputs, and outcomes). Each participant was sent a copy of the logic models to familiarise themselves with them before the focus group session. This process resulted in three separate logic models. The lead researcher developed a draft consolidated logic model using the data from the three models in collaboration with the research team. This process involved combining each model into a final version, considering individual assumptions and potential external factors. The draft consolidated logic model was presented to participants in a focus group for validation attended by people from each participant group (n=8). Feedback was gathered, and adjustments were made during the session to reflect the group's collective input accurately. The final consolidated logic model was checked with two National Health Service (NHS) community therapy service managers to evaluate the organisational impact of the intervention. This took the form of a researcher (CL) presenting the logic model to the managers and providing the opportunity for them to comment on its feasibility and implementation within an NHS setting. This stage was conducted remotely for convenience and is presented in Figure 4.2. This information was used in subsequent stages.

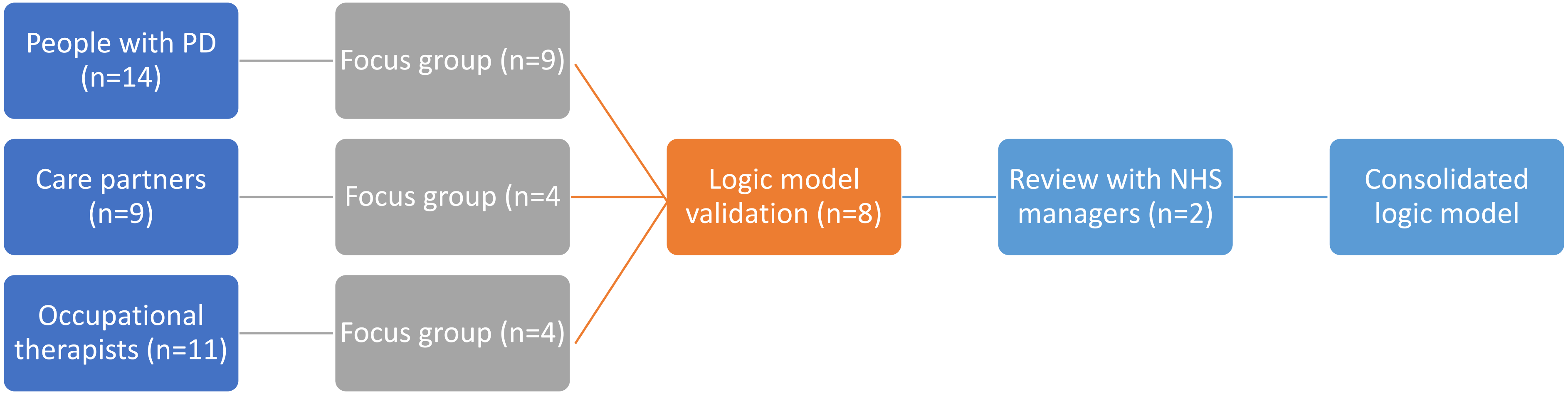


Figure 4.2. Process of aggregating the multiple logic models to develop the OBtAIN-PD.

Stage 5: Detailed description of key interventions

A detailed protocol for the OBtAIN-PD intervention was written based on the data collected from stages 2-4. Individual components- the activities, inputs, and outcomes identified by participants- were reconsidered (Sermeus, 2015). This was completed by the research team with input from PPI representatives.

Stage 6: Translation into a set of process and outcome indicators

Process and outcome indicators were developed to help verify compliance with the intervention during fidelity testing (Berry et al., 2009; Nolan & Berwick, 2006). This was completed by the research team with PPI input and took the form of an intervention manual. A final review with the occupational therapist group was performed to check the intervention manual's content and comprehension and inform a final version.

The UK Health Research Authority granted ethical approval for this study (22/NW/0021).

Participants

The co-production was with all potential end users: people with PD, care partners, and occupational therapists. The recruitment target was n=30, with the sample split equally between people with PD, care partners, and occupational therapists (10 participants per group). Twelve weeks were allocated for recruitment.

People with PD and care partners were recruited purposively using a maximum variation strategy to maximise sample diversity across the stages of disease progression: diagnosis, maintenance, complex, and palliative stages (MacMahon & Thomas, 1998; Robinson, 2014). Snowball sampling helped access participants from under-represented groups who use health or social care services but are seldom heard by these services and decision-makers (Emerson, 2015). We collected demographic data based on the UK Census to verify participant diversity (Office for National Statistics, 2020). Both groups were recruited via Parkinson's UK's 'Research Support Network'.

Occupational therapists were primarily recruited via the Royal College of Occupational Therapists Specialist Sections for 'Neurological Practice' and 'Mental Health'. In addition, snowball sampling was used to recruit occupational therapists who may not be part of these groups but may have relevant experience in either PD or anxiety-related OT interventions (Emerson, 2015).

Results

The final sample was n=34. The people with PD and care partners participated in *stages 2* and *3*. Occupational therapists participated in *stages 2*, *3*, and *6*. The recruitment target of 10 in each stakeholder group was exceeded for people with PD (n=14) and occupational therapists (n=11) and below the target for care partners (n=9). Sixteen participants (people with PD n=6, care partners n=5, occupational therapists n=5) consolidated the raw logic model. The demographic data of the participants are shown in Table 4.1. There was notably less gender diversity in the occupational therapist group.

Table 4.1: Participants demographic characteristics.

Characteristic		**All participants (n=34)**	**People with Parkinson's (n=14)**	**Care Partners (n=9)**	**Occupational Therapists (n=11)**
Gender	Male (including transgender men)	11 (32%)	6 (43%)	4 (44%)	1 (9%)
	Female (including transgender women)	22 (65%)	7 (50%)	5 (56%)	10 (91%)
	Prefer not to say	1 (3%)	1 (7%)	0	0
Age	25-34 years*	4 (12%)	0	1 (11%)	3 (27%)
	35-44 years	13 (38%)	3 (21%)	5 (56%)	5 (45%)
	45-64 years	9 (26%)	5 (36%)	1 (11%)	3 (27%)
	65-74 years	6 (18%)	5 (36%)	1 (11%)	0
	75 years and above	2 (6%)	1 (7%)	1 (11%)	0
	Median years PD diagnosis duration (range)	N/A	5 (1-22)	N/A	N/A
Employment status	Working as an employee	19 (56%)	5 (36%)	4 (44%)	10 (91%)
	Self-employed or freelance	3 (9%)	2 (14%)	1 (11%)	0
	Retired	9 (26%)	6 (43%)	3 (21%)	0
	Long-term sick or disabled	2 (6%)	1 (7%)	1 (11%)	0
	On maternity or paternity leave	1 (3%)	0	0	1 (9%)
Annual income (£GBP)	£20,001 to £30,000	3 (9%)	0	1 (11%)	2 (18%)
	£30,001 to £40,000	4 (12%)	1 (7%)	1 (11%)	2 (18%)
	£40,001 to £50,000	7 (20%)	2 (14%)	1 (11%)	4 (36%)
	£50,001 to £60,000	1 (3%)	1 (7%)	0	0
	£70, 001 to £80,000	2 (6%)	1 (7%)	0	1 (9%)
	Prefer not to say	17 (50%)	9 (64%)	6 (67%)	2 (18%)
Marital status	Single/ never married	5 (15%)	2 (14%)	3 (33%)	0
	Married/ domestic partnership	23 (67%)	10 (71%)	4 (44%)	9 (82%)
	Divorced	6 (18%)	2 (14%)	2 (22%)	2 (18%)
Sex. Ori.	Straight or Heterosexual	30 (88%)	12 (86%)	7 (78%)	11 (100%)
	Gay or Lesbian	4 (12%)	2 (14%)	2 (22%)	0
Religion	No religion	17 (50%)	5 (36%)	5 (56%)	7 (64%)
	Christian	11 (32%)	5 (36%)	2 (22%)	4 (36%)
	Jewish	3 (9%)	2 (14%)	1 (11%)	0
	Muslim	2 (6%)	1 (7%)	1 (11%)	0
	Any other (not described)	1 (3%)	1 (7%)	0	0
Ethnicity	White- English, Welsh, Scottish, Nothern Irish, or British	27 (79%)	9 (64%)	7 (78%)	11 (100%)
	Asian or Asian British	2 (6%)	1 (7%)	1 (11%)	0
	Black, African, Caribbean, or Black British- African	3 (9%)	2 (14%)	1 (11%)	0
	Other ethnic group- Arab	1 (3%)	1 (7%)	0	0
	Any other ethnic group	1 (3%)	1 (7%)	0	0

*No participants younger than this were involved in the study

Inputs for the intervention

Participants identified the resources needed to support the intervention and generated 58 raw statements. These were consolidated into five inputs: “Resources”, i.e the need for proper funding and staffing, physical resources, and time; “Education for professionals” about PD; “Education for people with Parkinson’s” about anxiety and how it affects PD; “Flexible delivery” of the intervention in a variety of settings, including in-person and remotely and by occupational therapists; and “Goal setting” by participants from each group.

Processes of the intervention

The processes included what needs to be done as part of the intervention (activities) and what and who should be targeted by the intervention (participation). Participants from each group generated 103 raw statements identifying the processes and activities they felt should be included in the new intervention. Participants from each group consolidated these statements into six aspects: “1:1 support first” meaning 1:1 support should be prioritised over group therapy; “Lifestyle changes” towards a healthier lifestyle to live well with anxiety;, “Providing meaningful information” that is concise and up-to-date, “Collaborative goal setting” rather than the therapist leading, “Use everyday activities”, i.e. using the person’s meaningful activities therapeutically (rather than abstract exercises or talking therapy); and “Involve friends and families” (where needed).

Outcomes of the interventions

Participants from each group generated 153 total statements on the short, medium and long-term outcomes they felt the new intervention should produce. Participants from each group consolidated these statements into “Reduce anxiety symptoms” on validated measures; the person with PD “Enjoying more meaningful activities” to them; “Better understanding” of one’s anxiety and how to manage it; “Improvement of clinical outcomes” using validated occupational therapy measures; and “Service level outcomes” such as reductions in new or re-referrals into services.

The consolidated logic model is presented in Figure 4.3. Illustrative verbatim quotes are shown in Table 4.2.

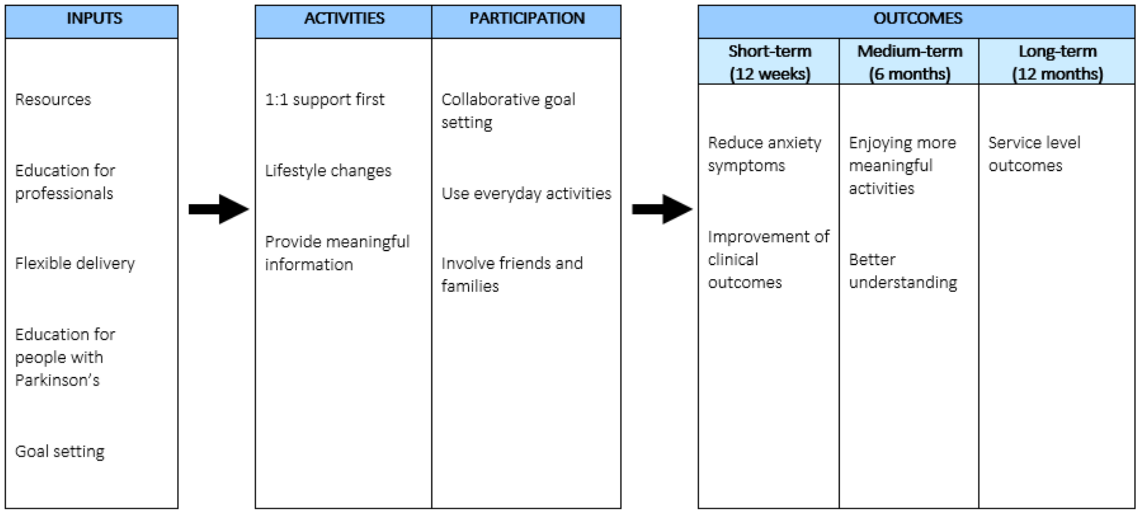


Figure 4.3. Consolidated logic model for the occupation-based complex intervention for living well with anxiety and Parkinson’s (OBtAIN-PD).

Table 4.2: Illustrative quotes from the consolidated logic model.

Inputs	*Resources*	“Staffing availability as a resource. Physical resources; easy access to equipment, services, groups.” (OT)
	Education for professionals	“We need more people with more knowledge. Help in more areas. Increased knowledge amongst those people who have most contact with PWPs.” (person with PD)
	Education for people with Parkinson’s	“Education. Information that anxiety makes the physical symptoms of Parkinson's worse. Acknowledging it is okay to be anxious.” (person with PD)
	Flexible delivery	“There needs to be options for delivery. Some people don't have online access, some do.” (care partner)
	Goal setting	“Goal setting resources will be important.” (care partner)
Processes	*1:1 support first*	“1:1 basis for the sessions to be delivered.” (person with PD)
	Lifestyle changes	“Developing understanding between the links between lifestyle and anxiety. Understanding that you won't get everyone. You need to see the benefits/ feel-good factor of what you are doing. Developing a positive snowball effect. Using real-life examples to demonstrate benefits.” (person with PD)
	Providing meaningful information	“Working with the persons partner to help the PWP do things so they do not become inactive, and building up the confidence of the carer.” (person with PD)
	Collaborative goal setting	“Goal setting- SMART goals used in o/p service- this works as a 'contract' as well between the service and patient.” (OT)
	Use everyday activities	“The intervention has to focus on what is important to the person. Everyone is individual.” (care partner)
	Involve friends and families	“Working with the persons partner to help the PWP do things so they do not become inactive, and building up the confidence of the carer.” (person with PD)
Outcomes (Short, Medium, and Long)	*Reduce anxiety symptoms*	“Really important to measure anxiety symptoms, important to show the person that it has reduced and I have a reading to show that.” (OT)
	Enjoying more meaningful activities	“Participating more in activities, and hobbies, that they enjoy doing.” (care partner)
	Better understanding	“Have understanding of what anxiety is, had an opportunity to practise some coping strategies and then call on those a year down the line. The carers would be able to draw on these skills as well, and be able to draw on support when needed and not start at the beginning of the process.” (person with PD)
	Improvement of clinical outcomes	“COPM improvement- includes goals and breaks them down in a really specific way. Not a massive additional time constraint.” (OT)
	Service level outcomes	“No referral back to the service at the 6 month timepoint- may have actually referred on to another service (long term conditions counselling team).” (OT)

Process flow

The consolidated logic model was presented to three NHS managers leading community rehabilitation teams. They felt the proposed model was feasible within current practice, and no further changes were suggested.

Intervention manual

Following the review with NHS managers, the research team drafted an intervention manual, information sheets, and collaborative goal-planning document, all with PPI input and based on the consolidated logic model. A review was completed with occupational therapists from the sample (n=5) to check the manual content and readability. Based on feedback, a training video was developed to accompany the intervention manual (Appendix 9).

Discussion

This study aimed to systematically co-produce an intervention that occupational therapists can deliver to help people with PD live well with anxiety using a logic modelling approach (Sermeus, 2015). The Medical Research Council's guidance for complex interventions guided the intervention development by providing a framework for the whole project, in which this study focused specifically on the development stage (Skivington et al., 2021). As primary stakeholders, people with PD, carers, and occupational therapists contributed to co-producing a logic model for the OBtAIN-PD. This logic model was checked with NHS managers. The resulting intervention manual was refined with occupational therapists.

All participant groups stated that having access to adequate resources, such as time, staffing, or physical materials, was necessary for the OBtAIN-PD. Resource limitations are associated with changes in care delivery and poorer clinical outcomes in some cases (Anesi & Kerlin, 2021). Lack of resources is an identified barrier to intervention implementation in PD and other neurological conditions (Hanssen et al., 2021; Laar et al., 2023). The NHS is recognised as a resource-constrained environment, especially community health services (Iliffe et al., 2021). The OBtAIN-PD must have a low-resource burden to be successfully implemented using only existing resources (Gesell et al., 2021; Ramaswamy et al., 2018). This may include using existing outcome measures, minimising the impact on clinicians' time, and providing flexibility on how the intervention can be delivered (Mathieson et al., 2019). For example, all participants highlighted providing adequate education to people with PD and occupational therapists, as necessary. Training and education provision can be a time-consuming endeavour if not delivered in a way that is appropriate to the context, thus introducing an implementation barrier (Mathieson et al., 2019). Any training related to the new intervention, either for the people with PD receiving it or the occupational therapists giving it, must be concise and convenient, such as e-learning (Wearne et al., 2011). The occupational therapists and managers felt that e-learning would be an appropriate training method, but face-to-face delivery would be preferred if the intervention included highly advanced concepts. There was no indication from the group of how much training would be required.

The participants of this study agreed with the concept of flexibility in the OBtAIN-PD. Previous research has identified flexibility in how interventions can be delivered as a facilitator for complex interventions, as community-based clinicians are responsible for their caseload organisation (Mathieson et al., 2019). Ensuring that the intervention can be delivered flexibly but with fidelity (by providing an intervention manual), supporting occupational therapists' caseload demands, and the needs of people with PD will facilitate the successful implementation of OBtAIN-PD.

The occupational therapists did not have a preference between group or individual intervention sessions, which is interesting given the benefits of group therapy in managing service demands. People with PD and care partners who participated in this study identified that OBtAIN-PD should be delivered primarily as a tailored individual intervention rather than in a group setting. Previous studies have reflected on the treatment preferences of people with PD (Lovegrove et al., 2017; Uebelacker et al., 2014; Weernink et al., 2017). This suggests that the OBtAIN-PD should be delivered as a tailored individual intervention.

Participants from all groups felt that including lifestyle changes and management would be necessary in the OBtAIN-PD and that initiating lifestyle changes would help them to live well with anxiety by reducing their anxiety symptoms. Preliminary research exists on lifestyle management approaches for people with PD, and more research is needed (Lister, 2020; Nag & Jelinek, 2019). Lifestyle management approaches focus on educating and motivating people to improve their quality of life through healthier habits and everyday behaviours (Clark et al., 2012). Lifestyle management approaches have been utilised in various contexts for supporting engagement in meaningful activity (Clark et al., 2012; Pyatak et al., 2022). Similar approaches have been used in occupational therapy interventions, including for adults with generalised anxiety disorder (Clark et al., 2012; Lambert et al., 2008; Lambert et al., 2007). This approach aligns with our study participants' opinion that the OBtAIN-PD should include providing meaningful information, collaborative goal setting, and the therapeutic use of everyday activity. These concepts are pillars of lifestyle management approaches (Clark et al., 2012; Pyatak et al., 2022). Furthermore, lifestyle management approaches for long-term conditions often involve collaboration with care partners such as friends and families (Frost et al., 2020; Pyatak et al., 2022). The fact that lifestyle management approaches resonate closely with our participant's opinions affirms the inclusion of these concepts in the OBtAIN-PD.

Outcome measure selection is essential for comprehensively evaluating complex interventions (Skivington et al., 2021). Establishing what outcomes an intervention aims to achieve allows the selection of appropriate outcome measurement tools (Datta & Petticrew, 2013). Participants from all groups stated that anxiety reduction is an essential outcome of the intervention and that they felt this was part of 'living well' with anxiety. The occupational therapy group reported that the Generalised Anxiety Disorder Assessment (GAD-7) would be a sensible tool to measure this as it is already established in clinical practice. The GAD-7 is a valid and reliable 7-item instrument used to assess the severity of generalised anxiety disorder and is commonly used in the NHS (Ruiz et al., 2011; Spitzer et al., 2006). As well as being valid and reliable, the GAD-7 is quick and easy to administer, which is an important facilitator (Mathieson et al., 2019). For these reasons, the GAD-7 would make it an appropriate measure for the OBtAIN-PD. People with PD and care partners in this study stated that enjoying more meaningful activities was an important outcome for them. The occupational therapists report that improvement in clinical measures is an essential outcome for the OBtAIN-PD, and multiple suggested using the Canadian Occupational Performance Measure (COPM). The COPM is a validated measure of a person's self-perception of performance in everyday living (Chesworth et al., 2002; Law et al., 1994; Tuntland et al., 2016). It has been recommended for people with PD (Bianchini et al., 2022; Kobayashi et al., 2023). The COPM has been used as a primary outcome measure in clinical trials of people with neurological conditions, including Parkinson's (Sturkenboom et al., 2014; Veenhuizen et al., 2019). Furthermore, it has been shown to detect improvements with occupational therapy in people with mental health disorders, young people, and older adults (Cup et al., 2003; Dedding et al., 2004; Eyssen et al., 2005; Horkoff, 2012). This suggests that the COPM would be an appropriate outcome measure for use with OBtAIN-PD. Regarding service level outcomes, participating people with PD and occupational therapists reported that prevention of re-referring to a community rehabilitation service within six months for the same problem will be an important outcome. Whilst a standardised measure for this outcome does not appear to exist, this data is routinely collected by services and thus would be feasible to monitor as part of the OBtAIN-PD.

Strengths and Limitations of the study

The structured process to which participants contribute directly is a strength of the co-production approach using logic modelling. The model portrays how the participants feel the intervention should be structured, including the resources needed and the desired outcomes. Online sessions allowed for a convenient method of participating, thus facilitating participation. We were able to tailor our engagement within the sessions to the individual groups for this particular research project, such as delivering group or individual sessions at convenient times for participants. How these approaches might need to be modified for other organisational contexts and research studies cannot be determined from an instrumental case study. This study may provide a helpful foundation for future co-production processes to be developed and assessed. Nonetheless, care should be taken when generalising specific aspects of our approach to other studies.

The sample size exceeded our target (n=34). Fewer care partners participated (n=9) than people with Parkinson's (n=14) and occupational therapists (n=11), of whom we over-recruited. Though not substantial, the under-recruitment of care partners likely reflects the barriers faced by care partners in taking part in research, such as time constraints due to caring responsibilities (Malm et al., 2021). Future studies should aim to address these barriers more comprehensively, as providing a convenient participation method is likely not enough (Malm et al., 2021; Robinson, 2014). The online sessions were convenient for participants and researchers, but the impact on recruitment cannot be ignored. Those who are less digitally literate may not have participated (Office for National Statistics, 2019).

Our sample was predominantly female but this figure is skewed by the occupational therapy sample which reflects the 90% female workforce (Ledgerd & World Federation of Occupational Therapists, 2020). The sample was more evenly matched for people with PD. This was unexpected, especially as PD tends to be more prevalent in men, and men are over-represented in most research (Baldereschi et al., 2000). Our findings may not fully represent the views of male people with PD, care partners, or occupational therapists. It could be argued that this is less relevant for occupational therapists, as the intervention is delivered on patient needs and is not dependent on the gender of the clinician. Future studies should consider amending their recruitment strategy to address this imbalance. Despite our efforts, our sample across all groups mainly consisted of white English people from Christian or non-religious backgrounds. Other ethnic and religious denominations are represented in this study in small numbers, so the external validity to other groups is limited. Future studies should design recruitment strategies to actively reach people from seldom-heard groups, as relying on peer referral methods like snowball sampling will likely yield limited results.

Conclusion

This study has systematically co-produced an intervention that occupational therapists can deliver to help people with PD live well with anxiety (OBtAIN-PD). The logic modelling approach provided a unique opportunity to co-produce the OBtAIN-PD with diverse participant stakeholders. These stakeholders included people living with PD (including care partners) and healthcare professionals. The identified desired inputs, processes and outputs for OBtAIN-PD resulted in a consolidated logic model. This provided the input for an intervention manual, information sheets, and goal-planning documentation.

The Logic model framework was be a helpful tool for identifying the inputs needed for a successful intervention, the key processes essential for implementation, and the outcomes that can be considered when determining the intervention's impact. The OBtAIN-PD will undergo initial testing in a feasibility randomised controlled trial.

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Chapter 5: Intervention Specification

This chapter aims to describe the OBtAIN-PD in more detail following the identification of components in chapters three and four. Using the MRC's framework for developing and evaluating complex interventions, the first stage involved identifying the characteristics of current occupational therapy interventions for community-dwelling adults with anxiety to identify potential active ingredients. The components for the new intervention were identified with input from participant stakeholders in the second stage. The third stage involved working closely with participant stakeholders to model the new intervention, using insights from the author's previous research (including this thesis) to co-create the OBtAIN-PD.

5.1 Developing the OBtAIN-PD

The MRC framework for developing and evaluating complex interventions and how the OBtAIN-PD relates to this is described in section 1.4. Developing a complex intervention involves three key functions and activities (Medical Research Council, 2008; Skivington et al., 2021) (Table 5.1). This research programme developed the intervention using these three key functions. The first stage of the criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI) was used to report the development of the intervention specification transparently (Möhler et al., 2012). The six items of the CReDECI first stage are summarised in Table 5.1. The table demonstrates how they relate to the MRC guidance (2008) and the OBtAIN-PD project.

Development of complex interventions, key functions and activities (MRC, 2008).	**Development of complex interventions; criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI) (Möhler et al., 2012)**	**Relation to the OBtAIN-PD project**
1. Identifying the evidence base.	1. Description of the interventions underlying theoretical considerations.	Chapter 2
2. Identifying/ developing appropriate theory.		Chapter 3
3. Modelling process and outcomes.	2. Description of all components of the intervention. 3. Rationale for the selection of the interventions components. 4. Illustration of any intended interactions between different components. 5. Rationale for the aim/ essential functions of the intervention's components. 6. Consideration of contextual factors and determinants of the setting in the modelling of the intervention.	Chapter 4 Chapter 6

Table 5.1: Development and reporting of the OBtAIN-PD in relation to the MRC framework (2008) and the OBtAIN-PD project.

The CREDECI was used to report the development and evaluation of complex interventions in healthcare (Möhler et al., 2012). Since the 2012 paper, the guidelines have been revised following a consensus process (Möhler et al., 2015). This has created a first-stage "Development" process with 4 stages. Here, stages 2 and 3 are combined, as well as stages 5 and 6, to produce a 4-stage process. Future work could report using the updated CREDECI2, although it was felt that the original 6-item description was more directive as to the steps an early career researcher with less experience in this method should follow.

The MRC does not provide specific expectations for detailing interventions. The Template for Intervention Description and Replication (TIDieR) checklist allows for structured intervention reporting (Hoffmann et al., 2014). The 12-item checklist extends the intervention-related aspects of CONSORT 2010 and SPIRIT 2013 statements (Chan et al., 2013; Schulz et al., 2010). The TIDieR checklist items are outlined briefly in Box 5.1.

1. Brief name
2. Why
3. What (materials)
4. What (procedures)
5. Who provided
6. How
7. Where
8. When and how much
9. Tailoring
10. Modifications (made in the course of the research study)
11. How well (planned measurement adherence and fidelity)
12. How well (actual adherence and fidelity)

Box 5.1: Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al., 2014)

Developing complex interventions is not a straightforward process (MRC 2008). However, several frameworks are available that guide how to manage the intervention mapping process. These frameworks are listed in Table 5.2. Sermeus (2015) critiqued various models for building complex interventions and identified that this informs their general approach. Subsequently, Sermeus (2015) and Abraham et al. (2015) proposed six-stepped processes for modelling complex interventions and intervention mapping, respectively. These processes are briefly outlined in Table 5.2. Both approaches were scrutinized in relation to the key steps for the development and reporting of the OBtAIN-PD, as outlined in Table 5.1.

The outcome of this appraisal identified that each approach encompassed the key functions and activities of developing complex interventions stated by the MRC (2008; Skivington et al., 2021). These two approaches sum up the considerations and decisions taken in developing the occupational therapy intervention specification for this study. An outline of the specific approach used to develop the OBtAIN-PD is also briefly given in Table 5.2. Whilst comparing the approaches to developing complex interventions, three main components emerge (see Table 5.2):

- Developing and describing the processes and outcomes of the complex intervention.

- Implementation considerations of the complex intervention.

- Evaluation of the processes and outcomes of the complex intervention.

Components of complex intervention development	**Six stages of intervention mapping (Abraham et al., 2015.)**	**Six step modelling for complex interventions (Sermeus, 2015)**	**Approaches to developing the OBtAIN-PD**
Developing and describing processes and outcomes	1. Needs assessment (e.g., what is the health problem). 2. Objective setting (primary and secondary outcome objectives).	1. Installing a project team and formulating key objectives of the complex intervention.	1. Completing the scoping review to identify potential intervention characteristics (Chapter 2) (Lovegrove et al. 2023a, 2023b) 2. Group concept mapping to identify intervention components (Chapter 3) (Lovegrove et al., 2023c)
	3. Identification of change mechanisms and techniques (processes and techniques which are active ingredients of the intervention).	2. Getting consensus on the components of the complex intervention. 3. Clustering of clinical activities into key interventions and building a process flow.	
Implementation considerations	4. Delivery methods (How best to deliver intervention). 5. Implementation (How will the intervention be delivered in practice).	4. Get the process organised and allocate resources. 5. Detailed description of the key interventions.	3. Logic modelling with stakeholders (Chapter 4) (Lovegrove et al., 2023d) 4. Applying the *Template for Intervention Description and Replication (TIDieR) checklist* (Hoffmann et al 2014).
Evaluation of the processes and outcomes	6. Evaluation (outcome and processes).	6. Translation into a set of process and outcome indicators.	5. The OBtAIN-PD feasibility cluster RCT (Chapter 6) (Lovegrove et al., 2023e).

Table 5.2: Approaches to developing complex interventions.

Ultimately, Sermeus's (2015) six-step modelling for complex interventions was used for intervention modelling as it aligned more clearly with the OBtAIN-PD project (Chapter 4) (Lovegrove, Bannigan, Marsden, et al., in press). The following sections detail the OBtAIN-PD in the context of the TIDieR checklist (Box 5.1) (Hoffmann et al., 2014).

5.1.1 Brief name

The full name for the intervention is the 'Occupation-based complex intervention for living with anxiety in PD'. The brief name for the intervention is the OBtAIN-PD.

5.1.2 Why

The OBtAIN-PD aims to help people with Parkinson's live well with anxiety. People with Parkinson's have expressed that they want an intervention to help them manage anxiety specifically and that this is a research priority (Deane et al., 2014; Lovegrove et al., 2017). The OBtAIN-PD intervention aims to restore and maintain engagement in meaningful social and habitual roles important to people with Parkinson's, such as participating in a club or pursuing a hobby (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017). In contrast, traditional NHS occupational therapy interventions tend to focus on compensatory techniques, such as providing equipment to maintain personal care. This forms the usual care group in the feasibility cluster RCT. People with Parkinson's with anxiety have identified this as less of a priority (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017). The OBtAIN-PD incorporates lifestyle modification (the altering of habits to develop and maintain long-term healthy behaviours) to help people with Parkinson's engage in meaningful activities and manage their anxiety effectively. A potential working mechanism of OBtAIN-PD may be the mediating role of personal control in managing their condition. Higher perceived personal control has been shown to have a positive effect on a person's psychosocial and physical wellbeing (Ashley et al., 2015; Tamagawa et al., 2012). In an RCT of web-based self-management intervention for cancer survivors, personal control had a statistically significant effect on depression and fatigue levels (Willems et al., 2017). Similar mechanisms have been reported in other occupation-based interventions and may work through stimulating occupational adaptation (the interaction between the person, occupation, and environment in response to challenge) (George-Paschal et al., 2022; Gilboa & Helmer, 2020; Johansson & Björklund, 2016; Walder et al., 2021).

5.1.3 What (materials)

The OBtAIN-PD intervention requires very few additional materials to reduce implementation barriers, especially in resource-constrained environments like the NHS. These additional materials are goal planning and information sheets, alongside the intervention manual. Providing an intervention manual will support flexible delivery of the OBtAIN-PD while promoting content fidelity, and supporting occupational therapists' caseload demands and the needs of people with Parkinson's. Occupational therapists are free to provide the intervention-specific goal-setting and information documentation either electronically or as hard copies, depending on the preference of the person with Parkinson's. Usual care occupational therapy can be provided alongside the OBtAIN-PD, but the OBtAIN-PD can be delivered without this.

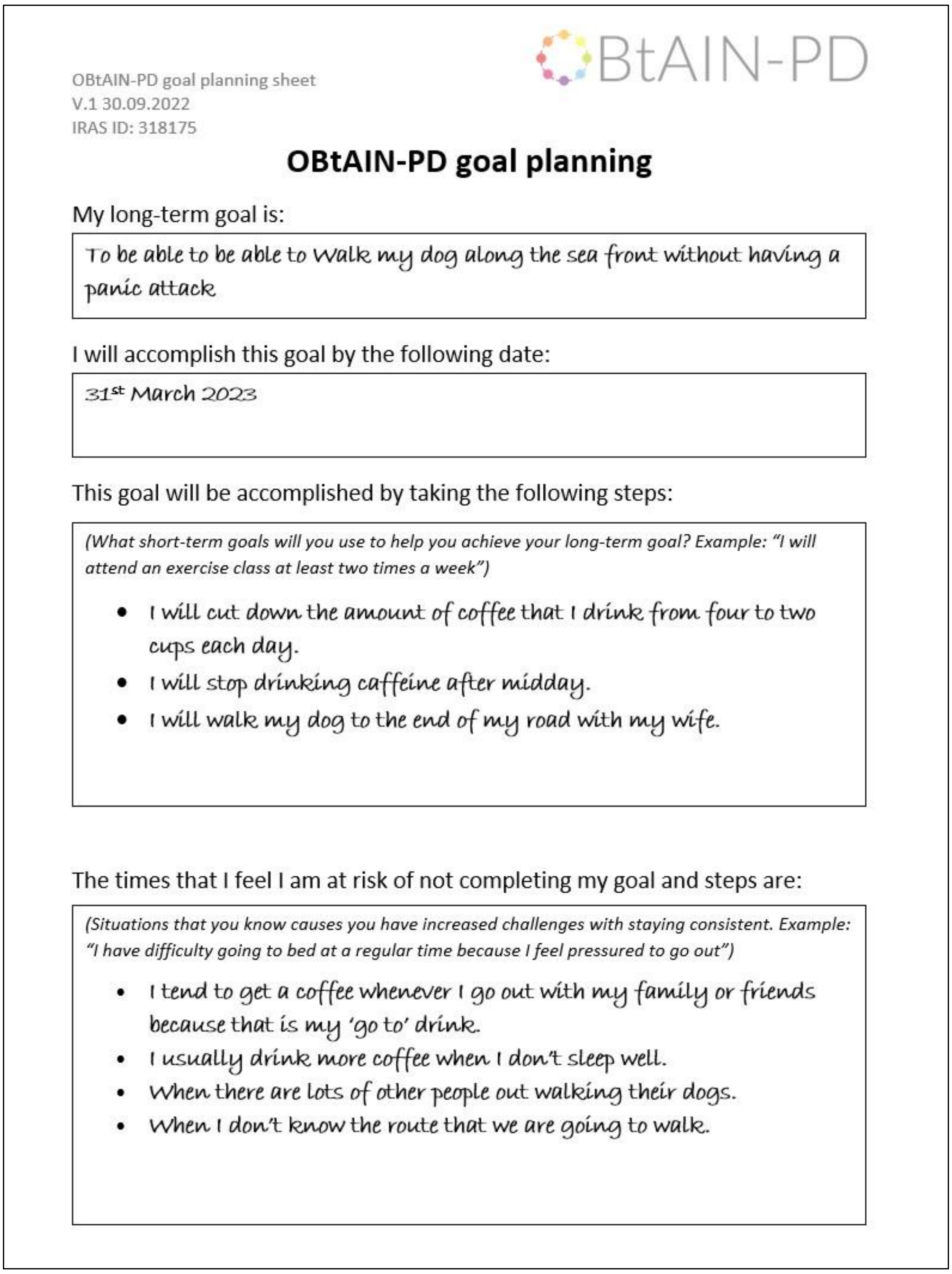
5.1.4 What (procedures)

Intervention may involve education, coaching, skill practice, and feedback. Table 5.3 provides an overview of the proposed activities performed during the planned feasibility cluster RCT for participants receiving OBtAIN-PD. The table also outlines the procedure for delivering the OBtAIN-PD. As the trial protocol (chapter 6) outlines, the suggested eight one-hour sessions will be conducted over 10 weeks (Lovegrove, Bannigan, Hayward, et al., in press). The table also indicates who will be responsible for delivering each activity. The activities are colour-coded based on the person who will perform them. The community rehabilitation team occupational therapists will perform the green-shaded activities, while the chief investigator (or delegated research team members) will perform the amber-shaded activities. More detailed descriptions of the activities will be provided in the following sections.

Session/ Activity	Time	Activity (confirmed & suggested)	Delivered by?
Referral sent to the community rehabilitation team (CRT)			Normal referral routes- consultants, Parkinson's specialist nurses, clinics, other AHPs
Referral triaged as per local protocol	As per local protocol	Referral triaged and prioritized. First appointment booked. Study and intervention details discussed.	CRT clinician
Screening log completed, information pack sent to participant	5 minutes maximum per potential participant	Complete screening log. If participant interested, send email of postal information pack (includes details of what is involved in OBtAIN-PD).	CRT clinician
Details sent to CI	1-2 minutes	Participant details emailed to Chief Investigator (CI), **or** CRT clinician sends details to CI	Participant **or** CRT clinician
Screening and informed consent process completed	30 minutes	Questions answered. Informed consent documentation completed. Participant details entered to trial database.	CI (Chris Lovegrove)
Baseline outcome measures taken	One week prior to first appointment. Clinical outcomes measures (60 minutes). Patient-reported outcome measures (15 minutes)	Canadian Occupational Performance Measure, Activity Card Sort, Generalised Anxiety Disorder assessment (GAD-7), Parkinson's Disease Questionnaire (PDQ-39), EQ-5D-5L, Barthel Index, Baseline clinical outcomes sent to the treating clinician.	CI. Participant- Patient-reported outcome measures
Session 1	60 minutes (or as required), complete the therapist contact form (max. 5 minutes)	Initial assessment and goal discussion. Complete the OBtAIN-PD goal planning sheet. Provide 'Parkinson's & Anxiety' information sheet. Complete Therapist contact sheet. Report adverse events (if needed).	CRT occupational therapist
Session 2 - 7	60 minutes (or as required), therapist contact form (max. 5 minutes)	Review goal planning. Treatment. Provide necessary information sheet (exercise, sleep, or diet & nutrition) if indicated. Amend goal sheet. Complete Therapist contact sheet. Report adverse events (if needed.	CRT occupational therapist
Sesson 8	60 minutes (or as required), therapist contact form (max. 5 minutes)	As per sessions 2-8. Complete final session procedure as per OBtAIN-PD manual.	CRT occupational therapist
12-week (from baseline assessments) follow-up	Clinical outcomes measures (60 minutes). Patient-reported outcome measures (15 minutes)	As per baseline	CI. Participant- Patient-reported outcome measures
24-week (from baseline assessments) follow-up	Clinical outcomes measures (60 minutes). Patient-reported outcome measures (15 minutes)	As per baseline	CI. Participant- Patient-reported outcome measures
Qualitative interview	60- 90 minutes	Semi-structured interview at a date and location convenient to the participant/ clinician	CI

Table 5.3: Summary of the activities of the OBtAIN-PD.

The goal planning sheet for OBtAIN-PD should be completed during the first session (Figure 5.1). The person with Parkinson's should complete this sheet (if possible) and keep it with them. The purpose of this sheet is to encourage the person receiving the OBtAIN-PD to take ownership of their goals and use it as a tool for future therapy sessions. Promoting ownership in both approaches has been shown to support positive and sustained behaviour change (Morton et al., 2015; Yıldız, 2020). Ownership is an important concept in acceptance and commitment therapy (ACT) and motivational interviewing (Coto-Lesmes et al., 2020; Wagner & Ingersoll, 2012), and this concept is included in the OBtAIN-PD. The goals should be related to managing anxiety and engaging in meaningful activities. The goal planning sheet should be reviewed at the beginning and end of each session and adjusted accordingly. If necessary, a new sheet should be provided.



OBtAIN-PD goal planning sheet
V.1 30.09.2022
IRAS ID: 318175

OBtAIN-PD goal planning

My long-term goal is:

To be able to be able to Walk my dog along the sea front without having a panic attack

I will accomplish this goal by the following date:

31st March 2023

This goal will be accomplished by taking the following steps:

(What short-term goals will you use to help you achieve your long-term goal? Example: "I will attend an exercise class at least two times a week")

- I will cut down the amount of coffee that I drink from four to two cups each day.
- I will stop drinking caffeine after midday.
- I will walk my dog to the end of my road with my wife.

The times that I feel I am at risk of not completing my goal and steps are:

(Situations that you know causes you have increased challenges with staying consistent. Example: "I have difficulty going to bed at a regular time because I feel pressured to go out")

- I tend to get a coffee whenever I go out with my family or friends because that is my 'go to' drink.
- I usually drink more coffee when I don't sleep well.
- When there are lots of other people out walking their dogs.
- When I don't know the route that we are going to walk.

Figure 5.1: Example of a completed goal planning sheet. This example is based on a real-life exemplar provided a person with Parkinson's acting as a PPI stakeholder.

During the first assessment and goal-setting discussion, it is important to communicate in a compassionate manner, i.e with empathy, kindness, and understanding, that guides individuals towards identifying the steps they need to take to achieve their goals. The aim is to inspire motivation within the person to make positive changes (Morton et al., 2015; Wagner & Ingersoll, 2012). The occupational therapist uses open-ended questions to learn more about a person with Parkinson's perspectives and ideas about how to change. Using affirmation, i.e. statements that recognise the person’s strengths and acknowledge positive behaviours, enables the occupational therapist to acknowledge a person's abilities in a non-demeaning way, which supports therapeutic relationship formation (Street & Richard, 2013). Research has shown that using affirmation can help acknowledge the recipient's emotions and feelings (Fosha, 2000). Reflective listening, also known as active listening, i.e. purposefully paying attention to what people are saying and demonstrating this, can help to clarify what the recipient is saying while simultaneously showing them that they are being heard. Reflective listening can motivate a person to consider change, thus preparing them to act towards it (Miller & Rollnick, 2012). Summarising, an application of reflective listening to link together and reinforce information that has been discussed should be used to reflect what the person has told the occupational therapist using their own words. Hearing their own words can effectively motivate people to consider change (Miller & Rollnick, 2012; Vansteenkiste & Sheldon, 2006). Examples of these communication approaches are shown in Table 5.4.

	Examples
Open-ended questions	• "What makes you think it might be time for a change?" • "What brought you here today?" • "What happens when you [insert risky/problem/unhealthy behaviour]?" • "What was that like for you?" • "What's different about (quitting smoking, improving your exercise, diet, etc.) this time?"
Affirming	• "That's a good suggestion." • "I appreciate that you are willing to meet with me today." • "It sounds like it has been very hard to cut down on coffee." • "It's clear that you're really aware of how important it is to get enough sleep."
Reflective listening	• "It sounds like…" • "It seems as if…" • "What I hear you saying…" • "I get the sense that…" • "I get the sense that this has been difficult…" • "What I hear you saying is that your [insert risky/problem/unhealthy behaviour] is affecting you by…."
Summarising	• "It sounds like you are concerned about your anxiety because it is stopping you from spending quality time with your grandchildren." • "You have been talking about improving your diet and losing weight as you feel it will help your anxiety. It seems you have started to recognise the less good things about being overweight. It's easy to understand why you want to work on this."

Table 5.4: Examples of the communication skills used during the OBtAIN-PD initial session.

During the initial session, the occupational therapist provides an information sheet titled "Parkinson's & Anxiety V1" to the person with Parkinson's (Appendix 10). This sheet provides introductory information about anxiety and Parkinson's based on current evidence (Lovegrove & Bannigan, 2021; Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove, Marsden, et al., in press; Lovegrove, Sturkenboom, et al., in press). During intervention development, people with Parkinson's, care partners, and occupational therapists felt it was important to receive information about why anxiety occurs in Parkinson's and the problems it causes (Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove, Sturkenboom, et al., in press). Behaviour change theories suggest that educating people about their experiences is crucial to increase a person’s intent to change (Ryan et al., 2008; Sinaise et al., 2023). It is not enough to provide education alone to change behaviours. It is important to explain to people why behavioural changes are necessary (Arlinghaus & Johnston, 2018).

The number of occupational therapy sessions provided depends on the person with Parkinson's goals, reason for referral, and interventions used. The treating occupational therapist makes this decision and it is not a prescription. When implementing complex interventions, supporting clinician autonomy can serve as a facilitator (Mathieson et al., 2019). The treatment delivered in the OBtAIN-PD sessions should be tailored to address the individual goals of the person with Parkinson’s. For instance, the example mentioned in the sample goal planning sheet:

“To be able to walk my dog along the seafront without having a panic attack.” (Figure 5.1)

There are multiple ways to approach the example goal:

- Exploring and identifying triggers that cause anxiety and finding ways to reduce them (Chapter 3, pages 108-110, Appendix 7; and 4, pages 132-134).
- Encouraging individuals to complete daily activities they are already doing to increase their sense of mastery and confidence (Chapter 3, pages 108-111, Appendix 7; and 4, pages 133-134).

- Supporting individuals to plan ahead can reduce potential stressors, such as timing walks when fewer people are around (Chapter 3, pages 108-109, Appendix 7).
- Grading activity involves gradually increasing engagement in an activity, such as a walk at the seafront, alongside the individual (Chapter 3, page 109, Appendix 7).
- Situational use of relaxation techniques, such as breathing exercises, can prevent anxiety from escalating during an activity (Chapter 3, pages 108-109, Appendix 7; and 4, pages 133-134).
- Cueing strategies, such as auditory or visual cueing, can be used to manage freezing episodes or initiate movement (Chapter 4, pages 108-109).
- Cognitive support strategies can include setting reminders or prompts on mobile devices and planning new and interesting activities to promote cognitive initiation (Chapter 3, pages 109, Appendix 7; and 4, pages 132-134).

This is not an exhaustive list of the interventions that can be provided by occupational therapists delivering the OBtAIN-PD. The list provides suggestions of the sorts of treatment activities that an occupational therapist may provide when working with a person with Parkinson's with anxiety.

During the intervention, the occupational therapist may need to provide the person with extra information to help them adapt their roles, routines, and lifestyles to help them live well with anxiety. This is consistent with other interventions that utilise lifestyle management strategies (Clark et al., 2012; Fox et al., 2021; Lambert et al., 2008; Lambert et al., 2007). As part of the OBtAIN-PD project, three information sheets were created on exercise, sleep, and diet and nutrition (Appendix 11). A summary of each information sheet is provided in Table 5.5. The information sheets have been created based on the input and feedback from people with Parkinson's, care partners, and occupational therapists (Lovegrove et al., 2017; Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove, Sturkenboom, et al., in press). They have been designed to include the necessary information for the OBtAIN-PD and are based on the current NHS guidance. The training emphasises that the information sheets should only be provided if the person with Parkinson's has identified the topic and should not be considered a sole intervention. People with Parkinson’s have previously expressed dissatisfaction at being provided information sheets as the sole treatment and the long-term impacts of such an approach are questionable (Hughes & Burch, 2020; Keyworth et al., 2020; Lovegrove, Bannigan, Marsden, et al., in press; Miller & Rollnick, 2012). These information sheets are designed to assist the delivery of OBtAIN-PD by providing information and facilitating discussion between the person and the occupational therapist. An active therapeutic partnership, where information is discussed collaboratively, has been identified as a key active ingredient in other complex interventions (McAllister et al., 2021).

Lifestyle interventions used by occupational therapists encompass a range of activities and strategies to promote health and well-being (Pyatak et al., 2022). Whilst occupational therapy has a long history of targeting lifestyle through everyday occupation to improve human health and wellbeing, lifestyle interventions tend to be structured programs using approaches such as health education and behaviour change theory (Bradley et al., 2022; Nielsen & Christensen, 2018; Uyeshiro Simon & Collins, 2017). Therefore, occupational therapists may use lifestyle interventions, but lifestyle interventions are not necessarily occupational therapy and may be delivered by various professionals (Pyatak et al., 2022; Younossi et al., 2023). These interventions are not limited to a specific diagnosis or population like people with Parkinson’s. Instead, they are applicable across diverse settings and client profiles. Lifestyle interventions in occupational therapy can include several key components.

Occupational therapists work with clients to modify activities based on their abilities and needs. This approach is commonly known as occupational or activity adaptation (Grajo et al., 2018; Johansson & Björklund, 2016). This may involve reorganising activities, using assistive devices, or altering the task itself to enable greater participation. In community-dwelling older adults, activity adaptation can improve performance in activities of daily living (Liu et al., 2018). A systematic review of interventions modifying activities for individuals with Alzheimer's-type and other dementias indicates strong evidence for this approach in addressing self-care and leisure occupations (Padilla, 2011). Establishing and modifying routines and habits is a fundamental aspect of lifestyle interventions in occupational therapy (Epley et al., 2021). By helping individuals create and maintain positive daily routines, therapists contribute to developing healthy lifestyle patterns (Arlinghaus & Johnston, 2019). In occupational therapy, the ReDO program equips individuals with the tools to analyse their occupational patterns, leading to a more fulfilling and healthy daily life (Erlandsson, 2013). It should be noted that the ReDO program is designed for women and aims to improve return-to-work outcomes (Eklund & Erlandsson, 2013; Erlandsson, 2013; Fox et al., 2021). Thus, the transferability to people with Parkinson’s at different life course and condition stages is limited. On the other hand, the Well Elderly Lifestyle Redesign® intervention used similar concepts and effectively improved health outcomes for participants experiencing various health disparities in different community settings (Pyatak et al., 2022). Furthermore, the Lifestyle Redesign® approach has been successfully replicated in other settings and populations, such as chronic pain management and diabetes

(Pyatak et al., 2019; Uyeshiro Simon & Collins, 2017). Occupational therapists are key in occupation-based and -focused health promotion and education (Morris & Jenkins, 2018). In the OBtAIN-PD intervention, occupational therapists provide people with Parkinson's with information and skills to make informed choices about their health that emphasise preventive measures and lifestyle modifications to routines and habits (Morris & Jenkins, 2018).

A common component of occupational therapy is stress management. Occupational therapists can assist people in developing effective stress management and coping strategies (Hogan et al., 2023). These may include mindfulness techniques, relaxation exercises, and incorporating enjoyable and stress-reducing activities into daily life (Hardison & Roll, 2016; Scott et al., 2001). Though an adjunct psychological approach, mindfulness-based stress reduction techniques have been used in occupational therapy interventions and may have a positive effect in reducing anxiety symptoms (Hardison & Roll, 2016; Hardison et al., 2021; Thompson, 2009). In Parkinson's, the evidence for mindfulness techniques in managing anxiety is inconclusive (McLean et al., 2017). Mindfulness was not specifically incorporated into the OBtAIN-PD programme for this reason.

The integration of lifestyle interventions in occupational therapy is supported by a growing body of evidence that highlights the positive impact of these approaches on health outcomes (Clark et al., 2012; Fox et al., 2021; Lambert et al., 2008; Lambert et al., 2007; Lambert et al., 2010; Pyatak et al., 2022). Research studies and clinical trials provide insights into the effectiveness of various lifestyle interventions in addressing a range of health conditions and improving overall well-being. Studies have shown that lifestyle interventions, including activity modification and dietary changes, can be used to effectively manage diabetes (Galaviz et al., 2018). A key active ingredient for occupational therapists seems to be working collaboratively with individuals to develop personalised strategies for incorporating physical activity and healthy eating habits into their daily lives (Reitz et al., 2020). In cardiovascular disease, lifestyle interventions, such as promoting regular physical activity and stress reduction techniques, contribute to improved cardiovascular health (Rippe, 2019). Lifestyle interventions focused on balance training, home modifications, and exercise have proven effective in preventing falls among older adults (Clark et al., 2012; Sherrington et al., 2020). Occupational therapists work to identify and address factors that contribute to fall risk, promoting safety and independence (Walker & Howland, 1991). This suggests that including lifestyle management interventions in OBtAIN-PD is reasonable. This is especially important due to the increased falls risk experienced by people with Parkinson’s and the benefits of regular physical activity for this population (Bhalsing et al., 2018; Pelicioni et al., 2019).

There is increasing evidence that lifestyle interventions can be an effective way to manage mental illness and improve mental and physical health, as well as overall quality of life (Manger, 2019). This can help to reduce the gap in life expectancy between individuals with severe mental illness and the general population (Manger, 2019). Lifestyle interventions can be effective in the management of anxiety (Correll et al., 2023). An occupational therapy-led lifestyle intervention was demonstrated to be both clinically and cost-effective in reducing symptoms of anxiety and depression (Lambert et al., 2008; Lambert et al., 2007; Lambert et al., 2010). The lifestyle review included in the intervention may have helped people to recognise their specific sensitivities and thus supported behaviour change (Lambert et al., 2008; Lambert et al., 2007). This is particularly valuable for inclusion in the OBtAIN-PD. People with Parkinson's often experience anxiety as a standalone symptom, but depression is a common comorbid NMS alongside other NMS such as cognitive impairment (Blundell et al., 2023; Lovegrove & Bannigan, 2021; Pontone & Mills, 2021).

Lifestyle interventions incorporating cognitive stimulation activities and routines have demonstrated positive outcomes for individuals with cognitive impairment (Logsdon et al., 2007; Wu et al., 2023). Lifestyle interventions can have a moderate effect in people with cognitive impairment that is detectable for up to a year beyond facilitated sessions (Whitty et al., 2020). In a recent single-blind RCT, a cognitive stimulation intervention tailored to a person's individual needs and interests reduced anxiety levels (Gómez-Soria et al., 2023). As cognitive impairment can be a symptom of Parkinson's, including in the early stages of the condition, lifestyle interventions with cognitive stimulation properties warrant inclusion in the OBtAIN-PD and will be supported by the tailored nature of the intervention (Aarsland et al., 2021; James et al., 2021; Pfeiffer et al., 2014; Whitty et al., 2020).

Information sheet	Summary
Exercise	• Explains what exercise and physical activity is. • Provides evidence-based recommendations for the amount per week (2.5 hours, 150 minutes). • Gives examples of non-exercise activity
Sleep	• Explains what sleep is and why it is important. • Provides NHS recommendations of how much sleep is needed per night (seven to nine hours). • Provides suggestions on how to improve sleep for the person to refer to.
Diet & Nutrition	• Provides general rules for following a healthy diet based on NHS recommendations. • Provides information on medication, adapted cutlery, and swallowing problems to help inform the person's thinking.

Table 5.5: Summary of the OBtAIN-PD information sheets.

The final part of each treatment session should involve reviewing what occurred during the session, assessing progress towards the participant's goal, and planning the next session if necessary. Based on the example in Figure 5.1, this process would include:

- Reviewing the person with Parkinson’s experience of the session.
- Using previously identified communication strategies (Table 5.4) to help identify what went well and what did not.
- Collaborate with the person to plan the next session. For instance, if they walked their dog for 5 minutes, they can aim for 10 minutes in the next session.
- Update the goal planning sheet if required.
- Confirm the date and time for the next treatment session.

Collaborating with the person with Parkinson's to agree on a plan for the next treatment session can evoke motivation towards positive lifestyle changes and enhance the likelihood of achieving their goal (Arbuckle et al., 2020; Frost et al., 2018).

After a person completes their goal and no further intervention is required, the goal planning sheet undergoes a review. During the final session, the occupational therapist has a discussion with the person with Parkinson's about the steps they have taken to achieve their goal. It is also discussed how they have dealt with any potential barriers that may have hindered their progress towards achieving their goal. Goal formation is a key component in fostering behaviour change; closing the intervention by focusing on goal accomplishment can be a supportive factor in maintaining behaviour change (Bailey, 2019; Swann et al., 2021).

To help maintain behaviour change, discussion of the following is encouraged:

- What are some habits that prevent you from doing the things that you want to?
- How do you react when you are not able to do the things that you want to?
- What helps you to develop new habits and routines?
- What are some barriers to making new habits?
- What are some unexpected things that may interfere with forming new habits and stop you from doing what you want to do? What steps can you take to prepare for such things?

5.1.5 Who provided

The OBtAIN-PD program is designed to be administered by registered occupational therapists with experience of working with people with Parkinson's. According to the GCM study and logic modelling study, people with Parkinson's and their caregivers prefer to receive treatment from a registered therapist rather than a therapy assistant (Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove, Sturkenboom, et al., in press). This aligns with other studies exploring the care preferences of people with Parkinson's (Uebelacker et al., 2014; Weernink et al., 2017).

To ensure the success of an intervention, the clinicians delivering it must be properly trained in using it (Gallo & Barlow, 2012). All participants emphasized the importance of providing occupational therapists with training as part of the intervention (Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove, Sturkenboom, et al., in press). Adequately trained clinicians leads to better adoption of interventions and contribute to improved outcomes and patient confidence (Gallo & Barlow, 2012). However, training and education provision can be time-consuming and may introduce implementation barriers if not delivered appropriately (Mathieson et al., 2019). The UK's NHS is a resource-constrained environment, particularly in community health services (Iliffe et al., 2021). Therefore, the OBtAIN-PD needed a low-resource burden to be successfully implemented using only existing resources (Gesell et al., 2021; Ramaswamy et al., 2018). To achieve this, occupational therapist training must be concise and convenient, such as e-learning (Wearne et al., 2011). The occupational therapists and managers agreed that e-learning would be an appropriate training method (Lovegrove, Bannigan, Marsden, et al., in press). E-learning approaches have been effectively used to teach clinicians to deliver other similar interventions (Hurley et al., 2019; Jones et al., 2023). As a response, the lead researcher created a 45-minute training video. The occupational therapist can access this video at a convenient time, date, and place. The learning objective of this training is to enable occupational therapist's to deliver the OBtAIN-PD competently. An OBtAIN-PD intervention manual is also provided to support the training (Appendix 12). Before delivering the OBtAIN-PD, the occupational therapists must complete the training video and read the intervention manual.

5.1.6 How

Based on findings from group concept mapping and logic modelling studies, the OBtAIN-PD intervention is delivered through individual sessions instead of group therapy, (Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove, Sturkenboom, et al., in press). This approach reflects the findings of previous studies that have examined the treatment preferences of people with Parkinson's (Lovegrove et al., 2017; Uebelacker et al., 2014; Weernink et al., 2017). Whilst group therapy groups are as effective as individual therapy in a range of modalities, listening to the preferences of people receiving interventions can facilitate engagement (Dilgul et al., 2018). Furthermore, group therapy may be less appropriate for individuals experiencing high levels of emotional distress caused by anxiety (Malhotra &

Baker, 2023). This will also allow the OBtAIN-PD to be delivered alongside usual occupational therapy care if required.

5.1.7 Where

The OBtAIN-PD can be administered in various settings for people with Parkinson's, such as the recipient's home, community, or outpatient clinics. Previous research has shown that flexible delivery methods can facilitate the implementation of complex interventions, particularly as community-based clinicians are responsible for organising their caseloads (Mathieson et al., 2019). The participants of the OBtAIN-PD project suggested that there should be some level of flexibility in the OBtAIN-PD program (Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove et al., 2024) (Chapter 4, pages 131-133).

5.1.8 When and how much

There is currently no accepted or researched dosage for OBtAIN-PD. Based on previous research studies of occupational therapy with people with Parkinson's, it is estimated that OBtAIN-PD will last 30 minutes per session over 10 weeks (Clark et al., 2012; Lambert et al., 2008; Lambert et al., 2007; Nag & Jelinek, 2019). The intervention sessions will include 30 minutes of usual care occupational therapy, i.e., 60 minutes. Furthermore, the estimated frequency and dosage align with other interventions utilising lifestyle management and modification techniques. The Redesigning Daily Occupations (ReDO™) programme consists of 11 group sessions over 10 weeks, each lasting 2.5 hours (Fox et al., 2021). This may suggest that the estimated dosage of the OBtAIN-PD may be too low. However, a similar occupational therapy-led lifestyle approach used 10 sessions over 16 weeks with sessions ranging from 0.5-1 hour in length has been effective for people with anxiety (Lambert et al., 2008; Lambert et al., 2007). The dosage of OBtAIN-PD is also similar to those used in other behaviour change interventions that focus on exercise self-efficacy and adherence in people with Parkinson’s (Ahern et al., 2024). These interventions resulted in positive changes in quality of life and symptom profiles, suggesting the estimated frequency and dosage of the OBtAIN-PD may be appropriate (Fox et al., 2019; Fox et al., 2021; Lambert et al., 2008; Lambert et al., 2007).

5.1.9 Tailoring

People with Parkinson's emphasized the importance of adapting OBtAIN-PD to their individual needs, enabling them to re-engage in meaningful occupations (Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove, Sturkenboom, et al., in press). The OBtAIN-PD was tailored to meet the individual occupational needs of people with Parkinson's, allowing for variation in the frequency of key activities utilised. All parts of the OBtAIN-PD trial manual must be completed, but the frequency of key activities may vary.

5.1.10 Modifications (made during the research study)

Any modifications made to the OBtAIN-PD during the feasibility cluster RCT will be collected via the *Therapist contact form* and during the interviews with occupational therapists.

5.1.11 How well (planned and actual measurement adherence and fidelity)

The feasibility cluster RCT will evaluate the fidelity to content using process evaluation (Lovegrove, Bannigan, Hayward, et al., in press) Treatment fidelity refers to whether the treatment was delivered as intended (Bellg et al., 2004). In contrast, treatment adherence refers to how much a participant's behaviours comply with medical or health advice (Persch & Page, 2013). During the scoping review, it was found that most of the studies included did not provide information on how occupational therapy intervention's fidelity and adherence were supported and measured (Chapter 2) (Lovegrove, Marsden, et al., in press). As part of the feasibility study, measuring fidelity and adherence to occupational therapy will be important. Understanding the processes is crucial to assessing complex interventions (Medical Research Council, 2008). It is recommended to conduct process evaluations of the study with the same high methodological standards and thorough reporting as the evaluation of outcomes (Medical Research Council, 2008).

A *Therapist contact form* was designed for the occupational therapists to complete after each occupational therapy session (Appendix 13). This means that the additional burden on occupational therapists was kept to a minimum, again an important barrier to minimise (Mathieson et al., 2019). Since the occupational therapists will already have a caseload, it is important to balance the need for information with their workload in the feasibility cluster RCT. In a previous protocol for an RCT evaluating the effectiveness of occupational therapy in Parkinson's, a process evaluation summary sheet was utilised to collect data (Sturkenboom, Graff, Borm, Adang, et al., 2013). A similar format was used for this study. The information requested in the *Therapist contact form* pertains to the TIDieR checklist questions (Hoffmann et al., 2014). A free text box allows occupational therapists to express their views and opinions.

In the feasibility cluster RCT, the interviews with occupational therapists aims to explore their experiences with the OBtAIN-PD trial and intervention. An inductive approach was used to generate information for the research objectives. An extensive interview schedule consisting of open-ended questions was created (see Appendix 14).

5.2 Summary

This chapter provides a detailed specification of the OBtAIN-PD intervention using the TIDier checklist (Hoffmann et al., 2014). The details of the OBtAIN-PD intervention are provided in the individual checklist items. The OBtAIN-PD will undergo initial testing as part of a feasibility cluster RCT.

Chapter 6: Feasibility Trial Protocol

The previous chapters outline the 'development' stages of developing an intervention following the MRC framework (Figure 1.3) (Medical Research Council, 2008; Skivington et al., 2021). This comprises identifying the evidence base (Chapter 2, scoping review), identifying and developing theory (Chapter 3, GCM study), and modelling processes and outcomes (Chapter 4, logic modelling study). The next stage of the framework is 'feasibility'. A feasibility RCT should be designed and delivered to assess predefined progression criteria related to the evaluation design (data collection and retention) or the intervention itself (such as optimal content and delivery) (Arain et al., 2010; Medical Research Council, 2008; Skivington et al., 2021). This chapter presents the feasibility cluster randomised controlled trial (RCT) protocol. The feasibility cluster RCT protocol indicates the transition from the 'development' to the 'feasibility' phase of the MRC framework. This cluster RCT aims to test the feasibility and fidelity of the OBtAIN-PD. Trial recruitment started in April 2023.

The article in this chapter is the Word version submitted for publication in *BMJ Open* (Lovegrove, Bannigan, Hayward, et al., in press). The complete list of references for both articles paper is included in the main thesis bibliography to improve readability. The article uses language in keeping with the journal's style.

6.1 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 protocol

ABSTRACT

Introduction

Anxiety is a common non-motor symptom of Parkinson's that is associated with reduced life quality, independence, and health outcomes. Current anxiolytic medications and the most promising behavioural interventions have inconclusive and mixed results. Occupational therapy is effective at promoting participation in activities of daily living and is recommended in national guidelines. This cluster randomised controlled trial aims to test 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.

Methods and analysis

Fifty people with Parkinson's will be recruited from Devon, UK, to undertake the OBtAIN-PD or usual care delivered by community-based occupational therapists across two National Health Service sites. Recruitment, attrition rates, and feasibility of proposed outcome measures (COPM, GAD-7, PDQ-39, Activity Card Sort, Barthel Index, fall logs) will be tested. Resource data will be collected to aid in the feasibility assessment. Fidelity to content will be assessed using process evaluation. Subjective experiences will be explored qualitatively (10 participants, occupational therapists, and decliners).

Ethics and dissemination

This trial has been registered with the ISRCTN registry. Ethical approval has been obtained from the Health Research Authority (REC reference 23/NE/0027) before data collection. Participants will receive a summary of the results at the end of the data analysis. We will publish the results in a peer-reviewed journal and on institution websites.

Trial registration number

ISRCTN registry (ISRCTN62762494).

Strengths and limitations of this study

1. Collecting resource-use data will assist in planning a full economic evaluation of the intervention in a definitive trial.
2. The cluster design may introduce an imbalance between trial arms, but this should also reduce contamination and improve the study's internal validity.
3. Assessor blinding might be challenging to achieve in a real-world practice setting, thus introducing the possibility of assessment bias.
4. Follow-up is limited to 24 weeks, which may not capture the long-term effects of the intervention.

INTRODUCTION

Background and rationale

Parkinson's disease, commonly referred to as Parkinson's, is the second-most common neurodegenerative condition in the UK, affecting approximately 145,000 people (Parkinson's UK, 2014). The cardinal symptoms include tremors, loss of automatic movement, and slowed movement (Kalia & Lang, 2015). Parkinson's also results in sensory, cognitive, and psychological impairments that cause significant disability and impede participation in everyday roles and activities, resulting in reduced quality of life (Benharoch & Wiseman, 2004; Duncan et al., 2014). Anxiety affects up to half of people with Parkinson's (PWPs) (Dissanayaka et al., 2014). Higher anxiety makes PWPs more prone than age-matched controls to falling and losing independence; it reduces their quality of life, leads to social role dysfunction, reduced participation, and increases health burden (Coventry et al., 2014; Pontone et al., 2019).

The psychological stressors associated with long-term conditions that PWPs experience can increase anxiety (Kano et al., 2011). Furthermore, PWPs may be more susceptible to anxiety than other long-term conditions due to Parkinson's associated dopamine deficiency, alongside other factors (Kienast et al., 2008). Dopamine is a modulator in the amygdala, a brain structure involved in fear and anxiety (Rosen & Schulkin, 1998). When dopamine is deficient, this produces neuronal hyper-excitability and exaggerated responses to perceived threats (Kienast et al., 2008; Rosen & Schulkin, 1998; Zarrindast & Khakpai, 2015)**.** Although PWPs can be treated with dopamine-replacement medication they often experience a marked increase in symptoms as the medication wears off throughout the day (Richard et al., 2004). Primary (or type-1) worry can, in turn, rapidly progress to type-2 worry (meta-worry, or 'worry about worry') (Wells, 2010). This can further increase anxiety symptoms, contributing to the maintenance of the hyper-excited neuronal anxiety circuit (Hofmann et al., 2012). Thus, as highlighted by the research team's previous research, living with anxiety in Parkinson's is a complex experience shaped by neurobiology, individual experiences, and life context that restricts participation in meaningful activities (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017).

Previous research has highlighted that PWPs living with anxiety place more importance on participation in meaningful roles and activities than group work (the common format for many anxiety treatments) (Lovegrove & Bannigan, 2021). Restricted participation in everyday activities has a central contributing role to heightened chronic anxiety (Coventry et al., 2014). Thus, a participation-focused approach to managing anxiety in PWPs is warranted. Approaches such as cognitive behavioural therapy (commonly known as CBT) have evidence of effectiveness and acceptability in the Parkinson's population (Reynolds et al., 2020; Roper et al., 2024). Due to the high incidence of cognitive impairment in PWPs, approaches such as CBT often require tailoring to individual PWPs (Roper et al., 2024). People with Parkinson's have expressed a preference for interventions focused on meaningful activity and 'doing' rather than psychotherapy (Lovegrove & Bannigan, 2021; Shah et al., 2022). In response to these issues, a novel occupation-based complex intervention to help people with Parkinson's to live well with anxiety (OBtAIN-PD) has been co-produced with PWPs, care partners, and occupational therapists as part of a logic modelling process using Medical Research Council (MRC) guidance for complex interventions (Skivington et al., 2021). During intervention co-production, participants stated that participation in meaningful activity should be the proposed primary outcome, with anxiety symptoms as a secondary outcome (Lovegrove & Bannigan, 2021; Lovegrove et al., 2024). The OBtAIN-PD intervention can be considered complex because of the number of components involved, the setting, the permitted degree of flexibility, and the training needed by the delivering occupational therapists (Skivington et al., 2021). This intervention provides a manualised treatment package targeting modifying an individual's lifestyle to remove barriers to engaging in activities that are important for PWPs and is delivered on a one-to-one basis.

As this is a new intervention, no current studies examine the feasibility, acceptability, or clinical or cost-effectiveness of the OBtAIN-PD intervention in PWPs.

STUDY AIMS AND OBJECTIVES

Our aim is to conduct a cluster randomised feasibility trial of the OBtAIN-PD in a real-world practice setting. We aim to provide high-quality data to facilitate designing and planning a future definitive trial by answering the feasibility study questions (Bowen et al., 2009). Our study objectives are to estimate the feasibility and acceptability of the trial procedures by answering a range of feasibility study questions (Figure 6.1). This trial aligns with the MRC framework for developing complex interventions (Fig 6.2) (Skivington et al., 2021).

1	Are the eligibility criteria suitable?
2	What are the numbers of eligible and interested participants from the target population? Specifically, conversion rates by recruitment method (invitation letter, personal contact with clinician).
3	What is the ability of clinicians to recruit participants and understand any differences between this for different referral pathways (for example GP vs Community Rehabilitation Teams vs consultant outpatient clinics vs self-referral)?
4	Are community rehabilitation teams willing to be randomised?
5	What are the retention rates as participants move through the trial?
6	What is the intervention fidelity between sites?
7	What is the feasibility and acceptability of the OBtAIN-PD intervention (adherence) for both participants and clinicians?
8	What is the completion rate and performance of self-report outcome measures, including completion rates, baseline scores, distributional properties and standard deviations, and responsiveness to refine the selection of the primary and secondary outcome measures for the definitive trial?
9	Facilitate a definition of occupational therapy treatment as usual for use in a future definitive trial.
10	What are the baseline factors, if any, associated with outcomes?
11	Inform estimates of the correlation between baseline and follow-up outcome measures to inform future sample size calculation.
12	What is the feasibility of collecting data to estimate intervention resource requirements and costs?
13	What is the feasibility of collecting data to estimate health, social care, and broader societal resource use and costs?
14	What is the feasibility of aligning the trial with existing clinical services i.e., referral date, first treatment date?
15	What are the total resources required for the full trial?

Figure 6.1: The OBtAIN-PD feasibility study questions.

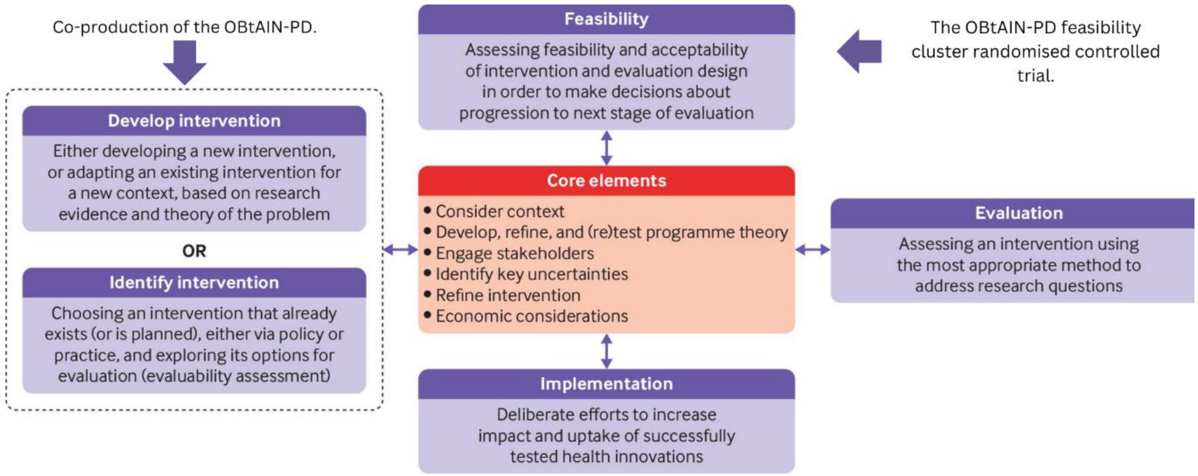


Figure 6.2: The OBtAIN-PD feasibility cluster randomised controlled trial in relation to the Medical Research Council framework. Adapted from Skivington et al. (2021).

STUDY DESIGN

This is a pragmatic feasibility cluster randomised controlled trial, with assessor-blinded outcome assessment, cluster randomising Community Rehabilitation Teams (CRTs) to implement either the OBtAIN-PD and usual occupational therapy care (intervention) or usual occupational therapy care alone (usual care). A cluster randomised design was chosen to help control for potential contamination between trial arms (Moberg & Kramer, 2015).

Four CRTs across two sites (therefore two CRTs at each with one intervention and one usual care) will be allocated on a 1:1 basis to implement the OBtAIN-PD intervention plus usual care, or usual occupational therapy care alone, stratified by site with a block size of two. This will be logistically convenient and accommodate the current pressures on National Health Services, while providing a control for contamination. Group allocation will be stratified by site.

METHODS

Participants, interventions, and outcomes

Study setting

This trial will be conducted in two National Health Service trusts in the Southwest of England, UK. Each trust will have two community rehabilitation teams (CRTs) involved in the trial. Each CRT covers a distinct geographical area within their respective Trusts. 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 usual care as part of their routine National Health Service role or the OBtAIN-PD intervention, which includes usual 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). The OBtAIN-PD trial began recruitment in April 2023 and ended recruitment in October 2023. The final 24-week follow-up will be completed in April 2024.

Eligibility criteria

The following criteria must be met to be enrolled in the study:

- They are over 18 years of age.
- The person has a diagnosis of idiopathic Parkinson’s, as diagnosed by a neurologist or movement disorder consultant.
- Experiences anxiety measured as ‘moderate’ (≥10) by the Generalised Anxiety Disorder Assessment (GAD-7) as part of the screening process.
- Willing and able to undertake eight intervention sessions over 10 weeks.

- Able to give informed consent.

Exclusion criteria for this RCT are:

- Participants unable to give informed consent.
- People who are unable to physically complete self-report forms and do not have someone to assist them.
- PWPs experiencing anxiety measured as ‘mild’ (9 or less) by the GAD-7.
- PWPs with a severe cognitive deficit that affects their ability to follow instructions assessed using the Montreal Cognitive Assessment (<23).
- ‘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.
- 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 in the last six months.

Interventions

USUAL CARE

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 (Carl et al., 2016; Sturkenboom, Graff, Borm, Veenhuizen, et al., 2013) and guided by both NICE guidelines (NICE, 2018) and the Royal College of Occupational Therapists ‘Occupational Therapy for People with Parkinson’s’ (Royal College of Occupational Therapists, 2018) guidelines. Usual care will be delivered by a community-based occupational therapist at each site (n=2). The site file will provide descriptions of a selection of areas that could be targeted and approaches used. This will include equipment provision, personal care practice, and addressing falls. In line with occupational therapy practice, the exact approaches used will be flexible to provide therapist autonomy based on patient needs. The usual care therapy input received by the participants will be recorded to further facilitate a definition of treatment as usual for a future study via intervention logs as part of the case report form. This form will collect the session date, time, duration, location, and content. Total participants contact time and administration time will be collected to ascertain the impact on the occupational therapists' time. Treatment as usual duration will last 60 minutes per session with an estimated eight sessions over a 10-week period based on patient need.

OBtAIN-PD

OBtAIN-PD is an intervention that focuses on re-establishing and maintaining engagement in meaningful social and habitual roles, like attending a club or engaging in a hobby that PWPs value (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017). In contrast, traditional National Health Service occupational therapy interventions that form the usual care group tend to focus on compensatory techniques (e.g., equipment to maintain personal care) that PWPs with anxiety have identified as less of a priority (Lovegrove & Bannigan, 2021; Lovegrove et al., 2017). The OBtAIN-PD has been co-produced with PWPs, care partners, and occupational therapists as part of the development phase of the MRC framework for developing and evaluating complex interventions (Skivington et al., 2021). The development of OBtAIN-PD is explained in more detail in previous articles (Lovegrove & Bannigan, 2021; Lovegrove et al., 2023; Lovegrove et al., 2024). The OBtAIN-PD will include lifestyle modification underpinned by Acceptance and Commitment Therapy concepts to help PWPs engage in the meaningful activities that they want to and to live well with their anxiety. The meaningful activities the participants choose to engage with will be individual and may include activities such as walking the dog or attending a social club. Collaborative goal-setting and motivational interviewing concepts will be part of the OBtAIN-PD to promote engagement and adherence. OBtAIN-PD will be delivered by a community-based occupational therapist at each site (N=2).

The intervention will be delivered in community settings, and the occupational therapists delivering OBtAIN-PD will receive specific training in its use. The training consists of a 30-minute training video supported by an intervention manual and completed examples of the patient goal and information sheets. Questions will be directed to a research team member (JM) who will act as a gatekeeper to prevent the lead researcher and assessor (CL) from becoming unblinded. The occupational therapists in both trial arms will be based in separate teams and will not share a clinical supervisor to reduce contamination risk. It is estimated that OBtAIN-PD will last 30 minutes per session, with eight sessions over a 10-week period (n=8) (Carl et al., 2016; Ghielen et al., 2017; Sturkenboom, Graff, Borm, Veenhuizen, et al., 2013). The intervention will include an additional 30 minutes of usual care, i.e., 60 minutes in 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 (Sturkenboom et al., 2014). The dosage of usual care occupational therapy and OBtAIN-PD are based on published pragmatic trials of occupational therapy for Parkinson’s (Carl et al., 2016; Sturkenboom, Graff, Borm, Veenhuizen, et al., 2013; Sturkenboom et al., 2014). In summary, OBtAIN-PD will run alongside usual care and provide a novel means of delivering occupational therapy targeting anxiety-related issues in performance. To minimise inter-therapist contamination, therapists will be advised to not discuss details of OBtAIN-PD with colleagues.

Participants in both groups will continue to receive usual medical and therapy management, such as physiotherapy. This will be monitored via a health, social care, and personal resource-use questionnaire.

Outcomes

We will conduct both a quantitative and qualitative evaluation. All participants will be requested to complete standardised, validated patient self-reported questionnaires. Electronic, web-based delivery will be utilised where possible. Paper versions of the questionnaires will be provided with stamped addressed envelopes to return by post for participants who do not have internet access. Email reminders will be used, with telephone calls used when required. The online patient-reported outcome forms will use appropriate completion rules to ensure data completeness.

All measures will be undertaken at baseline and post-intervention (12- and 24-weeks following baseline assessment). The follow-up assessments will be anchored to the baseline. This timeframe is anticipated to be adequate for delivery intervention, including potential wait times. The 12- and 24-week follow-ups are important to comprehensively assess potential benefits and the maintenance of any observed effect. All outcome measure activity is summarised in Table 6.1.

Table 6.1: Outcome measure activities					
Outcome Measured	**Instrument used**	**Screening**	**Baseline**	**12-weeks**	**24-weeks**
Self-perceived performance and satisfaction in everyday activities	Canadian Occupational Performance Measure (COPM)		✓	✓	✓
Participation	Activity Card Sort (ACS3)		✓	✓	✓
Anxiety symptoms	Generalised Anxiety Disorder Assessment (GAD-7)	✓	✓	✓	✓
Health-related quality of life	The Parkinson's Disease Questionnaire (PDQ-39)		✓	✓	✓
Quality of life	EQ-5D-5L		✓	✓	✓
Independence in everyday self-care activities	Barthel Index		✓	✓	✓
Subjective experience	Qualitative interviews				✓

Baseline assessment

Baseline outcome measures will be completed in the week before treatment sessions commence to allow for relevant therapy goal-related information (derived from the COPM) to be transferred to the treating occupational therapist. If the GAD-7 has been repeated at this point and the participant score is ≤6, indicating a minimal clinically important change (Toussaint et al., 2020) of four points from the inclusion criteria score, the participant will be informed of this and withdrawn from the study. Due to the nature of anxiety in Parkinson's (Kano et al., 2011), it is anticipated that this will be a rare occurrence.

Proposed primary outcome

The Canadian Occupational Performance Measure (COPM) is the proposed primary outcome measure for the future definitive trial undergoing testing. The findings of this study will determine the suitability of the COPM for the future trial. The standard COPM is a valid measure of a person's self-perception of performance in everyday living (Cup et al., 2003; Dedding et al., 2004; Eyssen et al., 2011; Eyssen et al., 2005) and has been recommended for PWPs (Gaudet, 2002). The COPM is a client-centred outcome measure for individuals to identify and prioritise everyday issues restricting their participation in everyday living. This measure focuses on occupational performance in all areas of life, including self-care, leisure, and productivity, and is measured using performance and satisfaction scores. The COPM has been used as a primary outcome in clinical trials of people with neurological conditions including Parkinson's (Sturkenboom, Graff, Borm, Veenhuizen, et al., 2013; Sturkenboom et al., 2014; Veenhuizen et al., 2019). The COPM has a minimum possible score of 1 and a maximum possible score of 10 for performance and satisfaction respectively. An improvement of 0.9 for performance and 1.9 for satisfaction is regarded as clinically significant (Eyssen et al., 2005). The COPM has adequate content and construct validity, with moderate responsiveness to change in mixed populations of older home-dwelling adults (Tuntland et al., 2016). This outcome measure will be administered via a secure web-based application or by clinical research teams in person or over the phone if the participant does not have internet access. During the development of this feasibility trial and the OBtAIN-PD, patient and public involvement (PPI) stakeholders felt that participating in meaningful activity was more important than reducing anxiety symptoms alone. Therefore, the COPM was selected as this feasibility RCT's proposed primary outcome measure.

Secondary outcomes

The Activity Card Sort (ACS) is an assessment of a person’s perceived level of participation that has demonstrated applications in clinical practice and research (Duncan & Earhart, 2011). It will be administered in the same session as the COPM. The ACS is a valid and reliable tool for assessing participation, with excellent intra and interrater reliability (ICC inter-rater = 0.85; ICC intra-rater = 0.89) (Katz et al., 2003; Poerbodipoero et al., 2016).

The following patient-reported outcome measures will be sent to the participant once informed consent has been gained. These measures will include:

- *GAD-7:* a valid and reliable 7-item instrument used to assess the severity of generalised anxiety disorder (Ruiz et al., 2011; Spitzer et al., 2006). The GAD-7 has demonstrated validity and reliability in various populations, with high internal consistency ($\alpha = 0.89$) (Johnson et al., 2019; Löwe et al., 2008; Rutter & Brown, 2017). The GAD-7 is commonly used in the ‘Improving Access to Psychological Therapies’ pathway and will provide a viable way of comparing the OBtAIN-PD against other interventions in the future. A score of ≥10 identifies a level of anxiety that has a direct impact on the quality of life and is a recommended cut-off that identifies a need for further clinical evaluation (Locke et al., 2015). The GAD-7 is used as both a screening tool and an outcome measure in this trial and will be re-sent to the participant if their first treatment session is not within one week of gaining consent.
- *PDQ-39:* This condition-specific questionnaire is a patient-reported measure of health status and quality of life and has been psychometrically evaluated in this population. It comprises 39 questions related to activities and symptoms. It takes approximately three minutes to complete. Minimally important changes are

available [>25-point change total score, > 20-point change symptom subscale] (Horváth et al., 2017).

- *EQ-5D-5L:* Evaluation of health-related quality of life. This measure has been used within clinical trials with PWPs and has been psychometrically validated for this population (Alvarado-Bolaños et al., 2015). The EQ-5D-5L can be used to calculate quality adjusted life-years (QALYs), enabling cost-utility analyses.
- *Barthel Index:* A common scale used to measure a person's performance in self-care activities of daily living and a widely used measure in research to determine the effect of an intervention on independence in these activities (Morley et al., 2012; Sainsbury et al., 2005).

At monthly intervals throughout the trial, participants will complete a log of falls, resource use, and any discomforts they believe to be associated with the OBtAIN-PD study (online or paper-based depending on participant requirements). This log will also collect medication details and any changes to inform analysis, such as introducing anxiolytic medication. The monthly serial collection of data enables the impact of the OBtAIN-PD on these areas to be identified and to assess the suitability of this data collection method, as well as monitor any adverse events. All patient-reported outcome measures included in this study are validated for use in Parkinson's Disease clinical care and research. The research team designed the falls and resource use log for this study.

Qualitative evaluation

An embedded qualitative research study will examine the intervention to explore mechanisms and components for subsequent testing. Ten PWPs and the trial occupational therapists will be interviewed. The participants will be asked if they want to take part in an interview at their final 24-week outcome measure session. If the participant wants to take part in an interview, a separate PIS for the qualitative interviews and a consent form will be provided. A provisional time and date for the interview will be set with the participant. The informed consent form will be completed with the participant immediately prior to the interview. The interview will be conducted online or on the telephone. Purposeful sampling will ensure the demographic representation of PWPs based on sex, location, and baseline GAD-7 score.

The specific aims of this will be to investigate:

- Acceptability of trial methods across both trial arms.
- Acceptability of the OBtAIN-PD.
- Impact that the OBtAIN-PD had on the lives of PWPs.
- Potential recruitment and retention barriers.
- Outcome measure suitability and burden.

Sample size

The target sample size is 50. The number of PWPs in the site catchment areas is estimated as 1800 with 70% (1300) known to the Parkinson's services. Around 50% are estimated to have anxiety (n=650) (Barone et al., 2009; Pontone et al., 2009). The presence of a severe cognitive impairment in Parkinson's that is likely to impair mental capacity has an estimated point prevalence of 5-10% (Aarsland & Kurz, 2010; Garcia-Ptacek & Kramberger, 2016; Hanagasi et al., 2017). Thus, the participant pool is approximately estimated with a precision of at least ±4% (i.e., width of 95% confidence interval). Assuming a retention rate of 80% at follow-up, this sample size would allow estimation of the overall retention rate with precision of ±11%. Assuming a non-differential follow-up rate of 80%, it is anticipated to follow up a minimum of 20 participants in each of the two treatment groups, which would provide data to help inform indicative sample size calculations for a definitive RCT.

Recruitment

Participants will be recruited through usual clinical pathways by staff unaware of allocation to reflect usual National Health Service practice as closely as possible whilst avoiding overwhelming the CRTs with an additional workload. Potential participants will be given an information pack by the clinician who has made contact. 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 lead researcher's telephone and email contact details. This information can also be emailed to participants at their request. The PIS and reply slip will encourage those who do not want to take part to return the reply slip stating their reasons for non-interest, but it will be emphasised that there is no obligation. 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.

Given the total sessions in the intervention and usual care group (8 sessions in 10 weeks), this recruitment rate results in an estimated 2-2.5 hrs/week of occupational therapy per site for each occupational therapist dedicated to this project (n=2 per site). This reflects the current workload allocation (<5%) for PWPs for community occupational therapists.

Allocation, concealment, and blinding

Randomisation will be undertaken by the Plymouth Clinical Trials Unit (CTU) to allow the lead researcher to remain blinded to group allocation. The CRTs will be provided with a unique, anonymous code. Within each site, the CRTs will be randomly allocated (1:1) into the usual care [60 minutes of usual occupational therapy management only per session] or intervention [30 minutes OBtAIN-PD plus 30 minutes of usual occupational therapy management per session]. The statistics team generated allocations. These were sent to the co-investigator (JM) who informed the four CRTs of their treatment allocations. Recruitment will commence within one to two weeks of cluster allocation. Participants will then be booked, and treatment provided as per arm allocation. The randomisation list and the program that generated it will be stored in a secure network location within the PenCTU, accessible only to those responsible for its provision. PenCTU staff, independent of the trial, will verify the integrity of the randomisation system throughout the trial according to established written protocols.

Access to the code/list will be confined to the PenCTU data programmer. No one else in the trial team will be aware of allocated trial arms until randomisation is completed, maintaining effective concealment. Following randomisation, only the individuals described above will be aware of the allocations to intervention or usual care arm; the blinded lead OBtAIN-PD researcher will NOT have access to treatment allocation.

Data will be collected on the following to aid in developing potential minimisation factors for a future definitive trial:

- Referral to Treat (RTT) length of time.
- Access to specialist Parkinson’s rehabilitation services such as home-based care pathways and specialist Parkinson’s therapists.
- Organisation size.
- Size of population served.

The trial participants cannot be blinded in this trial due to the nature of the intervention they are receiving. Similarly, the National Health Service treating occupational therapists cannot be blinded. The occupational therapists will be aware of their allocation following the randomisation of their CRT. Participants will be aware of the treatment they receive from their first treatment session with the occupational therapist, such as through the receipt of OBtAIN-PD branded materials. The recruiting clinicians (consultants, Parkinson's nurses, allied health professionals, and CRN research nurses) will not be informed of community rehabilitation teams' group allocation. The only exception will be the occupational therapists in the community rehabilitation teams who will identify potential participants in their usual referral triage process.

The OBtAIN-PD lead researcher conducting all eligibility checks, screening assessments, consent, and outcome assessments will be blinded to the participants’ allocated group until database lockdown, along with the team statistician. A second, unblinded statistician generated the group allocation script. Clinical outcomes will be taken remotely wherever possible, and participants will be asked to not reveal their geographic location or the treatment they have received to preserve assessor blinding. At each time-point, all outcome measures 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, 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 the electronic database any cases of inadvertent unblinding to group allocation at the end of the trial. If this occurs, they will be asked to explain how this unblinding happened. The research team (including the trial statistician) will finally be unblinded after the creation of a locked analysis data set and analysis has been undertaken.

Data collection, management, and analysis

A web-based system developed by PenCTU will be used to electronically capture participant-level data and for general trial management. This consists of a bespoke online system for participant screening, consent, randomisation, and management integrated with REDCap Cloud (Harris et al., 2019), which will capture electronic case report forms.

When registered on the data collection website, the OBtAIN-PD Research team will allocate each participant a unique trial number. PenCTU Data Management staff will monitor the completeness and quality of data recorded in the database and correspond regularly with the OBtAIN-PD research team to capture any missing data where possible and ensure continuous, high-quality data. All data will be collected and stored in accordance with the UK Data Protection Act 2018 and the General Data Protection Regulation 2018.

Reporting of the trial will be in accordance with the CONSORT guidance for pilot and feasibility studies and a detailed statistical analysis plan will be written and signed off prior to database lock. A CONSORT diagram will display data from screening, recruitment and follow-up logs and be used to generate estimates of eligibility, recruitment, consent, and follow-up rates. Reasons for withdrawal will be reported where available. Completion rates will be estimated for outcome measures at each time point, including the health, social and wider care resource-use data. 95% confidence intervals will accompany recruitment and retention rates to inform assumptions for planning the definitive trial. Adherence data will contribute to the evaluation of intervention acceptability and feasibility. As a feasibility trial, it is not powered to detect differences in outcomes between the groups – as such, no inferential statistical testing will be undertaken, and the analysis will be descriptive, using appropriate summary statistics and plots to illustrate any potential between-group differences.

The demographic and clinical characteristics of the sample at baseline will be summarised overall and by allocated group, using appropriate descriptive statistics (e.g. means and standard deviations for normally distributed data, numbers, and percentages for categorical variables) to informally check for balance between the groups.

The variables derived from participant reported outcomes will be calculated in accordance with published guidance. The amount of missing data will be summarised, but no imputation will be carried out unless in accordance with published guidance.

At each follow-up, all participant reported outcomes will be summarised overall and by the allocated group with appropriate descriptive statistics. The change in these outcomes between baseline and follow-up will also be calculated and descriptive statistics for these reported overall and by allocated group, on an intention-to-treat basis. The between-group differences in change between baseline and follow-up will be reported with 95% confidence intervals. Estimates of the correlation between baseline and follow-up outcome measures will be used to inform a future sample size calculation for a definitive RCT.

Qualitative evaluation

The qualitative data for analysis will include verbatim transcripts from the one-to-one interviews of participants and National Health Service occupational therapy staff. 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. All trial occupational therapists will be offered an interview. These 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 or web application (Microsoft Teams) to support transcription. The recordings will be securely deleted once the interviews have been transcribed and anonymised using pseudonyms. The anonymised transcribed data will be uploaded into NVivo 12 software for organisation and analysis (QSR International, 2012). Data will be analysed using thematic analysis adopting Braun and Clarke's six-phase process of (i) data familiarisation; (ii) generating initial codes; (iii) searching for themes; (iv) reviewing themes; (v) defining and naming themes and (vi) writing up to identify patterns of meaning within the data sources (Braun & Clarke, 2014; Braun & Clarke, 2023). Two researchers will refine initial themes to maximise credibility and dependability. The occupational therapist interviews will be completed between December 2023 and March 2024. The participant interviews are scheduled to begin in April 2024.

Interviewees will be invited to review a draft of the analysis as part of a member-checking process to ensure their experiences are accurately represented.

Economic Evaluation

The resources required to provide the intervention will be assessed, and a framework will be established for future cost-effectiveness analysis alongside a full RCT. Data on intervention resources will be collected via within-trial reporting, including participant-level contact and non-contact time and training for delivery staff. Participants will self-report health, social and wider care resource use using a resource use questionnaire adapted for this trial. Participants will complete the EQ-5D-5L (the anticipated primary economic outcome measure in a full trial) and assess the feasibility of estimating QALYs over the follow-up period. The economic evaluation methods will be developed to provide a future policy-relevant cost-effectiveness analysis of the intervention in the context of the UK National Health Service and Social Services.

MONITORING

The trial monitoring plan has been developed and agreed upon by the Trial Management Group (TMG) and Trial Steering Committee (TSC). The TMG will meet monthly. The TSC will meet three times over the 24-month project period, with the first meeting taking place prior to the start of study recruitment. The TSC will include members independent from the trial and an independent chair and statistician.

The likelihood of participants being harmed by the interventions in either trial arm is very low. As such, the collection and reporting of adverse events in this trial is restricted only to those events that are classified as Serious Adverse Events (SAEs). In the context of clinical care and in accordance with local practice, adverse events (AEs) detected by the treating occupational therapists will be recorded in an electronic case report form. PenCTU will immediately notify a research team member (JM) of any reported AEs/SAEs. This team member will then complete an assessment of causal relationship.

ETHICS AND DISSEMINATION

We obtained ethical approval from our institution's Faculty of Health Research Ethics and Integrity Committee (Project ID 3757) and the Health Research Authority (REC reference 23/NE/0027). Participants can withdraw from the trial at any time without giving a reason; this will not affect their ongoing or future care. Data will be available upon request from the corresponding author upon trial completion. We will store data securely on an encrypted institution server. Data will be anonymised before archiving. We will publish the results in a peer-reviewed scientific journal. Participants will receive a summary of the findings at the end of the data analysis. The results will also be published on institution websites, as well as presented at conferences and to professional and patient groups.

PATIENT AND PUBLIC INVOLVEMENT

Lay members, including PWPs, care partners, and occupational therapists have provided patient and public Involvement (PPI) input. Our PPI has provided input into key aspects of study design. Discussion with our PPI representatives has led the trial to implement the recording of self-report measures via a web-based app to minimise burden, and interviewing decliners. PPI representatives will be involved in the development of topic guides for the qualitative component of the trial. In addition, an options appraisal was conducted at the 2022 Royal College of Occupational Therapists annual conference. It was attended by 124 occupational therapists from various clinical backgrounds including (but not exclusively) acute, community, mental health, and academic services. Recommendations from this appraisal have been incorporated into this protocol and include the flexibility of treatment session delivery method, competency assessment for the occupational therapists involved in the trial, and regular contact/ support for the trial occupational therapists in addition to the provided training. A Patient Advisory Group (PAG) has been recruited to support the research team with patient-relevant advice and guidance on the delivery and progression of the study.

ETHICS STATEMENTS

Patient consent for publication

Not applicable.

6.2 Chapter Summary

This chapter has outlined a protocol for a cluster feasibility randomised controlled trial. This trial aims to assess the feasibility and acceptability of conducting a trial of the OBtAIN-PD in a real-world clinical practice setting. During the initial TSC meeting, criteria for progression were established, which are based on a traffic light system: green (proceed), amber (make changes), and red (halt). These progression criteria can be found in Table 6.2. If these criteria are not met, it indicates that a full trial may not be feasible unless the accompanying qualitative study suggests clear ways for improvement. A list of recommendations will be created to help refine the full RCT.

PROGESSION CRITERION	NOTES	RED %	AMBER %	GREEN %
Participant recruitment feasibility	Proportion of approached patients providing consent within the 10-month recruitment window	≤ 50%	51-69%	≥ 70%
Participant recruitment rate (overall)	Actual total recruitment compared to target total recruitment	≤ 50%	51-69%	≥ 70%
Participant recruitment rate (monthly)	Actual maximum achieved monthly recruitment rate compared to target monthly recruitment rate	≤ 50%	51-69%	≥ 70%
Participant retention rate	Proportion of randomised participants providing final study follow up visit data	≤ 40%	41-79%	≥ 80%
Intervention fidelity	Proportion of interventions delivered as per protocol	≤ 60%	61-74%	≥ 75%
Primary outcome data completeness	Proportion of randomised participants providing sufficient data at <primary outcome assessment timepoint> to support analysis*	≤ 60%	61-79%	≥ 80%
Interview completion	Proportion of interviews completed with participants and trial occupational therapists	≤ 50%	62-75%	≥ 75%
Site willingness	Willingness of the four individual CRTs to participate in the full cluster RCT	≤ 25%	50%	≥ 75%

Table 6.2: The OBtAIN-PD feasibility cluster RCT progression criteria.

Chapter 7: Discussion and Conclusions

The purpose of this final chapter is to summarise the findings included in this thesis andinterpret these in the context of what is already known to demonstrate how they have addressed the thesis aim and added to existing knowledge. This is followed by discussion of strengths and limitations of this thesis, reflections on the challenges encountered, recommendations for future research, and concluding the thesis.

7.1 Scoping review- summary and recommendations

Anxiety is a widespread cause of disability worldwide that impedes participation in daily life, and occupational therapists aim to help people participate in daily life activities to their satisfaction. To determine what occupational therapy interventions are available globally for adults with anxiety, the scoping review in this thesis identified and analysed 18 studies that reported on eight different interventions. Although various outcome measures were used, only one intervention included occupational therapy-specific measures. It is suggested that future interventions and research should incorporate occupational therapy outcome measures and appropriate impairment-based measures to demonstrate the effectiveness of occupational therapy services. While most interventions are delivered in groups, individual occupational therapy sessions can also be beneficial. Goal setting and tailoring should be used to enhance the effectiveness and impact of occupational therapy interventions for adults living with anxiety. Rigorously designed clinical trials of occupational therapy interventions for adults living with anxiety are needed, including economic evaluations to demonstrate cost-effectiveness.

7.2 Group concept mapping- summary and recommendations

This study identified eight priority components for future intervention, presented as clusters. Individual ideas within these clusters were rated highly on importance and feasibility and could serve as starting points for intervention development. The clusters, such as “Coping” and “Support from others”, highlighted the individual and social factors supporting participation in meaningful roles and activities that needed to be considered in intervention development. Access to timely peer support and the development of coping strategies were highlighted as important considerations for the next phase of intervention development. To integrate the components identified in this study into a new intervention to help people with Parkinson’s live well with anxiety, future research should involve stakeholders in co-producing the intervention. Additionally, removing barriers to research participation for care partners and occupational therapists will be important as providing convenient data collection will likely not suffice.

This novel study involved people with Parkinson's, their care partners, and occupational therapists. They were asked to identify the most important components for developing an occupation- and community-based intervention to address Parkinson ’s-related anxiety. This was done through an online GCM methodology that involved key stakeholders, as per the MRC framework (Skivington et al., 2021). The study identified eight clusters that served as starting points for intervention development. These clusters include exercise, lifestyle changes, self-help, coping, access to information, professional help, peers and groups, and support from others. The statements within each cluster rated highly on importance and feasibility were prioritised in developing the intervention. The study's findings were used to co-produce the OBtAIN-PD intervention.

7.3 Logic modelling- summary and recommendations

In this study, a new intervention called OBtAIN-PD was developed for occupational therapists to help people with Parkinson's live well with anxiety. The intervention was co-produced with the help of diverse stakeholders, including people with Parkinson’s, care partners, and occupational therapists. A logic model was created by identifying the necessary inputs, processes, and outputs, which served as a foundation for an intervention manual, information sheets, and goal-planning documentation.

Logic model frameworks can help determine what is needed to make an intervention successful, including the essential processes and outcomes. The comprehensive and staged approach to developing OBtAIN-PD using the MRC framework will strengthen the viability of the intervention and increase the likelihood that it will benefit people with Parkinson’s (Bleijenberg et al., 2018). Others who want to co-produce similar interventions with stakeholders could use this same framework. The OBtAIN-PD will undergo initial testing in a feasibility RCT.

7.4 Feasibility cluster RCT protocol- summary

Chapter 6 introduced the protocol for a feasibility cluster RCT of the OBtAIN-PD. The intervention, specified in Chapter 5, will be standardised and tested in a real-world practice setting to assess its feasibility and acceptability. The study also aims to define occupational therapy as usual care for people with Parkinson's who experience anxiety. Resource-use data will be collected to assist in planning a complete economic evaluation of the intervention in a definitive trial.

A cluster design may introduce an imbalance between trial arms, but this can also reduce contamination and improve the study's internal validity. However, assessor blinding may be challenging in a real-world practice setting, which could introduce the possibility of assessment bias. The follow-up period is limited to 24 weeks, which may not capture the long-term effects of the intervention.

This chapter (Chapter 7) provides a discussion of the thesis, the aim of which was to co-produce an occupation-based complex intervention for living well with anxiety and Parkinson’s (OBtAIN-PD) (Chapter 1). The results and findings are brought together and interpreted from the various phases of the research and related to the broader literature (Chapter 5). Recommendations for future research are presented in a later section (Section 7.10).

7.5 Complex interventions

Informed by the MRC framework for developing complex interventions, OBtAIN-PD was developed to help people with Parkinson’s live well with anxiety. Since 2006, several significant conceptual, methodological, and theoretical advancements have occurred with the MRC framework. These advancements have been integrated into a new framework commissioned by the National Institute of Health Research (NIHR) and the MRC (Skivington et al., 2021). The framework's objective is to assist researchers in collaborating with other stakeholders to pinpoint the key questions about complex interventions and to design and conduct research with diverse perspectives and appropriate methods. The scoping review, group concept mapping, and logic modelling study just described were used to co-produce the OBtAIN-PD. Using the MRC framework as a structured approach allows reporting of the OBtAIN-PD according to the TIDieR checklist, which provides transparency and enables future replication (Hoffmann et al., 2014). Complex intervention research involves more than evaluating whether an intervention works. It also includes identifying its impact, assessing its value, theorising the working mechanisms, considering its context, analysing how it contributes to system change, and using evidence to support decision-making. These areas are detailed in Chapters 2, 3, 4, and 5, demonstrating the extent to which a comprehensive development phase was achieved (Skivington et al., 2021).

Outcomes following complex interventions can be uncertain due to their intricate components, making prediction of outcome difficult (Levati et al., 2016). Multiple factors contributed by various participants across several studies may influence the outcome of OBtAIN-PD (Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove, Sturkenboom, et al., in press). Therefore, interpreting results is complicated and could be better assessed using a process evaluation. A process evaluation is included in the OBtAIN-PD feasibility cluster RCT to determine whether the OBtAIN-PD are implemented as intended and result in certain outputs (Lovegrove, Bannigan, Hayward, et al., in press) (Chapter 6). During the OBtAIN-PD project, participants emphasised the importance of involving care partners, friends, and family in the intervention (Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove, Sturkenboom, et al., in press). This is in keeping with other studies investigating occupational therapy for people with Parkinson’s (Sturkenboom et al., 2014; Welsby et al., 2019). Other occupational therapy interventions using lifestyle management approaches also use this sort of involvement in their delivery (Clark et al., 2012; Fox et al., 2021; Lambert et al., 2008). Research from other long-term conditions suggests that the support of family and friends is closely linked to the self-efficacy of individuals with diabetes. This support can help them maintain lifestyle changes and optimise diabetes management outside of formal care (Rintala et al., 2013; Rosland et al., 2008). Improved clinical outcomes in people with type 2 diabetes are associated with higher levels of social support (Strom & Egede, 2012). In individuals with chronic obstructive pulmonary disorder, higher levels of social support are linked to increased physical activity and greater participation in pulmonary rehabilitation programs (Chen et al., 2017). It will be important to quantify adherence and self-care practices among participants in the future feasibility RCT and analyse if there is an effect of this on the primary outcome between intervention groups.

7.6 Occupational Therapy

The OBtAIN-PD program aims to assist individuals with Parkinson's disease in managing anxiety by encouraging involvement in meaningful activities. Engaging in occupational activities is necessary for all individuals, including those living with Parkinson's, as it promotes good health and wellbeing (Bar & Jarus, 2015; Reitz et al., 2020). This perspective on individuals with Parkinson's disease and the role of occupational therapists in supporting their engagement in daily activities embodies Yerxa's (1998) belief that occupational therapists are *"search engines for potential"* (pg. 413). Specifically, Yerxa proposed, *"Occupational therapists discover a person's resources and emphasize what that person can or might be able to do instead of the person's incapacities; what's right instead of what's wrong"* (p. 413). This quote seems to align with the aims and objectives of the OBtAIN-PD. Participants in group concept mapping (Chapter 3) and logic modelling studies (Chapter 4) highlight the importance of adapting their lifestyle to promote better habits and routines to improve quality of life (Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove et al., 2024). The participant's ideas regarding establishing time usage patterns for occupational engagement are supported by a long-standing philosophy of occupational therapy. In his classic work on this philosophy, Adolph Meyer (1922) explained that it is important to live life with a rhythm, particularly in balancing work, play, rest, and sleep. To achieve this balance, one must actually engage in these activities:

"Our body is not merely so many pounds of flesh and bone figuring as a machine, with an abstract mind or soul added to it. It is throughout a live organism pulsating with its rhythm of rest, and activity, beating time (as we might say) in ever so many ways, most readily intelligible and in the full bloom of its nature when it feels itself as one of those great self-guiding energy-transformers which constitute the real world of living beings. Our conception of man is that of an organism that maintains and balances itself in the world of reality and actuality by being in active life and active use, i.e., using and living and acting its time in harmony with its own nature and the nature about it. It is the use that we make of ourselves that gives the ultimate stamp to our every organ." (p.5)

The participants in the OBtAIN-PD project study agreed that people with Parkinson's disease still strive to lead an active and fulfilling life (Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove et al., 2024). For example, participants in the group concept mapping study stated it was important to engage in meaningful activities regularly, and the logic modelling participants felt it was important to engage in activities that the person enjoys (Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove et al., 2024). Similarly, the PPIE stakeholders for this project felt that a focus on 'doing' was important. A person's life is made up of both moments of engagement and disengagement in different activities. However, OBtAIN-PD aims to help people with Parkinson's live well with anxiety by promoting a balance in one's lifestyle. According to Matuska and Christiansen (2008), lifestyle balance means having patterns of engagement in activities that meet psychological needs rather than just an equal distribution of different types of activities: *"a satisfying pattern of daily occupation that is* *healthful, meaningful, and sustainable to an individual within the context of his or her current life circumstances"* (p.11). Occupational patterns must fulfil certain psychological needs such as maintaining biological health and physical safety, establishing rewarding and self-affirming relationships, feeling engaged, challenged, and competent, and creating meaning and a positive identity. For example, Kitwood (2011) identified specific psychological needs for individuals with dementia (a neurodegenerative condition with some similarities to the advanced stages of Parkinson's) (van der Steen et al., 2019), including attachment, comfort, inclusion, identity, occupation, and ultimately, love. People with Parkinson's receiving OBtAIN-PD may satisfy a proportion of their psychological needs through occupational engagement and promote a balanced lifestyle.

The participants of the logic modelling study (Chapter 4) describe the possibility that people living with Parkinson's could achieve more in life than just biological health and physical safety as long as they receive adequate support (Lovegrove, Bannigan, Marsden, et al., in press). Through their discussions and views, participants seemed to suggest that occupational therapists working to create an occupationally enlivening environment can promote rewarding relationships, opportunities to be challenged and feel competent, create meaning, and maintain personal goals. Whilst not the original aim or focus of OBtAIN-PD, this may provide insight into a potential working mechanism that warrants further research. In this way, the participants in these studies were inspirational; they set the bar high for occupational therapists working with people with Parkinson's who are experiencing anxiety. The goal for people with Parkinson's must no longer be stagnant in safety and physical health; the overarching goal can be lifestyle balance through occupational engagement. The aim of OBtAIN-PD is to help people with Parkinson's live well with anxiety, so this could provide an avenue for further research. Although this view may seem a stretch in the resource-strained UK public services, the participants suggest an occupational therapy practice that lives up to the profession's core beliefs and warrants further research.

7.7 Developing Evidence

The scoping review presented in Chapter 2 suggested that future research should focus on reporting the impact of occupational therapy interventions on activity outcomes. Research is an accepted component of evidence-based occupational therapy practice in the UK (Royal College of Occupational Therapists, 2019). It makes sense to incorporate research capacity into evidence-based practice frameworks, particularly within the National Health Service (NHS), as it recognises the importance of research in informing practice decisions. However, the findings from the scoping review (Chapter 2) suggest that there may be a need to enhance the profession's research capacity to ensure inclusivity across all occupational therapy practitioners (Di Bona et al., 2017; Slade et al., 2018), thereby promoting high-quality research with increased emphasis on evaluating effectiveness through participation and occupation focused outcome measures (Lovegrove, Marsden, et al., in press). It is imperative to conduct rigorous and well-designed studies to evaluate the effectiveness of occupational therapy interventions for adults with anxiety and people with Parkinson's. The studies reviewed in the scoping review (chapter 2) suggest that conducting randomised controlled trials (RCTs) and quasi-experimental studies in this clinical field is feasible. However, the number of such studies is still limited. The scoping review highlights the urgent need for more high-quality research in occupational therapy, particularly in mental health (Bannigan et al., 2008; Kirsh et al., 2019). In order to enhance the research capabilities of occupational therapists and make the most of their knowledge and skills, including those of early career professionals, we need to reshape the way we view research.

While research utilisation is an essential part of the job for all occupational therapists, only some occupational therapists will be researchers. Ensuring that occupational therapy researchers have adequate and meaningful support will be paramount to developing the evidence for occupation-based interventions. Pighills et al. (2013) frame research capacity as a continuum. The continuum encompasses the consumption of research produced by others; in the UK, this is commonly referred to as evidence-based practice, which refers to using high-quality research findings to support and underpin clinical practice (Pighills et al., 2013). It could benefit the profession to adopt a research capacity framework based on a continuum such as the one outlined by Pighills et al. (2013). This could help broaden the perspective of what research capacity involves, making it more accessible for the majority of members to identify ways in which they can contribute to it.

7.8 International Context

Anxiety is a common human emotion. Whatever country a person lives in, feelings of worry, fear, and apprehension are part of our shared psychological landscape (Grogans et al., 2023). However, how these emotions are expressed, understood, and managed can differ substantially based on cultural context (Pugh et al., 2022). Alongside healthcare system variations between different cultures, this may impact the feasibility or effectiveness of OBtAIN-PD in these international systems (Evans & Stoddart, 2017; Nilsen & Bernhardsson, 2019). The articles identified in the scoping review (chapter 2) are predominantly from Western cultures with established public-funded healthcare systems (Lovegrove, Marsden, et al., in press)It is important to Consider how international variations in healthcare may affect the delivery of OBtAIN-PD when planning future research.

Different languages have unique ways of describing emotional experiences (Lindquist et al., 2015). For instance, some cultures might have specific words or phrases to express anxiety that don’t directly translate into English (Jackson et al., 2019). These linguistic nuances can affect how individuals communicate their distress. Cultures also have varying norms regarding emotional expression, often referred to as emotional display rules (Hwang & Matsumoto, 2020; Zhou et al., 2023). Some societies encourage open emotional expression, while others emphasise stoicism (Moore et al., 2013). These norms impact how anxiety symptoms are displayed and perceived (Jackson et al., 2019). With this in mind, the language and examples used in OBtAIN-PD will likely need considerable adaptation when researching the implementation of OBtAIN-PD in different countries and cultures.

Healthcare interventions often require cultural adaptation for successful scaling and implementation (Heim et al., 2019). For example, researchers have explored the effectiveness of CBT in non-Western cultures. When delivering CBT to culturally diverse clients, clinicians often make modest adaptations. These might include incorporating culturally relevant metaphors, adjusting homework assignments, or considering cultural beliefs about emotions (Jankowska, 2019). Case studies have shown promising outcomes when CBT is culturally adapted (Wallace et al., 2021)Furthermore, mindfulness has similarly been adapted for different cultures. Cultural adaptation of mindfulness has involved modifying mindfulness-based interventions (MBIs) to align with the cultural values, beliefs, and practices of different populations. This process ensures that mindfulness practices are more accessible and effective across diverse cultural contexts. For example, a systematic review and meta-analysis of MBIs for Hispanic populations found that culturally adapted MBIs were associated with significant improvements in depression symptoms, stress reduction, and chronic illness management (Castellanos et al., 2020). The study highlighted the importance of incorporating cultural elements to enhance the relevance and acceptance of mindfulness practices among Hispanic individuals (Castellanos et al., 2020). Similarly, mindfulness practices have been adapted for use in various cultural settings, including Asian, African, and Indigenous communities (Karl et al., 2022; Kirmayer, 2015). These adaptations often involve integrating traditional cultural practices and languages, which can help individuals connect more deeply with mindfulness techniques (Karl et al., 2022; Kirmayer, 2015). Overall, the cultural adaptation of the OBtAIN-PD will be crucial in ensuring that it is effective and meaningful for people from diverse backgrounds. For example, the OBtAIN-PD is currently an individual 1:1 treatment, but the delivery may be more effective as a group-based intervention involving trusted community leaders in a collectivist culture. Similarly, these cultural adaptations will need to be reflected in the training for the healthcare professionals delivering OBtAIN-PD (Mahon, 2023)

Differences in infrastructure across countries greatly impact the delivery of healthcare interventions, creating barriers that can hinder access to quality care (Alderwick et al., 2021). These disparities are often rooted in economic, political, and social factors, leading to varied healthcare outcomes globally (Alderwick et al., 2021). Economic disparities are a primary factor influencing infrastructure quality. High-income countries typically have well-developed healthcare infrastructure, including advanced medical facilities, robust supply chains, and extensive healthcare networks. In contrast, low- and middle-income countries often struggle with inadequate infrastructure due to limited financial resources. This can result in poorly equipped hospitals, insufficient medical supplies, and a lack of trained healthcare professionals (Al-Worafi, 2023b). For instance, a study on healthcare facilities in developing countries highlights that limited resources and workforce shortages are significant challenges (Al-Worafi, 2023b). These limitations can lead to overcrowded services, long waiting times, and inadequate patient care, which ultimately affect health outcomes and will need consideration for the OBtAIN-PD.

Geographic barriers also play a crucial role in healthcare delivery. In rural and remote areas, the lack of infrastructure, such as roads, transportation, and communication networks, can severely limit access to healthcare services. People in these regions may have to travel long distances to reach the nearest healthcare facility, which can be particularly challenging in emergencies (Edelman et al., 2021). For example, in many parts of Sub-Saharan Africa and across the Philippines, poor road conditions and limited transportation options make it difficult for patients to access healthcare services (Geleto et al., 2018; Gregorio et al., 2023; Varela et al., 2019). This geographic isolation can lead to delays in receiving care, exacerbating health issues and increasing mortality rates (Edelman et al., 2021). Future adaptation of the OBtAIN-PD will need to account for these geographical barriers, especially as it has been developed in the context of UK infrastructure and the NHS.

Technological advancements in healthcare, such as telemedicine and electronic health records, have the potential to improve healthcare delivery. The OBtAIN-PD utilises various delivery methods, including telephone calls and video conferencing. However, the adoption of these technologies varies widely between countries. High-income countries often have the necessary infrastructure to support these technologies, while low- and middle-income countries may lack the required digital infrastructure and technical expertise (Al-Worafi, 2023a). A review of telemedicine implementation in developing countries found that inadequate digital infrastructure and limited internet connectivity are major barriers (Al-Worafi, 2023a). These technological gaps can prevent the effective use of telemedicine, limiting access to remote consultations and digital health services, and will need to be accounted for in the future development of the OBtAIN-PD for international populations.

While considerable effort was made to ensure diverse representation in the co-production of the OBtAIN-PD, it is undoubtedly limited to the UK's health and social care context. With this in mind, a likely future avenue of research will be exploring the OBtAIN-PD's cultural adaptation across diverse populations. This could include collaborating globally with researchers, clinicians, and policymakers to share knowledge and develop culturally sensitive adaptations of the OBtAIN-PD.

7.9 Strengths and Limitations

Developing the OBtAIN-PD using the MRC framework for complex interventions is a key strength of this thesis. Collaborative approaches were employed to design the OBtAIN-PD, which aims to address the challenges associated with living with anxiety and Parkinson's disease. A structured approach to intervention design can increase the potential for successful implementation and minimize the risk of subjects being exposed to ineffective interventions (Bleijenberg et al., 2018). A feasibility RCT design with an embedded qualitative study will ensure a realistic assessment of the capability to conduct a future RCT. The feasibility cluster RCT will use well-established validated outcome measures and will be conducted in multiple centres to assess the intervention in different contexts (Craig et al., 2018). Semi-structured interviews will provide substantial insight into the experiences of participants and occupational therapists in delivering and receiving the OBtAIN-PD. The feasibility cluster RCT design means that it will not be possible to determine whether the OBtAIN-PD is clinically or cost-effective. This is frustrating, considering it takes an average of five years to design and implement a definitive RCT and 17 years for new understanding and knowledge to be incorporated into clinical practice (Morris et al., 2011).

The lack of diversity in some of the baseline characteristics of the population recruited for the group concept mapping and logic modelling studies raises concerns about whether they truly represent people with Parkinson's and care partner populations in the UK. This is a limitation. Although participants from all nations of the UK were recruited, the samples are predominantly white British from Christian backgrounds. While people with Parkinson's and care partners from different ethnic backgrounds were also recruited, their numbers are relatively low. This is important to ensure that the causal effects of the intervention on the study's population are truly generalizable to the real-world setting (He et al., 2020). Therefore, the next steps of the OBtAIN-PD research project, including the feasibility cluster RCT and future definitive RCT, must address barriers to participation for people from different ethnic backgrounds and seldom-heard groups to ensure that the results are generalisable. For example, using the PROGRESS-Plus framework to identify the characteristics that stratify health opportunities and outcomes may help consider equity when planning these studies and collecting data (Karran et al., 2023; O'Neill et al., 2014)

We recruited fewer occupational therapists during the intervention development studies than people with Parkinson’s and care partners. This could be considered a limitation of the study. However, it is not surprising given the substantial clinical pressures on occupational therapists in the UK, particularly in the NHS (Walker, 2023). On the other hand, the demographics of the occupational therapist group, specifically gender, could be argued to be representative of the occupational therapy workforce. The sample was predominantly white British, similar to the other participants, resulting in similar transferability issues. To address the barriers to participation, the next steps of the OBtAIN-PD project will need to consider more than just providing convenient methods for participation such as recruiting through community organisations and non-probability approaches (Valerio et al., 2016).

7.10 Challenges and lessons learned

Reflecting on my experiences conducting the research work for this thesis, there were several challenges to carrying out this research as a clinical academic occupational therapist working across clinical practice and research. Consequently, lessons can be learned for the future.

Striking a balance between the ideal research methodology and design and the practical aspects of conducting research in clinical settings can create tensions, especially when designing research with busy clinical settings and clinicians in mind. In the OBtAIN-PD project, occupational therapists expressed their research interest informally and reported barriers to service-level participation. The lessons learned from this experience highlight the importance of engaging with those most likely to facilitate and engage in research in practice during the research design and development stage (Boaz et al., 2018; Boaz et al., 2015).

The project aimed to co-produce a new intervention called OBtAIN-PD. This intervention has the potential to improve the lives of people with Parkinson's and anxiety. However, balancing this with research monitoring, management, and governance was challenging. After some reflection, it was realised that this area requires further development and strict processes will be needed to monitor and support recruitment. The practical implications of this will be explored during the feasibility cluster RCT.

Occupational therapists who contributed to developing the intervention and the RCT protocol in the GCM, logic modelling, and PPIE consultation reported that a ‘lead in’ time to become familiar with the study processes would be beneficial (Lovegrove, Bannigan, Marsden, et al., in press; Lovegrove et al., 2024). Therefore a recommendation for a future pragmatic RCT would be to include this as part of the study’s overall timescales.

This particular PhD project was financially supported by an HEE-NIHR Clinical Doctoral Research Fellowship award (NIHR301565). The fellowship is a research training award dedicated to health and social care professionals, except for doctors and dentists, who aspire to build careers combining research and research leadership with ongoing practice and professional development. This fellowship is part of the Integrated Clinical and Academic (ICA) pathway. Despite being thoroughly enjoyable, this pathway still faces critical issues such as a lack of clear entry points, no model of career progression, and insufficient post-doctoral posts (Baltruks & Callaghan, 2018; Trusson et al., 2019). These closely mirror previous analyses of factors hypothesised as critical to establishing a robust and sustainable clinical academic career pathway for nurses, midwifery and the allied health professions (Latter et al., 2009; Westwood et al., 2018). Current pay systems, infrastructure and differing cultures in healthcare organisations and universities create barriers. These factors present substantial obstacles to early career researchers, and support from employers to remain research-active can be felt lacking (Avery et al., 2022). Employment conditions, especially salaries and pensions, could usefully be examined to ensure they don't disadvantage non-medical health professionals pursuing a clinical academic career (Baltruks & Callaghan, 2018). Alongside the ongoing debate around the concerns and issues raised by this career path, which is outside the scope of this thesis to discuss in detail, there remains an appetite in the UK and many parts of the world to explore formalised training pathways underpinned by infrastructure and funding.

7.11 Implications for Future Research

After completing the OBtAIN-PD project, it is essential to consider how its contributions will inform future research.

Outcome measurement

The scoping review highlighted that current occupational therapy interventions for anxiety primarily utilise impairment-based outcome measures, such as the GAD-7, rather than occupational therapy-specific measures. The occupational therapists in the OBtAIN-PD project emphasised the importance of using occupation therapy-specific measures and provided suggestions to incorporate them into the OBtAIN-PD. These suggestions might have been missed if only people with Parkinson's and care partners were involved, as these groups may not consider service level factors such as outcome measurement. This approach is in keeping with the MRC's framework for developing and evaluating complex interventions. Future research studies developing complex interventions should follow this framework and be vigilant to include both those delivering and receiving interventions in the co-production.

Delivery mode

Most occupational therapy interventions for anxiety are delivered in group settings. People with Parkinson's desire personalised intervention for individual goals. This will help tailor interventions more effectively based on a person's needs. Future research aimed at designing occupational therapy treatments for anxiety must avoid group sessions as the default delivery method. Instead, an individual approach involving tailoring and goal setting should be considered to improve the effectiveness and impact of occupational therapy interventions for adults with anxiety. Ultimately, clinical trials of occupational therapy interventions for adults with anxiety, including economic evaluations, are needed.

Stakeholder involvement

The OBtAIN-PD components were identified collaboratively with people with Parkinson’s, care partners, and occupational therapists using GCM. This study used a structured methodology for data collection that prioritised participant input. Most participants had Parkinson's and anxiety. Future complex intervention development studies should consider using the GCM methodology to involve stakeholders meaningfully in providing consensus on a given topic during the development phase (Lovegrove et al., 2024; Skivington et al., 2021).

Recruitment

In the GCM study, the number of care partners and occupational therapists who participated was less than those with Parkinson’s. Additionally, most of our sample were females. Although digital delivery was a convenient way to conduct this research, it might have impacted the engagement of potential participants. In future research, the recruitment strategy and sampling frame may need to be changed to address such imbalances, such as sampling through community organisations or oversampling methods (Bonevski et al., 2014; Valerio et al., 2016). Merely providing a convenient data collection method may not be enough to ensure participant engagement.

The logic modelling study encountered challenges like those of previous studies. However, the logic modelling approach presented a unique opportunity to co-create the OBtAIN-PD with a diverse group of stakeholders. Logic model frameworks proved valuable for identifying the necessary inputs for successful intervention, the crucial implementation processes, and the outcomes to determine the intervention's impact. Future research should consider using logic modelling frameworks in similar co-creation partnerships. However, the study also experienced imbalances in its sample, and future studies should develop recruitment strategies that actively target seldom-heard groups. Relying on peer referral methods and convenient data collection methods such as snowball sampling may yield limited results.

7.12 Conclusion- final thoughts

An occupation-based complex intervention for living well with anxiety in Parkinson’s (OBtAIN-PD) has been co-produced with people with Parkinson’s, care partners, and occupational therapists. The OBtAIN-PD aims to help people with Parkinson's manage their anxiety and engage in meaningful activities. A feasibility cluster randomised controlled trial (RCT) protocol has been presented (Chapter 5). This feasibility RCT aims to determine the feasibility of conducting a fully powered RCT within an NHS setting while also testing the feasibility and fidelity of the OBtAIN-PD. A fully powered RCT is planned to assess the clinical and cost-effectiveness of the OBtAIN-PD based on the results of the feasibility trial.

The research presented in this PhD thesis has contributed to the body of knowledge by synthesising and drawing together the existing evidence of occupational therapy interventions for anxiety (Chapter 2). The project has involved various stakeholders in identifying the necessary components for the new intervention (Chapter 3). The OBtAIN-PD was co-produced based on findings from relevant studies and previous research (Chapter 4). As far as we know, this is the first research program to utilise group concept mapping and logic modelling methodologies for co-producing a new intervention designed explicitly for people with Parkinson's. It is based on what they believe they need to lead a fulfilling life while managing anxiety. This PhD programme has allowed me to acquire research skills that will support my clinical academic career. The next step in the OBtAIN-PD journey is to conduct the feasibility cluster RCT based on the presented protocol (Chapter 5).

Fortunately, the COVID-19 pandemic has not substantially impacted my PhD journey. Data collection for the group concept mapping and logic modelling studies was completed online. These approaches protected participants and the research team from COVID-19 and were also entirely appropriate for these methodologies. The COVID-19 pandemic prompted the adoption of new skills, such as conducting remote informed consent, which will shape future RCT development.

The journey described in this thesis has been enjoyable, and it is the realisation of nine years of my early clinical academic career. I am enthusiastic about developing my skills and conducting research to improve the lives of individuals with Parkinson's and other groups. Developing and testing innovative strategies is essential in meeting the rapidly increasing numbers and complications arising from Parkinson’s in health and social care. The OBtAIN-PD may be a potentially important strategy for helping people with Parkinson’s to live well with anxiety.

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Research Outputs

Publications in peer-reviewed journals

Lovegrove CJ., Sturkenboom I., Foster M., Marsden J., and Bannigan K. (2023) What community-based interventions are used to improve the participation, quality of life, and wellbeing in adults with Parkinson's disease? A scoping review protocol. *JMIR Research Protocols*

Lovegrove CJ., Sturkenboom I., Foster M., Marsden J., and Bannigan K. (*in press*) What community-based interventions are used to improve the participation, quality of life, and wellbeing in adults with Parkinson's disease? A scoping review. *JMIR Aging*

Lovegrove CJ., Sturkenboom I., Marsden J., and Bannigan K. (2024) Concept mapping to define components for an occupation-based intervention for Parkinson's & anxiety. *Journal of Parkinson's Disease*

Lovegrove CJ., Marsden J., Bannigan K., and Sturkenboom I. (*in press*) Developing an occupation-based complex intervention for living well with anxiety and Parkinson's Disease (OBtAIN-PD): a logic modelling approach. *BMJ Open*

Lovegrove CJ., Bannigan K., Hayward C., Ingram W., Bailey M., Aspinall P., Hosking J., Sturkenboom I., and Marsden J. (*in press*) Evaluating the occupation-based complex intervention for living well with anxiety and Parkinson's disease (OBtAIN-PD): A feasibility cluster randomised controlled trial protocol. *BMJ Open*

Conference abstracts and presentations

"Developing an occupation-based complex intervention for living well with anxiety in Parkinson's (OBtAIN-PD): A feasibility cluster randomised controlled trial", Faculty of Health Postgraduate Research Showcase, UK, 2023

"Evaluating the Occupation-Based Complex Intervention for living well with anxiety and Parkinson's Disease (OBtAIN-PD): a feasibility cluster randomised controlled trial protocol", (poster) World Parkinson's Congress, Barcelona, Spain, 2023

"Developing an occupation-based complex intervention for living well with anxiety and Parkinson's (OBtAIN-PD): a logic modelling approach", (poster) World Parkinson's Congress, Barcelona, Spain, 2023

"Defining the components of an occupation-based intervention for people with Parkinson's with anxiety using Group Concept Mapping", (poster) World Parkinson's Congress, Barcelona, Spain, 2023

"I am the expert in my own body: meaningful stakeholder involvement in intervention development", Neuro Convention, Birmingham, UK, 2023

"I feel like I'm going to die: why anxiety in Parkinson's is more than just worrying", Neuro Convention, Birmingham, UK, 2023

"Developing an occupation-based complex intervention for living well with anxiety and Parkinson's (OBtAIN-PD)", Glasgow Caledonian University Research Showcase, Scotland, UK, 2023

"What is the lived experience of anxiety for people with Parkinson's? A phenomenological study", (poster) World Federation of Occupational Therapists International Congress, Paris, France, 2022

"Developing an occupation-based complex intervention for living well with anxiety and Parkinson's (OBtAIN-PD)", World Federation of Occupational Therapists International Congress, Paris, France, 2022

Notable Awards

Extraordinary Endeavour (nominated) and Exceptional Care (nominated)- Extraordinary People Awards, Royal Devon University Healthcare NHS Foundation Trust, 2023

Royal College of Occupational Therapists Research Champion, 2023-present

CPD Event Award (nominated), Glasgow Caledonian University Occupational Therapy Society Awards, 2022

Appendices

Appendix 1: Protocol search (Chapter 2)

S20	Limit S19 to all adult/English language only	84
S19	S9 AND S12 AND S18	159
S18	S13 OR S14 OR S15 OR S16 OR S17	2,507,632
S17	TI (interven* or group* or home or homes or goal* or treat* or manag*) OR AB (interven* or group* or home or homes or goal* or treat* or manag*)	2,348,880
S16	(MH "Psychosocial Intervention")	66
S15	(MH "Goals and Objectives") OR (MH "Goal-Setting") OR (MH "Goal Attainment")	20,292
S14	(MH "Group Processes+")	247,999
S13	(MH "Support Groups+") OR (MH "Group Exercise")	13,368
S12	S10 OR S11	205,440
S11	TI "quality of life" OR AB "quality of life"	129,603
S10	(MH "Quality of Life+") OR (MH "Psychological Well-Being")	150,321
S9	S4 AND S8	1,167
S8	S5 OR S6 OR S7	210,945
S7	(MH "Stress, Psychological+")	89,483
S6	TI anxi* or (stress* n2 relat*) OR AB anxi* (stress* n2 relat*)	89,982
S5	(MH "Anxiety+") OR (MH "Anxiety Disorders+")	89,584
S4	S1 OR S2 OR S3	45,119
S3	TI "occupational therap*" OR AB "occupational therap*"	24,287
S2	(MH "Occupational Therapists") OR (MH "British Association and College of Occupational Therapists")	10,258
S1	(MH "Occupational Therapy+") OR (MH "Occupational Therapy Practice")	29,362

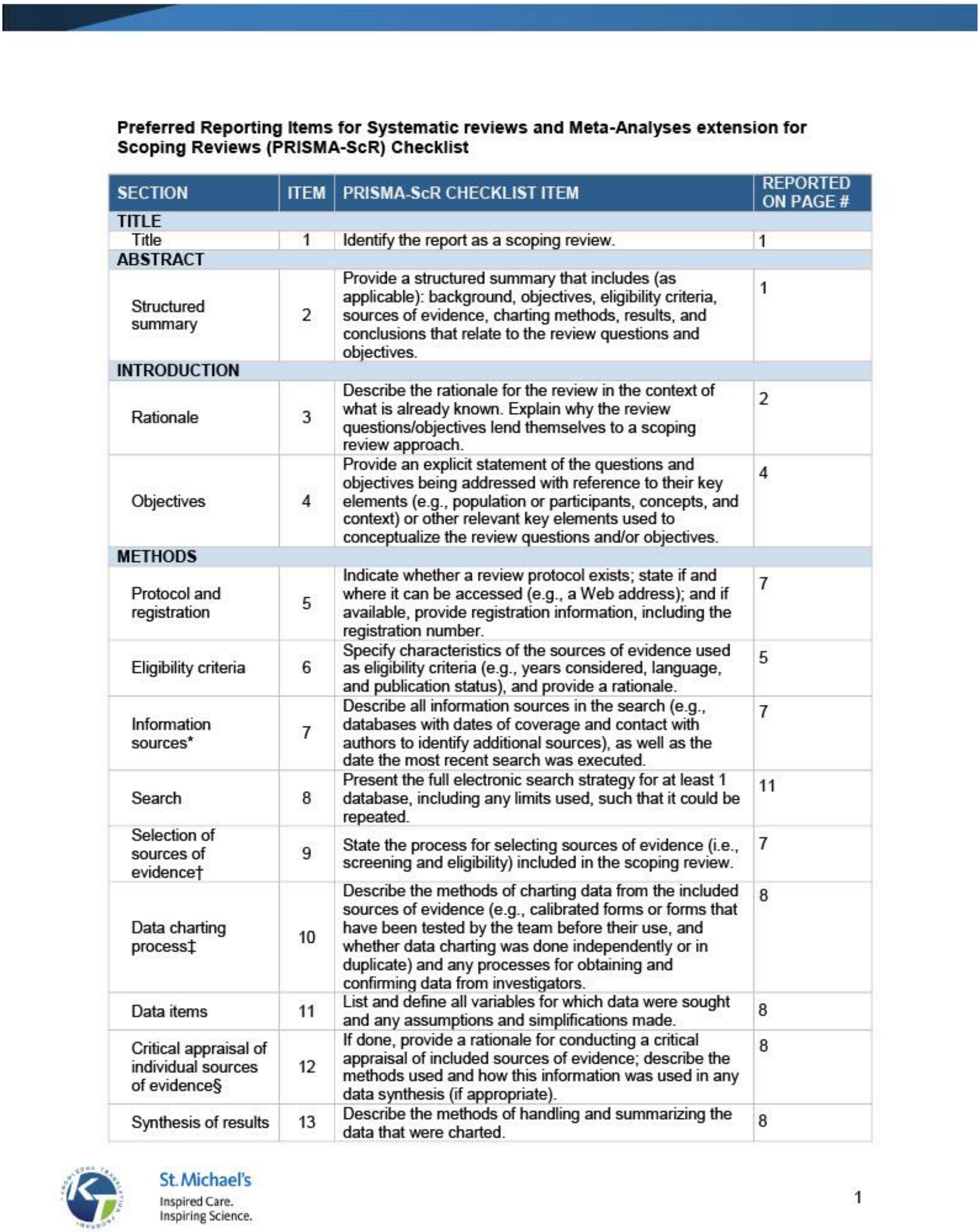
Note: This search was run on CINAHL (via Ebsco) on 9 July, 2021.

Appendix 2: Data extraction tool (Chapter 2)

Item Number	Item	Where located?	
		Primary paper (page or appendix number)	Other details
1	**Brief name** **(***Name of phrase that describes the interventions)*		
2	**Why** *(Rationale, theory, or goal of the elements essential to the intervention)*		
3	**What** *(Describe any physical of informational materials used in the intervention and how they were provided)*		
4	**Procedures** *(Describe each procedure, activity, and/or process used in the intervention)*		
5	**Who provided** *(For each provider, describe their expertise, background, and any specific training given)*		
6	**How** *(Describe modes of delivery)*		
7	**Where** *(Describe type(s) of location(s) where the intervention occurred)*		
8	**When and how much**		

	(Describe the number of times the intervention was delivered and over what period of time)		
9	**Tailoring** *(If the intervention was planned to be personalised, titrated, or adapted, then describe what, why, when, and how)*		
10	**Modifications** *(Describe any changes during the course of the study/ intervention)*		
11	**Planned** *(If intervention adherence or fidelity was assessed, describe how and by whom; if any strategies were used to maintain or improve fidelity, describe them.)*		
12	**Actual** *(If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.)*		

Appendix 3: PRISMA-SCr checklist (Chapter 2)



Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	2
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	4
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	7
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	5
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	7
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	11
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	7
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	8
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	8
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	8
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	8

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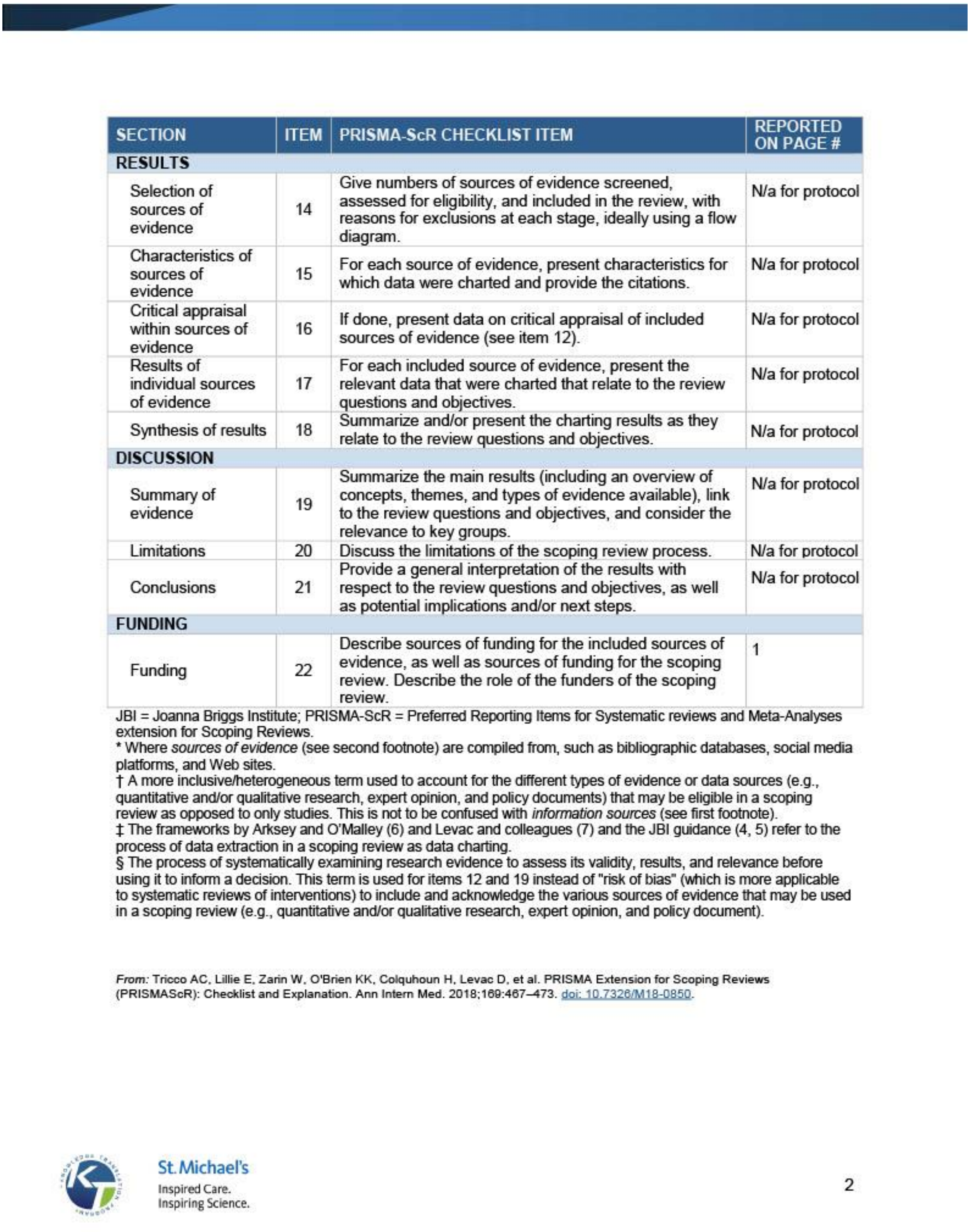

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	N/a for protocol
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	N/a for protocol
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	N/a for protocol
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	N/a for protocol
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	N/a for protocol
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	N/a for protocol
Limitations	20	Discuss the limitations of the scoping review process.	N/a for protocol
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	N/a for protocol
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	1

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

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Appendix 4: Scoping review searches (Chapter 2)

Cochrane Database 22nd November, 2021

#1	MeSH descriptor: [Occupational Therapy] explode all trees	803
#2	MeSH descriptor: [Occupational Therapists] explode all trees	9
#3	"occupational therap*":ti,ab	0
#4	#1 or #2	807
#5	MeSH descriptor: [Anxiety] explode all trees	8588
#6	MeSH descriptor: [Anxiety Disorders] explode all trees	7380
#7	MeSH descriptor: [Stress, Psychological] explode all trees	6544
#8	(anxi* or "stress related"):ti,ab	54014
#9	#6 or #7 or #8	60914
#10	#4 and #9	39

Psychology & Behavioural Sciences Collection (Ebsco) 22nd November, 2021

S6	S1 AND S5	167
S5	S2 OR S3	512,658
S4	S1 AND S2 AND S3	40
S3	interven* or group* or home or homes or goal* or treat* or manag*	492,112
S2	"quality of life" or wellbeing or well-being or "well being"	53,757
S1	"occupational therap*" AND (anxi* or (stress* n2 relat*))	202

Embase search (via Ovid) 22nd November, 2021

1	exp occupational therapy/	23427
2	exp occupational therapist/	7413
3	"occupational therap*".ti,ab.	21712
4	1 or 2 or 3	33376
5	exp anxiety/ or exp anxiety disorder/	469346
6	exp mental stress/	170892
7	(anxi* or (stress* adj2 relat*)).ti,ab.	380003
8	5 or 6 or 7	716621
9	4 and 8	1962
10	exp "quality of life"/	555402
11	exp wellbeing/	98573
12	("quality of life" or wellbeing or well-being or "well being").ti,ab.	611658
13	10 or 11 or 12	795297
14	exp support group/	13440
15	exp group process/	9119
16	exp motivation/	148347

17	exp psychosocial intervention/	619
18	(interven* or group* or home or homes or goal* or treat* or manag*).ti,ab.	13844975
19	14 or 15 or 16 or 17 or 18	13927713
20	9 and 13 and 19	509
21	limit 20 to (english language and exclude medline journals)	81
22	13 or 19	14163426
23	9 and 22	1647
24	limit 23 to (english language and exclude medline journals)	239

Medline search (via Ovid) 22nd November, 2021

1	exp Occupational Therapy/	14007
2	exp Occupational Therapists/	483
3	"occupational therap*".ti,ab.	14862
4	1 or 2 or 3	21027
5	exp Anxiety/ or exp Anxiety Disorders/	171357
6	exp Stress, Psychological/	143341
7	(anxi* or (stress* adj2 relat*)).ti,ab.	274197
8	5 or 6 or 7	452223
9	4 and 8	678
10	exp "Quality of Life"/	227009
11	(wellbeing or "quality of life").ti,ab.	335407
12	10 or 11	399343
13	exp Self-Help Groups/	10514
14	((group* adj3 exercis*) or (support* adj2 group*)).ti,ab.	31803
15	exp Group Processes/	184737
16	exp Goals/	18452
17	((goal adj2 set*) or (attain* adj3 goal*)).ti,ab.	9796
18	exp Psychosocial Intervention/	433
19	(interven* or group* or home or homes or treat* or manag*).ti,ab.	10229161
20	13 or 14 or 15 or 16 or 17 or 18 or 19	10359816

21	9 and 12 and 20	100
22	limit 21 to english language	95
23	12 or 20	10468152
24	9 and 23	512
25	limit 24 to english language	466

PubMed Search 22nd November, 2021

#17	**#7 and #16** Filters: **English** Sort by: **Most Recent**	486
#16	**#10 or #13** Filters: **English** Sort by: **Most Recent**	9,600,000
#15	**#7 and #10 and #13** Filters: **English** Sort by: **Most Recent**	92
#14	**#7 and #10 and #13** Sort by: **Most Recent**	97
#13	**#11 or #12** Sort by: **Most Recent**	10,565,089
#12	**interven*[Title/Abstract] OR group*[Title/Abstract] OR home[Title/Abstract] OR homes[Title/Abstract] OR goal*[Title/Abstract] OR treat*[Title/Abstract] OR manag*[Title/Abstract]** Sort by: **Most Recent**	10,446,377
#11	**((("Self-Help Groups"[Mesh]) OR "Group Processes"[Mesh]) OR "Goals"[Mesh]) OR "Psychosocial Intervention"[Mesh]** Sort by: **Most Recent**	211,636
#10	**#8 or #9** Sort by: **Most Recent**	376,593
#9	**"quality of life"[Title/Abstract]** Sort by: **Most Recent**	312,891
#8	**("Quality of Life"[Mesh])** Sort by: **Most Recent**	227,016
#7	**#3 and #6** Sort by: **Most Recent**	702
#6	**#4 or #5** Sort by: **Most Recent**	442,025
#5	**anxi*[Title/Abstract] OR "stress related"[Title/Abstract]** Sort by: **Most Recent**	260,329
#4	**("Anxiety"[Mesh] OR "Anxiety Disorders"[Mesh]) OR "Stress, Psychological"[Mesh]** Sort by: **Most Recent**	298417
#3	**#1 or #2** Sort by: **Most Recent**	21,546
#2	**"occupational therap*"[Title/Abstract]** Sort by: **Most Recent**	16,256
#1	(**"Occupational Therapy"[Mesh]) OR "Occupational Therapists"[Mesh]** Sort by: **Most Recent**	14,247

Trip Advanced search 22nd November, 2021

ALL of these words: anxiety quality
in the Document
ANY of these words: intervention group groups home homes goal goals manage management managing treat treating treatment
in theDocument
THIS exact phrase: occupational therapy
in the Document
Excluding Words: child children adolescents teenagers

in the Document
174 results

Proquest Dissertations & Theses
25th November, 2021

345 results

"occupational therapies" OR "occupational therapist" OR "occupational therapists" OR "occupational therapy") AND (anxi* or (stress* NEAR/2 relat*)) AND ("quality of life" OR wellbeing) AND (support OR group* OR goal* OR intervention* OR home or homes OR treat* OR manag*) AND adult* NOT (child* OR adolescen* OR teen*)
345 results

PsycArticles search 25th November, 2021 (via Proquest)

S3	(MAINSUBJECT.EXACT.EXPLODE("Occupational Therapy") OR MAINSUBJECT.EXACT.EXPLODE("Occupational Therapists") OR noft("occupational therap*")) AND ((MAINSUBJECT.EXACT.EXPLODE("Anxiety Management") OR MAINSUBJECT.EXACT.EXPLODE("Anxiety Disorders") OR MAINSUBJECT.EXACT.EXPLODE("Anxiety")) OR MAINSUBJECT.EXACT("Psychological Stress") OR noft(anxi* OR (stress* NEAR/2 relat*)))	20
S2	(MAINSUBJECT.EXACT.EXPLODE("Anxiety Management") OR MAINSUBJECT.EXACT.EXPLODE("Anxiety Disorders") OR MAINSUBJECT.EXACT.EXPLODE("Anxiety")) OR MAINSUBJECT.EXACT("Psychological Stress") OR noft(anxi* or (stress* NEAR/2 relat*))	15,139
S1	MAINSUBJECT.EXACT.EXPLODE("Occupational Therapy") OR MAINSUBJECT.EXACT.EXPLODE("Occupational Therapists") OR noft("occupational therap*")	258

Appendix 5: Abbreviations used in the scoping review (Chapter 2)

- ADIS-IV: Anxiety Disorders Interview Schedule
- BAI: Beck Anxiety Inventory
- BDI-II: Beck's Depression Inventory
- CBT: Cognitive Behavioural Therapy
- CINAHL: Cumulated Index to Nursing and Allied Health Literature
- COPM: Canadian Occupational Performance Measure
- CSQ: Client Satisfaction Questionnaire
- DASS: Depression, Anxiety, and Stress Scales
- DSM: Diagnostic and Statistical Manual of Mental Disorders
- EQ-5D: EuroQol- 5 Dimension
- EQ-VAS: EuroQol Visual Analogue Scale
- GAD: Generalised Anxiety Disorder
- GHQ-28: General Health Questionnaire-28
- HADS: Hospital Anxiety and Depression Scale
- Haq-II: Helping Alliance Questionnaire
- ICER: Incremental Cost-Effectiveness Ratio
- JBI: Joanna Briggs Institute
- JBI EBP database: Joanna Briggs Institute Evidence-Based Practice database
- JBI SUMARI: Joanna Briggs Institute System for the Unified Management of the Assessment and Review of Information
- MADRS-S: Montgomery–Åsberg Depression Rating Scale
- MANSA: Manchester Short Assessment of Quality of Life
- MEDLINE: Medical Literature Analysis and Retrieval System Online
- NIHR: National Institute for Health Research
- OBQ: Occupational Balance Questionnaire
- OVal-pd: Occupational Value Assessment with predefined items
- PANAS: Positive and Negative Affect Schedule
- PLOS: Public Library of Science
- PMS: Pearson Mastery Scale
- PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

- PRISMA-P: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols
- PRISMA-ScR: Preferred Reporting Items for Systematic Review and Meta-Analyses Extension for Scoping Reviews
- PSS: Perceived Stress Scale
- QALY: Quality-adjusted life year
- RCT: Randomised Controlled Trial
- ReDO®-10: Redesigning Daily Occupations® programme
- SCL-90-r: Symptom Checklist-90-Revised
- SDO: Satisfaction with Daily Occupations
- SF-36: Short Form Health Survey Questionnaire
- SOC: Send of Coherence tool
- STAI: State-Trait Anxiety Inventory
- QCRI: Qatar Computing Research Institute
- TIDieR: Template for intervention description and replication
- TTM®: Tree Theme Method®
- UK: United Kingdom
- USD: United States Dollar
- WEIS-SR: Work Environment Impact Scale- Self Rating
- WHODAS 2.0: World Health Organization Disability Assessment Schedule 2.0
- WRS: Work Role Self-Assessment
- WSAS: Work And Social Adjustment Scale

Appendix 6: Group Concept Mapping statements (Chapter 3)

One thing that would help a person with Parkinson's to live well with anxiety might be...		Importance Scale [2.2222]-[4.8000] Median = 2.4 n = 46	Feasibility Scale [2.5152]-[4.5758] Median = 2.2879 n = 33
Full Map Go-Zone			
R=0.44181457652678			
#	Statements	Average Rating	Average Rating
3	To have access to meditation classes.	3.4444	3.3333
5	Singing.	3.1957	3.5152
6	Going to a Parkinson's dance class.	2.8913	2.9394
8	Tai-chi.	3.0217	3.3030
11	Shiatsu.	2.5652	2.8182
12	Qi Gong.	2.6739	2.7576
14	Meditation.	3.3636	3.6250
17	To get help with planning your finances.	3.2667	3.1515
18	One to one support to improve self-confidence.	3.7333	2.9394
19	Small focus groups to improve self-confidence.	3.4565	3.2727
29	Having a one-to-one session before joining a group.	3.1087	3.1818
38	Free access to apps like headspace.	3.2391	3.5152
46	Using cognitive behaviour therapy.	3.4667	3.4375
49	To increase assertiveness.	3.5000	3.3226
53	Mentor/lifestyle coaches who can advise on matters unrelated to medications.	3.4565	2.8485
57	A matched and paired "Buddy" to discuss developments with.	3.6222	2.9091
63	A biofeedback gadget.	2.9111	2.6970
64	Access to counselling outside normal working hours.	3.4545	2.5152
72	Reviewing your diet with a specialist.	3.7111	3.5152
74	A blog/magazine to share experiences and good PD news for the local area.	3.4348	3.3939
82	An app that can divert your attention when you feel anxious.	3.3696	3.3333
84	A little set of laminated cue cards that can be used as a calming strategy.	2.7609	3.5313
87	Having immediate access to a calming phone app.	3.0222	3.5758
88	Having a designated person to contact for reassurance in a moment of panic.	3.7333	2.9375
93	A visual infographic with ideas and quick fixes for dealing with anxiety.	3.3043	3.3333
96	The opportunity to talk openly in a group of people with Parkinsons led by an experienced group worker.	3.5435	3.3636
100	Wearing an invisible disability lanyard when out.	2.7333	3.3030
104	To write poetry.	2.2222	2.6970

106	Intense exercise.	3.4565	3.2727
109	Visualisation.	3.1111	3.6250
110	Swimming.	3.0217	3.3636
112	To meditate in a PD group.	2.7333	3.0000
113	Doing yoga.	3.3182	3.5152
115	Literature you could give to an employer.	3.2955	3.5758
117	Having a "buddy" they can text or call when they're feeling particularly anxious.	3.7556	3.0909
9	Timely access to services when needed.	4.6304	3.4242
25	To continue in any type of work for as long as possible.	3.8913	3.4545
26	Having access to specialist outpatient services.	4.3778	3.4545
30	Finding the right support group for you.	4.1957	3.3030
34	Having peer support.	3.9773	3.5455
37	A designated phone line which you can call any time.	3.9130	3.0606
39	Free person centred counselling as soon as diagnosed.	4.2609	2.9688
40	Having a structured support network with a list of who is responsible for what.	3.8261	3.5455
41	To have a dedicated helper who can get to know the patient individually.	3.8261	2.8485
42	Increasing general awareness of PD in society.	4.2000	3.6061
44	To speak to other people with Parkinson’s of a similar age and stage in disease.	4.0000	3.5758
50	To manage potential causes.	4.1111	3.3939
51	To identify potential causes.	3.9333	3.4242
52	To turn anxiety into a driver for action and motivation.	4.1333	3.2727
55	Focused support with sleep problems.	4.2727	3.6061
59	Access to specialist fitness trainers who understand the physical effects of PD on the body.	4.1957	3.1875
60	A tool to help isolate the source of the anxiety.	3.8261	3.2424
66	To make available counselling for more than the current allocation of 6 weeks.	4.2500	2.9394
67	To ensure that GPs receive training in movement and non movement symptoms.	4.4565	3.3333
69	Having rapid access to a neurologist.	4.1522	2.6970
75	Access to qualified PD nurses for day to day support.	4.5000	3.3438
76	To attend a specific Parkinson's exercise classes.	3.8261	3.6061
83	Having a designated contact to talk through your feelings of anxiety.	3.9348	3.0000
99	Letting other people know how you feel.	4.0000	3.5455
103	Help easing back into it all in reconnecting after lockdown.	4.0435	3.3030
116	Letting others know what makes me anxious.	3.9130	3.5758
2	To plan your day.	3.7442	4.1515

4	Learning how to meditate at home for a few minutes each day.	3.6000	3.9394
7	Listening to calming music.	3.6667	4.3939
20	An app to take the person through a breathing exercise.	3.3478	4.0303
23	Access to easy to understand books.	3.2609	3.7576
32	Having a favourite "comfort" book close by.	2.8222	3.8788
58	Strategies to help with eating in public.	3.6304	3.7273
68	Creating of a list of every day necessary activities.	3.5111	4.1212
86	Having a practised mantra to repeat when anxiety sets in.	3.2609	3.8485
89	Play a game.	2.9111	3.8182
90	A reading list of recommended books on living with anxiety.	3.1778	4.0909
94	Recorded relaxation messages that could be easily listened to.	3.2222	3.7879
95	A card in your purse/ wallet with a preprepared mantra that can be read in moments of anxiety.	2.9111	4.0303
98	To have a daily five to ten minute nap in the afternoon.	3.1957	3.8788
118	Using mindfulness.	3.6818	4.0606
1	To simplify your life.	4.0000	3.8485
10	Support to help people develop their own coping strategies.	4.2609	3.6667
13	Exploring different ways to relax.	4.2609	4.2424
15	Having knowledge about the condition.	4.5000	4.5455
16	Knowing where to go to get specific information and support.	4.6000	4.2121
21	To have a regular exercise routine you enjoy.	4.5000	4.2121
22	Breathing exercises to help you to relax.	4.2000	4.5758
24	Access to easy to understand current research articles.	3.8478	3.6667
27	Taking time out of the day to relax.	4.3043	4.0606
28	Get a medication review to make sure you are on the right ones.	4.5217	4.1212
31	To think of ways that you can continue to interact with others e.g.online, face to face, by, phone, etc.	4.0870	4.0909
33	Doing things that make you laugh.	4.4348	4.0000
35	Not putting off taking some rescue medication.	3.9783	3.8182
36	Engaging with a creative activity.	4.0222	3.8485
43	Understanding the personal drivers that create anxiety.	4.2609	3.7879
45	Use the 5 A's; Acknowledge, Accept, Allow, Adapt, & Adjust.	3.8478	3.9394
47	To engage in meaningful activities.	4.4222	4.0606
48	To understand how cognition is affected by anxiety.	4.1087	3.8788
54	Planning for the future.	4.1957	3.9394
56	To develop coping strategies for social situations.	4.3111	3.9394

61	Honesty from PD clinicians about the likely progress of the condition in order to prepare mentally.	4.2609	3.7813
62	Training in simple breathing techniques which can be used at any time.	4.1304	4.1515
65	More support for newly diagnosed people.	4.5652	3.7879
70	A booklet that guides users through changes they can make to live well with Parkinsons.	4.0444	4.2424
71	To live in the moment.	4.4667	3.9697
73	To practice clean sleeping habits.	4.1136	3.9063
77	Keeping active.	4.8000	4.3030
78	Maintaining social interests e.g. sports.	4.5111	3.8788
79	Access to up to date research.	4.0000	4.0909
80	Having a balanced diet.	4.2444	4.3030
81	Better information and support regarding the later stages of Parkinson’s Disease.	4.0667	4.1212
85	To devise a 5-minute exercise program that can be done anywhere.	3.8444	4.1515
91	To take a walk in the open air if possible.	4.4130	4.5152
92	Encouragement to share anxiety with partners and close friends.	4.1304	3.8182
97	To get involved in projects to advance the understanding, treatment, and elimination of Parkinsons.	4.1304	3.9697
101	Planning ahead to give yourself plenty of time.	4.3696	4.3030
102	Understanding how PD anxiety is different from other anxiety.	4.3333	3.8438
105	To try new things.	3.9783	3.6970
107	Finding out what triggers your anxiety.	4.3913	3.8750
108	Learning to live in the moment.	4.3261	4.1212
111	Accepting my condition rather than being frustrated by what I can’t do.	4.4565	3.9688
114	Trying not to do too much especially with time restraints	4.2222	3.9394
119	Enagingin hobbies.	4.3913	3.9091

Appendix 7: Logic modelling information pack (Chapter 4)

Ethics approval: 3115
Version 1.2 20/04/22
IRAS Project ID: 302129

UNIVERSITY OF
PLYMOUTH
School of Health Professions

Information pack

Title of Project: Developing an occupation-based complex intervention for living well with anxiety and Parkinson's Disease (OBtAIN-PD): a logic modelling approach

Name of Researcher: Mr Chris Lovegrove

Dear participant,

Thank you for agreeing to participate in our research study to identify the things that people with Parkinson's, their care partners, and occupational therapists feel should be included in a new intervention to help people with Parkinson's live well with anxiety.

You will soon be receiving the details of the session that you will be taking part in. This will be run by the lead researcher, Chris Lovegrove. Prior to your session, please read this information pack. It contains summaries of the research team's recent research findings. Reading this information will help to stimulate your ideas for the main session.

When you are reading this information, please keep the following prompt in mind to help direct your thinking:

I think that an intervention to help people with Parkinson's with anxiety should include…

If you have any questions about the information in this pack or would like any further details, please do not hesitate to contact the lead researcher at Christopher.lovegrove@postgrad.plymouth.ac.uk

Yours sincerely,

Chris Lovegrove
NIHR Clinical Doctoral Research Fellow
Occupational Therapist

1

Study 1: What is the lived experience of anxiety for people with Parkinson's? A phenomenological study

The full open-access article can be found here.

Purpose

Anxiety is a common non-motor symptom of Parkinson's and there is no specific pharmacological intervention for people with Parkinson's who experience anxiety. Yet there is little specific research documenting how individuals with this condition experience anxiety. It is important to explore the experiences of people with Parkinson's to identify potential issues in developing future non-pharmacological interventions. This study explored the lived experience of anxiety for people with Parkinson's.

Materials and Methods

This study explored the lived experience of anxiety for people with Parkinson's by describing the findings from an interview with individuals; a technique called descriptive phenomenology. Six participants were recruited through the charity Parkinson's UK, using a maximum variation sampling strategy. Face to face interviews were conducted. Data analysis employed thematic analysis.

Results

Three key themes encapsulated the data: Finding ways to cope to "Try not to let it rule your life", highlights that finding ways to cope with anxiety is important but needs to be tailored to the individual. Amplifies symptoms "It's emotionally draining it it's also physically draining", highlights how anxiety makes people's existing Parkinson's symptoms worse, including their cognitive symptoms. "Anxiety is a funny thing" experienced in myriad ways, discusses how anxiety is usually experienced as a negative, ubiquitous presence, though some people found a positive aspect to it. A model of the experience of PWP experience of anxiety was proposed and can be seen in the article.

Conclusions

Anxiety is a complex experience constructed of interlinked parts affecting people with Parkinson's in lots of different ways. Researchers and healthcare professionals should take these findings into account when designing future studies and interventions. Future interventions should be based on the experiences of those living with anxiety and not healthcare professional or researcher assumptions.

Study 2: Defining the components of an occupation-based intervention for people with Parkinson's with anxiety using Group Concept Mapping

This research study is now closed. An article is currently being written by the research team and will be submitted to a scientific journal.

Purpose

Anxiety is a common symptom of Parkinson's disease. There is currently no gold standard treatment for anxiety in Parkinson's. People with Parkinson's (PWPs) have expressed that new interventions should be focused on 'doing' as opposed to talking therapies. This study engaged with key stakeholder groups to identify the key components required for the future co-production of an anxiety-focused intervention in Parkinson's. The aim of this study was to define the components of an occupation-based intervention for PWPs with anxiety by identifying, organising, and prioritising ideas on how to live well with anxiety in Parkinson's, according to PWPs, their carers, and occupational therapists.

Methods and Materials

Participants were invited to take part in an online group concept mapping process with five stages. These are called brainstorming, idea synthesis, sorting activity, rating activity, and analysis. Based on participants' responses a cluster map, pattern match, and 'go-zone' charts were created through a process called multivariate statistical analysis.

Results

Eighty-three people participated, with 64 taking part in more than one activity. Participants consisted of 72 people with Parkinson's, six carers, and five occupational therapists. Following the 'idea synthesis' activity, 119 statements were included in the final map with eight clusters. There was significant agreement between the importance and feasibility rating activities. 'Go-zone' charts (charts that show what things should be focused on in the future) highlight the statements considered priorities for intervention development. The final clusters, with example statements, were:

- Exercise (Keeping active, intense exercises, to have a regular exercise routine you enjoy)
- Lifestyle Changes (To engage in meaningful activities, planning for the future, engaging in hobbies)
- Self help (To plan your day, exploring different ways to relax, using mindfulness)

- Coping (To develop coping situations for social situations, finding out what triggers your anxiety, planning ahead to give yourself plenty of time)
- Access to information (Access to up to date research, literature you could give to an employer, having knowledge about the condition)
- Professional help (Knowing where to get specific information and support, to understand how cognition is affected by anxiety, understanding of PD anxiety is different from other anxiety)
- Peers and groups (Support to help people develop their own coping strategies, having a one-to-one session before joining a group, having a structured support network with a list of who is responsible for what)
- Support from others (Strategies to help with eating in public, one to one support to improve self confidence, help easing back into it all in reconnecting after lockdown)

Conclusion

This study used a systematic approach to identify important concepts for possible inclusion in a new intervention to help people with Parkinson's to live well with anxiety.

Study 3: Characteristics of occupational therapy interventions for community-dwelling adults with anxiety: a scoping review

This review has now finished. An article is currently being written by the research team and will be submitted to a scientific journal.

Purpose

Anxiety is linked to decreased life quality and wellbeing. Developing an overview of studies of occupational therapy interventions for people with anxiety is a necessary first step to understanding the existing knowledge and increasing the impact of future interventions: This scoping review identified: i) what occupational therapy interventions exist for adults with anxiety; ii) the intervention characteristics, including outcomes used and impact observed.

Methods and Materials

The review considered all studies and publications of occupational therapy that include community-dwelling adults with a diagnosis of anxiety who are aged 18 years and older and diagnosed with an anxiety disorder. Multiple databases were searched. Potentially relevant studies were retrieved in full and assessed against the inclusion criteria. Study selection was completed by two independent reviewers. Data were extracted using a data extraction tool.

Results

The literature searches found 2,058 articles. After the assessment process was completed, 19 articles were completed in the final review. Group sessions were a commonly used type of intervention. However, individual sessions were also delivered and valued by the people who used them. Lifestyle management and cognitive behavioural approaches were the most used intervention types. Some approaches used exercises like yoga to help people with anxiety. One study used a creative arts approach to support people with anxiety. Few of the studies used a scientifically rigorous approach. Of the studies that delivered or tested a treatment, these were conducted in a GP surgery or a hospital setting. None were conducted in the person's own home or in the community.

Conclusions

This review highlights the need for further well-conducted research studies into occupational therapy interventions for community-dwelling adults with anxiety. It also provides a snapshot of the characteristics of current occupational therapy interventions for this group of people.

Appendix 8: OBtAIN-PD intervention manual (Chapter 4)

OBtAIN-PD

Introduction

This manual will provide guidance for the provision of the **Occupation-Based Complex Intervention for living well with anxiety and Parkinson's Disease** (**OBtAIN-PD)** for the OBtAIN-PD feasibility cluster randomized controlled trial (RCT).

If your team has not been allocated to provide the OBtAIN-PD and you are providing usual care occupational therapy only, please stop reading this manual and inform the research team by emailing Jonathan.marsden@plymouth.ac.uk

This manual provides guidance and structure on how to deliver the OBtAIN-PD by an Occupational Therapist for a person with Parkinson's with anxiety but is not prescriptive as to the content of individual sessions.

Development of the OBtAIN-PD

The OBtAIN-PD project has its roots in clinical practice. The chief investigator (CI, Chris Lovegrove) was working in an inpatient ward for neurology with people with Parkinson's whose treatment was medically optimized, yet their participation in meaningful occupation remained substantially impeded. On assessment, these people were experiencing uncontrolled anxiety that was exacerbating their Parkinson's symptoms. A literature review revealed that there is currently no 'gold-standard' treatment for anxiety in Parkinson's and that current treatments seem to be less effective for people with Parkinson's. The CI became interested in exploring the development of a new intervention to help people with Parkinson's to live well with anxiety.

Formally spanning 2015 to 2023, the OBtAIN-PD project has consisted of four studies (excluding this feasibility trial) that have involved over 120 people with Parkinson's, care partners, and occupational therapists. These studies are:

- A foundational qualitative research study exploring the lived experience of people with Parkinson's (Lovegrove & Bannigan, 2021)
- A group concept mapping study to identify the key components of what would become the OBtAIN-PD (article in peer review)
- A scoping review to identify what occupational therapy interventions for adults with anxiety already exist, and what the characteristics of those interventions are (article in peer review)
- A study using an approach called 'logic modelling' to use the information from the above studies to co-produce the initial version of the OBtAIN-PD (article to be submitted for peer review in February/ March 2023)

Alongside these studies, we have conducted continuous Patient & Public Involvement (PPI) in the form of several consultations to involve people with Parkinson's, care partners, and occupational therapists in the development of our research studies. Using PPI can improve the quality and real-world relevance of research studies. We have conducted a range of PPI consultations to support this project, including a published article (Lovegrove *et al., 2017*) and an interactive session at the 2022 Royal College of Occupational Therapists' Annual Conference. This session was attended by over 100 occupational therapists.

The aim of this research project is to conduct a cluster randomized feasibility trial of the OBtAIN-PD in a real-world practice setting. We aim to use the data from this study to inform the design and planning of a future definitive trial, and to further develop and refine the OBtAIN-PD.

Overview of OBtAIN-PD sessions

The number of treatment sessions provided will depend on the person with Parkinson’s goals.

The OBtAIN-PD trial protocol suggests eight one-hour sessions over a 10-week period based on published evidence. This is number of sessions **is not** prescriptive and is suggested for trial planning purposes. As the occupational therapist delivering the OBtAIN-PD you can decide how many sessions a patient receives (and over what time frame) to meet their goal based on your clinical decision-making,. For example, you may deliver all eight sessions (or more if you decide it is required) to meet the persons goal, or you may deliver only three sessions. There is no strict rule of how many sessions should be provided.

The below table provides an overview of activities performed the trial for the participants receiving the OBtAIN- PD based on the **suggested** eight one-hour sessions over 10 weeks as outlined in the trial protocol, and who will deliver the different activities. The different activities will be described in more detail in later sections.

Activities in the table are colour-coded according to who performs them. Green-shaded activities are performed by the community rehabilitation teams. Amber-shaded activities are performed by the CI (or delegated members of the research team).

Overview of activities (OBtAIN-PD)

Session/ Activity	Time	Activity (confirmed & suggested)	Delivered by?
Referral sent to the community rehabilitation team (CRT)			Normal referral routes- consultants, Parkinson's specialist nurses, clinics, other AHPs
Referral triaged as per local protocol	As per local protocol	• Referral triaged and prioritized • First appointment booked • Study details discussed	CRT clinician
Screening log completed, information pack sent to participant if they are interested	5 minutes maximum per potential participant	• Complete screening log • If participant interested, send email of postal information pack (provided)	CRT clinician
Details sent to chief investigator	1-2 minutes	Participant details emailed to chief investigator **Or** CRT clinician sends details to CI at Christopher.lovegrove@nhs.net	Participant **or** CRT clinician
Screening and informed consent process completed	30 minutes	• Questions answered • Informed consent documentation completed • Participant details entered to trial database	Chief Investigator (Chris Lovegrove)
Baseline outcome measures taken	One week prior to first appointment Clinical outcomes measures (60 minutes) Patient-reported outcome measures (15 minutes)	• COPM • eACS3 • GAD-7 • PDQ-39 • EQ-5D-5L • Barthel Index • Baseline clinical outcomes sent to the treating clinician	Chief Investigator (Chris Lovegrove) Participant- Patient-reported outcome measures
Session 1	60 minutes (or as required by the patient), complete the	• Initial assessment and goal discussion	CRT occupational therapist

	therapist contact form (max. 5 minutes)	• complete the OBtAIN-PD goal planning sheet • Provide 'Parkinson's & Anxiety' information sheet • Complete Therapist contact sheet (see below) • Report adverse events (if needed, see below)	
Session 2	60 minutes (or as required by the patient), complete the therapist contact form (max. 5 minutes)	• Review goal planning • Treatment • Provide necessary information sheet (exercise, sleep, or diet & nutrition) if indicated • Amend goal sheet • Complete Therapist contact sheet (see below) • Report adverse events (if needed, see below)	CRT occupational therapist
Session 3	60 minutes (or as required by the patient), complete the therapist contact form (max. 5 minutes)	• Review goal planning • Treatment • Provide necessary information sheet (exercise, sleep, or diet & nutrition) if indicated • Amend the goal sheet • Complete Therapist contact sheet (see below) • Report adverse events (if needed, see below)	CRT occupational therapist
Session 4	60 minutes (or as required by the patient), complete the therapist contact form (max. 5 minutes)	• Review goal planning • Treatment • Provide necessary information sheet (exercise, sleep, or diet & nutrition) if indicated • Amend the goal sheet • Complete Therapist contact sheet (see below) • Report adverse events (if needed, see below)	CRT occupational therapist
Session 5	60 minutes (or as required by the patient), complete the therapist contact form (max. 5 minutes)	• Review goal planning • Treatment • Amend the goal sheet • Complete Therapist contact sheet (see below) • Report adverse events (if needed, see below)	CRT occupational therapist

Session 6	60 minutes (or as required by the patient), complete the therapist contact form (max. 5 minutes)	- Review goal planning - Treatment - Amend the goal sheet - Complete Therapist contact sheet (see below) - Report adverse events (if needed, see below)	CRT occupational therapist
Session 7	60 minutes (or as required by the patient), complete the therapist contact form (max. 5 minutes)	- Review goal planning - Treatment - Amend the goal sheet - Complete Therapist contact sheet (see below) - Report adverse events (if needed, see below)	CRT occupational therapist
Session 8	60 minutes (or as required by the patient), complete the therapist contact form (max. 5 minutes)	- Review goal planning - Conclusion - Complete Therapist contact sheet (see below) - Report adverse events (if needed, see below)	CRT occupational therapist
12-week (from baseline assessments) follow-up	Clinical outcomes measures (60 minutes) Patient-reported outcome measures (15 minutes)	As per baseline	Chief Investigator (Chris Lovegrove) Participant- Patient-reported outcome measures
24-week (from baseline assessments) follow-up	Clinical outcomes measures (60 minutes) Patient-reported outcome measures (15 minutes)	As per baseline	Chief Investigator (Chris Lovegrove) Participant- Patient-reported outcome measures
Qualitative interview	60- 90 minutes	Semi-structured interview at a date and location convenient to the participant/ clinician	Chief Investigator (Chris Lovegrove)

A summary of both the clinical and patient-reported outcome measures is provided in *appendix 1*.

1. Initial assessment- delivered by CRT occupational therapist

Objectives

- Identify the person's occupational performance history, and how their current performance may differ from the past.
- Identify what values, roles, and interests give meaning to their activities.
- Identifying/clarifying the patient's perceived problems in activities and participation and priorities.
- Identifying/clarifying occupational therapy needs of care partner (if necessary).
- Examining and analysing aspects of the person, the activity, and the environment that hinder and promote meaningful participation. Identifying facilitating factors is important as they are used during treatment.
- Identify what factors influence the person's anxiety.
- Identify how anxiety affects the person's performance.
- Observe current occupational performance.
- Identify what the person wants to change and what they want to remain the same.
- Analysing the possibilities of changing the person, the activity, and the environment to positively influence participation.

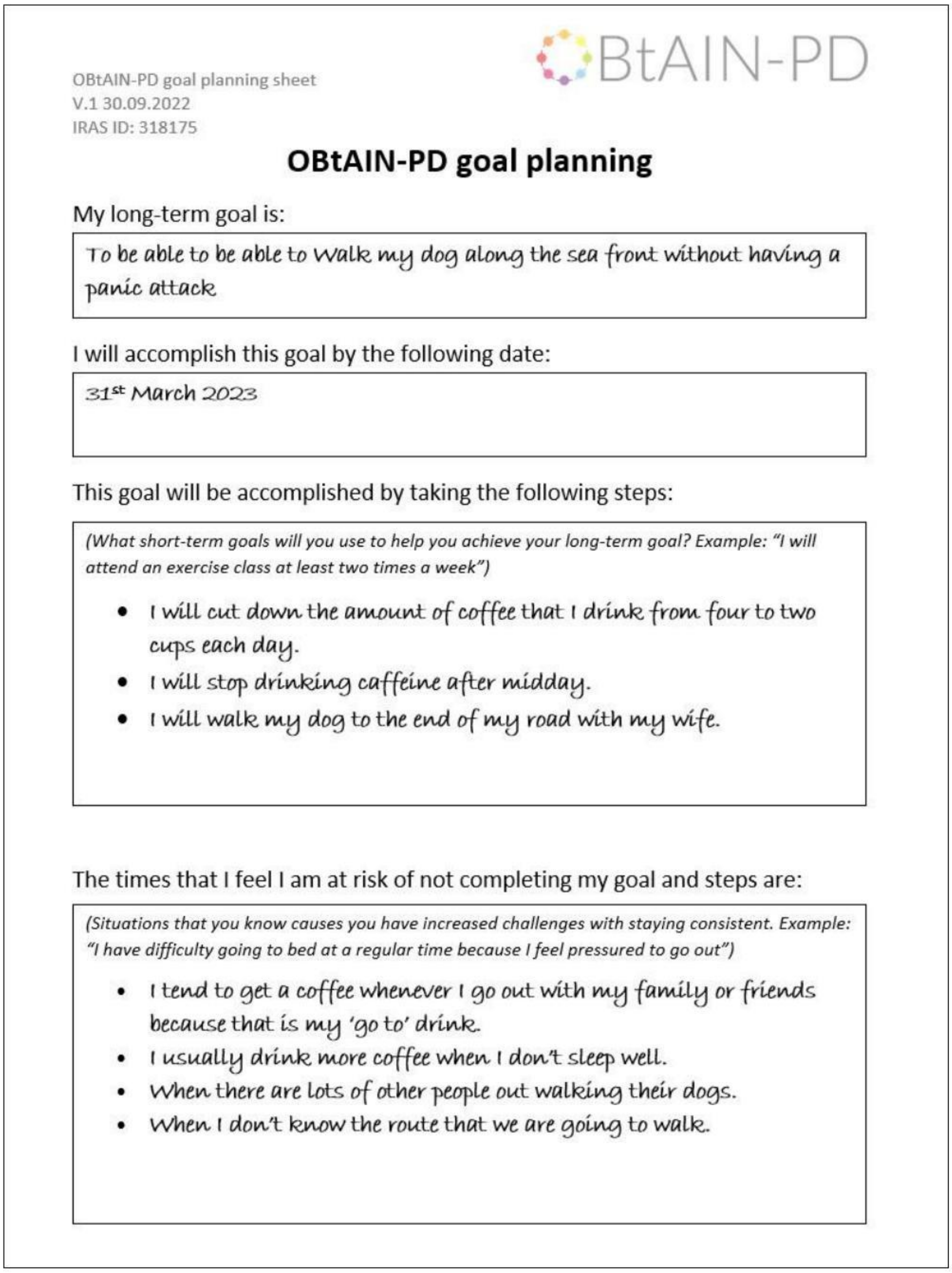
Timing

The delivery of the initial assessment is flexible, depending on what suits the patient or carer best, and the occupational therapist's own style i.e., face-to-face, online, or telephone. Please follow the structure presented below when delivering the initial assessment. Some patients and care partners will want to rapidly do something and talk more about their issues along the way. Others will prefer to have an in-depth discussion first. As per usual practice, the initial interview will provide a complete picture of the referred issue to aid the occupational therapist in developing a treatment plan.

The chief investigator, Chris Lovegrove, will provide the outcomes of the baseline clinical outcome measures (COPM, eACS3) to the occupational therapist prior to the initial assessment appointment. During the initial assessment, the clinician will perform any additional clinical assessments that they deem necessary and check with the person that these are still the most important issues to address in sessions. This is important as goal setting is a core principle of the OBtAIN-PD approach.

As part of the OBtAIN-PD intervention, please complete the "OBtAIN-PD goal planning sheet". Ideally, this should be completed by the patient (if they are able) and retained by them. The purpose of this is to promote 'ownership' of the goals by the patient and to use this as a tool for future therapy sessions. Goals should be related to managing the impact of anxiety and engaging in meaningful activities. Paper copies of the goal planning sheet will be provided by the research team, as well as a link to an online version should more copies be required quickly. The goal planning sheet should be reviewed at the beginning and end of each session and adjusted accordingly, providing a new sheet if needed.

An example of a completed goal planning sheet with dummy data is included below.



OBtAIN-PD goal planning sheet
V.1 30.09.2022
IRAS ID: 318175

OBtAIN-PD

OBtAIN-PD goal planning

My long-term goal is:

To be able to be able to Walk my dog along the sea front without having a panic attack

I will accomplish this goal by the following date:

31st March 2023

This goal will be accomplished by taking the following steps:

(What short-term goals will you use to help you achieve your long-term goal? Example: "I will attend an exercise class at least two times a week")

- I will cut down the amount of coffee that I drink from four to two cups each day.
- I will stop drinking caffeine after midday.
- I will walk my dog to the end of my road with my wife.

The times that I feel I am at risk of not completing my goal and steps are:

(Situations that you know causes you have increased challenges with staying consistent. Example: "I have difficulty going to bed at a regular time because I feel pressured to go out")

- I tend to get a coffee whenever I go out with my family or friends because that is my 'go to' drink.
- I usually drink more coffee when I don't sleep well.
- When there are lots of other people out walking their dogs.
- When I don't know the route that we are going to walk.

Figure 1. Example of a completed goal planning sheet. This example is based on a real-life example given by a person with Parkinson's.

During the initial assessment and discussion on goals, your communications should focus on 'guiding' people in a compassionate manner to empower them to identify the steps to achieve their goals themselves. The purpose of this is to evoke motivation within the person to make positive change. To achieve this, when working with a person with Parkinson's the following communications skills should be used:

- ***Open-ended questions**:* using open-ended questions allows to find out more about the person's perspectives and ideas about how to change. These questions are also crucial in building and strengthening a collaborative therapeutic rapport. *Example: "How would you like things to be different?"*

- ***Affirming:*** this can be achieved through recognising and commenting on the person's strengths and abilities. Research in approaches such as motivational interviewing has shown that it helps rapport building by acknowledging the person's emotions and feelings. *Example: "This sounds like this has been really challenging. No wonder you have felt overwhelmed."*

- ***Reflective listening:*** Sometimes known as 'active listening', the purpose of reflective listening is to clarify what the person is saying for both the purposes of understanding correctly and to reflect to the person that they are being listened to. This can be useful in helping the person to consider change. *Example: "So I can check that I have understood what you have told me, you said…"*

- ***Summarising:*** this is closely linked to reflective listening. During summarising, the clinician reflects what the person has told them using their own words. This has the effect of the person 'hearing themselves' talk about change, which can be an effective motivator.

During the initial assessment, it is important to listen for 'change talk' to help guide the goal and treatment planning. Change talk are phrases that signal that the person is more willing, able, or ready to make a change. **The role of the clinician is to support the client to generate their change talk in a collaborative way, and to avoid imposing it.** Change talk can occur in several forms and can be exemplified by statements that indicate a desire for, ability to, reasons for, and a need to change. Some examples are included below:

- Desire statements indicate a desire to make a change e.g., *"Getting more exercise would make me feel so much better about myself."*

- Ability statements reflect the person's belief in their ability to make change e.g., *"With some help, I think I might be able to cut back on how much I eat."*

- Reason statements reflect the person's reasons for wanting to change e.g., *"I have to control my anxiety so I can spend time with my grandchildren."*

- Need statements indicate a need for change that might be more emotional than 'reason' statements (which tend to be more objective). E.g., *"My anxiety has to change, or my marriage will fall apart."*

During the session, reflecting this language back to the person when summarising can help to strengthen the person's commitment and motivation to change.

Some further examples of these communication skills are provided below.

	Examples
Open-ended questions	• "What makes you think it might be time for a change?" • "What brought you here today?" • "What happens when you [insert risky/problem/unhealthy behaviour]?" • "What was that like for you?" • "What's different about (quitting smoking, improving your exercise, diet, etc.) this time?"
Affirming	• "That's a good suggestion." • "I appreciate that you are willing to meet with me today." • "It sounds like it has been very hard to cut down on coffee." • "It's clear that you're really aware of how important it is to get enough sleep."
Reflective listening	• "It sounds like…" • "It seems as if…" • "What I hear you saying…" • "I get the sense that…" • "I get the sense that this has been difficult…" • "What I hear you saying is that your [insert risky/problem/unhealthy behaviour] is affecting you by…."
Summarising	• "It sounds like you are concerned that you are concerned about your anxiety because it is stopping you from spending quality time with your grandchildren." • "You have been talking about improving your diet and losing weight as you feel it will help your anxiety. It seems you have started to recognise the less good things about being overweight. It's easy to understand why you want to work on this."

When completing the goal planning sheet, these communication skills should be used to support the person to complete the *"this goal will be accomplished by taking the following steps"* box. Examples of language to use to help the person decide on these steps include:

- "What changes were you thinking about making?"
- "How would you like things to turn out?"
- "After reviewing all of this, what's the next step for you?"
- "It sounds like things can't stay the same. What do you think you might do to change this?"
- "What are you going to do next?"
- "What do you think will help at this point?"

This is not an exhaustive list of phrases. You may have phrases that you routinely use in clinical practice. It is OK to use these as long as the conversation remains focused on guiding and eliciting from the person what they plan to do, rather than giving instruction or advising.

"What if the person wants a quick fix?"
It is common for people using health and care services to seek answers or fixes. OBtAIN-PD is intended to empower people with Parkinson's to find their own solutions to living well with anxiety. In keeping with this, a simple phrase to help remind the person of their autonomy can be useful. An example would be; "You are the expert on yourself, so I'm not sure I am the best person to judge what will work for you. But I can give you an idea of what research evidence shows us and what other people have done in your situation."

During the initial session, you should complete the standard paperwork that is required for your service. Following the session, you must complete a therapist contact sheet as described in section 3.

As part of the session, provide the person with the information sheet titled "Parkinson's & Anxiety V1". This sheet has been designed to provide introductory information about anxiety and Parkinson's, something that people with Parkinson's feel is important to receive at the beginning of the intervention to help them understand what is going on. Please talk through this sheet with the person, using some of the following questions to guide the conversation:

- Would you mind me telling you a little more about anxiety in Parkinson's?
- (After reading the sheet) Are there any things raised in the information sheet that remind you of your anxiety?
- What things contribute to your anxiety?
- How does your anxiety change throughout the day?
- How does the environment affect your anxiety?
- How does your anxiety affect the things that you do?

You should document the session in the patient's medical notes as per usual practice.

2. Treatment sessions

Purpose
To assist and support the patient and care partner in optimising meaningful participation by addressing barriers to engaging in meaningful occupation (as identified by the person with Parkinson's).

Treatment provision and timing
Treatment may take the form of education, advising and coaching, instructing, practising skills, and giving feedback. The potential content of treatment sessions is expanded on below.

The number of treatment sessions provided by the occupational therapist depends on the reason for referral, the patient's goals and the types of interventions delivered. This is a clinical decision made by the treating occupational therapist and is not prescribed.

The OBtAIN-PD approach is designed to be flexible in its application. Occupational therapy intervention should be tailored to each person; this is what creates dynamic and meaningful outcomes. Each person's treatment goal will be different, but the OBtAIN-PD provides a framework towards delivering this treatment, developed in co-production with people with Parkinson's, carer partners, and occupational therapists.

Information sheets
During the intervention, you may need to provide the person with extra information to help them adapt their roles, routines, and lifestyles to help them live well with anxiety. Three information sheets are available for you to give out; *"Exercise", "Sleep",* and *"Diet & nutrition"*. These information sheets are based on currently published NHS guidelines. A summary of each information sheet is provided below.

Information sheet	Summary
Exercise	- Explains what exercise and physical activity is. - Provides evidence-based recommendations for the amount per week (2.5 hours, 150 minutes). - Gives examples of non-exercise activity
Sleep	- Explains what sleep is and why it is important. - Provides NHS recommendations of how much sleep is needed per night (seven to nine hours). - Provides suggestions on how to improve sleep for the person to refer to.
Diet & nutrition	- Provides general rules for following a healthy diet based on NHS recommendations. - Provides information on medication, adapted cutlery, and swallowing problems to help inform the person's thinking.

The subjects and contents of these information sheets have been developed based on the thoughts and opinions of people with Parkinson's, care partners, and occupational therapists on what they felt should be included in the OBtAIN-PD. The information sheets **should not** be provided unless the topic has been identified by the person with Parkinson's, and **should not** be provided as a treatment. These information sheets are intended to aid the delivery of OBtAIN-PD by providing information and supporting discussion between the person and the occupational therapist.

Treatment
As part of the initial discussion, you will have supported the person to identify how they will accomplish their goal. Each treatment session should start by reviewing these steps and how the person has managed to work towards them.

Treatment should focus on directly addressing the person's own individual goal. For example, the goal used on the example goal planning sheet:

> ***"To be able to walk my dog along the sea front without having a panic attack."***

As opposed to 'talking' therapies such as cognitive behavioural therapy (CBT), OBtAIN-PD specifically focuses on engaging the person in their chosen meaningful occupation to remove barriers to participation. People with Parkinson's have expressed that they want their participation barriers addressed in pragmatic and direct ways.

Thus, this goal could be addressed in a variety of ways:

- Identifying the triggers that result in the person feeling anxiety and looking for ways to reduce them.
- Identifying parts of the activity that the person is already doing and encouraging them to complete that daily to increase their sense of mastery and confidence.
- Supporting the person to plan ahead to reduce potential stressors e.g., timing the walk when there are fewer people around.
- Graded exposure- supporting the person to engage in the activity at the location (in this case, a walk at the sea front), and gradually increasing this each session in collaboration with the individual.
- Situational use of relaxation strategies, such as breathing techniques, during the activity to prevent anxiety from escalating.
- Cueing strategies, such as auditory or visual cueing, to help with the management of freezing episodes or the initiation of movement.
- Cognitive support strategies, such as setting up reminder or prompts on mobile device, or planning novel (new and interesting) activities to promote cognitive initiation.

This is not an exhaustive list of the treatments provided by occupational therapists delivering the OBtAIN-PD. The list provides suggestions of the sorts of treatment activities that an occupational therapist may provide when working with a person with Parkinson's with anxiety.

You may use different treatments from the list above based on the individual's needs. Please provide usual occupational therapy intervention as needed e.g., providing compensatory equipment to reduce falls risk in ADLs. Usual occupational therapy intervention should form a maximum of 50% of the session. For a description of usual care occupational therapy, please refer to the usual care manual (v1.1).

Session close and planning
The final part of each treatment session should focus on reviewing what has occurred during the treatment session, reviewing this in relation to the participant's goal, and planning the next session (if required). This process should include:

- Reviewing the person's experience of the session.
- Using the previously identified communication strategies to help the person identify what went well (and what didn't go so well).
- Plan the next session in collaboration with the person. For example, if the person walked their dog for 5 minutes, they may aim for 10 minutes in the next session.
- Updating the goal planning sheet if required.
- Confirm the date and time for the next treatment session.

Final session
If the person has completed their goal, and they do not require any further intervention, please review the goal planning sheet.

As part of the closing discussion, discuss with the person the steps that they have taken to accomplish their goal, and how they have addressed the potential barriers that they faced towards addressing their goal. Goal formation is a critical component in fostering behaviour change; closing the intervention by focusing on goal accomplishment can be a supportive factor in maintaining behaviour change.

To help maintain behaviour change, please discuss the following with the person:

- What are some habits that prevent you from doing the things that you want to?
- How do you react when you are not able to do the things that you want to?
- What helps you to develop new habits and routines?
- What are some barriers to making new habits?
- What are some unexpected things that may interfere with forming new habits and stop you from doing what you want to do? What steps can you take to prepare for such things?

Remember to tick the 'discharge' box on the therapist contact sheet (see below). This will indicate to the research team that this is the final treatment session.

Please discharge the person as per your team's process.

3. Therapist contact sheet and Adverse Event Monitoring

Monitoring how interventions are delivered is an important part of a clinical trial. This information is used to establish the average length of a treatment session, how many sessions are required on average, the most common treatments used, and any extra resources that might have been needed.

To help collect this information, the treating clinician will be required to complete a 'Treating Therapist Contact Sheet' (*appendix 2).*

This form has been designed to be completed remotely on a mobile work device in a matter of minutes. Once completed, the treating occupational therapist will be able to submit it directly to the trial database from the device. It is important that the contact sheet is completed promptly at the end of the session so that the information is as accurate as possible.

Paper copies will be provided so that the treating occupational therapist can log the session in the event of a device failure, or a mobile or internet provider fault. The information on the paper forms will need to be transferred to the online form as soon as is feasibly possible and submitted. Once submitted, the paper copy can be disposed of in a secure confidential waste bin.

Reportable adverse events (such as injurious falls, new panic attacks, or increases in freezing episodes) in a therapy session can be reported directly to the Peninsula Clinical Trials Unit (PenCTU) at the number provided on the form. This information will then be passed on to a co-investigator (Professor Jon Marsden) who will investigate in line with trial processes.

To further support the monitoring of adverse events, the participants will be required to complete a falls, adverse event, and social cost log every four weeks. This will be delivered electronically and completed online. A copy of this log can be seen in *appendix 3.*

Appendix 1: Outcome measures

Outcome measure	Use	Delivered by?
The Canadian Occupational Performance Measure (COPM)	The standard Canadian Occupational Performance Measure (COPM) is a valid measure of a person's self-perception of performance in everyday living. The COPM is a client-centred outcome measure for	Chief investigator (Chris Lovegrove) at baseline, 12-week,

	individuals to identify and prioritise everyday issues that restrict their participation in everyday living. The COPM is the proposed primary outcome for the future definitive trial	and 24-week follow-up.
Activity Card Sort (eACS3)	An assessment of a person's perceived level of participation with demonstrated applications in clinical practice and research.	Chief investigator (Chris Lovegrove) at baseline, 12-week, and 24-week follow-up.
Generalised Anxiety Disorder assessment scale (GAD-7)	A valid and reliable 7-item instrument used to assess the severity of generalised anxiety disorder. The GAD-7 is commonly used in the 'Improving Access to Psychological Therapies' pathway and will provide a viable way of comparing the OBtAIN-PD against other interventions in the future. A score of ≥10 identifies a level of anxiety that has a direct impact on the quality of life and is a recommended cut-off that identifies a need for further clinical evaluation.	Participant at baseline, 12-week, and 24-week follow-up.
European Quality of Life-5 dimensions (EQ-5D-5L)	Evaluation of health-related quality of life. This measure has been used in trials with people with Parkinson's and has been psychometrically validated for this population. The EQ-5D-5L can be used to calculate quality adjusted life-years (QALYs), enabling cost-utility analyses.	Participant at baseline, 12-week, and 24-week follow-up.
The Parkinson's Disease Questionnaire (PDQ-39)	This condition-specific questionnaire, a patient reported measure of health status and quality of life, has been psychometrically evaluated in people with Parkinson's.	Participant at baseline, 12-week, and 24-week follow-up.
Barthel Index	A self-reported scale used to measure a person's performance in activities of daily living and a widely used measure in research.	Participant at baseline, 12-week, and 24-week follow-up.
Fall, adverse event, and social cost log	A commonly used tool in research for measuring falls frequency and freezing of gait in people with Parkinson's, and will be used to measure adverse event (AE) rates in this study including AEs that are not falls such as panic attacks. Data regarding societal costs will be collected, such as unplanned loss of workdays for the participants and carers, and personal expenditure on support services.	Participants at baseline and then every four weeks after this.

BtAIN-PD

Appendix 2 Treating Therapist Contact Sheet

Treating Therapists Contact Sheet
V1 2.09.2022
IRAS ID: 318175
Sponsor: University of Plymouth
Chief Investigator: Chris Lovegrove

(insert trial logo here)

Participant study number: ☐☐☐☐☐

Participant initials: ☐☐☐☐☐

Date: D D M M Y Y

Time: H H : M M **AM** ☐ **PM** ☐

Session number: ☐☐

Type of contact: Home visit ☐ Online consultation ☐ Telephone consultation ☐

First visit ☐ Follow-up ☐ Discharge ☐

Location of contact: (Please enter location here)

Did you provide any equipment: Yes ☐ No ☐

What did you prescribe: (Please enter here)

What was covered in the session (brief summary or bullet points):

(Please enter here)

Total participant contact time: H H : M M

Total administration time: H H : M M

Any other comments: (Please enter here)

Safety Monitoring

If you become aware of any serious adverse event that has occurred because of the intervention delivery, please call the PenCTU Trial Managers on 01752 315256

Appendix 2 Participant diary

OBtAIN-PD DIARY

Monthly diary for week commencing: __ __ / __ __ / __ __ __ __

Region: LiveWell South West ☐ **Royal Devon** ☐

Participant ID: __ __ __ __

(Insert trial logo)

Version 1.0 28.11.2022
IRAS Project ID: 318175
Example Completed Diary

Number of Falls	None ☐	Less than usual ☐	About the same ☒	More than usual ☐	A lot more than usual ☐
Number of falls that caused you an injury	None ☒	Less than usual ☐	About the same ☐	More than usual ☐	A lot more than usual ☐
Freezing of Gait episodes	None ☐	Less than usual ☒	About the same ☐	More than usual ☐	A lot more than usual ☐
Panic Attacks	None ☐	Less than usual ☒	About the same ☐	More than usual ☐	A lot more than usual ☐
Unplanned GP appointment	None ☒	Less than usual ☐	About the same ☐	More than usual ☐	A lot more than usual ☐
Unplanned hospital attendance	None ☐	Less than usual ☐	About the same ☐	More than usual ☒	A lot more than usual ☐
Unplanned social services visit	None ☒	Less than usual ☐	About the same ☐	More than usual ☐	A lot more than usual ☐
If you are in paid employment, have you had to reduce the number of hours you worked this week due	No. I worked the same hours ☐		Yes. I have had to reduce my working hours ☐		Yes. I have had to stop work completely ☐

to Parkinson's and anxiety?			
If you are not employed: due to your Parkinson's and anxiety, have you had to reduce the number of hours per week you spend carrying out your normal daily activities (e.g., gardening, housework, social activity)?	No ☐	Yes. I have had to reduce my normal daily activities a little ☒	Yes. I have stopped my normal daily activities completely ☐
Over the last week, has a relative or friend taken time off work to look after you?	Not at all ☐	Yes, a little ☒	Yes. They had to stop work completely ☐
Have you incurred any other costs because of your Parkinson's and anxiety this week?	Yes ☐	No ☐	
If yes, please list them here.	£20- raised toilet seat £4- parking at hospital Cancelled social event with friends		

(Insert trial logo)

Version 1.0 28.11.2022
IRAS Project ID: 318175

4 weekly log

Number of Falls	None ☐	Less than usual ☐	About the same ☐	More than usual ☐	A lot more than usual ☐
Number of falls that caused you an injury	None ☐	Less than usual ☐	About the same ☐	More than usual ☐	A lot more than usual ☐
Freezing of Gait	None ☐	Less than usual ☐	About the same ☐	More than usual ☐	A lot more than usual ☐
Panic Attacks	None ☐	Less than usual ☐	About the same ☐	More than usual ☐	A lot more than usual ☐
Unplanned GP appointment	None ☐	Less than usual ☐	About the same ☐	More than usual ☐	A lot more than usual ☐
Unplanned hospital attendance	None ☐	Less than usual ☐	About the same ☐	More than usual ☐	A lot more than usual ☐
Unplanned social services visit	None ☐	Less than usual ☐	About the same ☐	More than usual ☐	A lot more than usual ☐
If you are in paid employment, have you had to reduce the number of hours you			Yes. I have had to reduce my working hours ☐		Yes. I have had to stop

worked this week due to Parkinson's and anxiety?	No. I worked the same hours ☐		work completely ☐
If you are not employed: due to your Parkinson's and anxiety, have you had to reduce the number of hours per week you spend carrying out your normal daily activities (e.g., gardening, housework, social activity)?	No ☐	Yes. I have had to reduce my normal daily activities a little ☐	Yes. I have stopped my normal daily activities completely ☐
Over the last week, has a relative or friend taken time off work to look after you?	Not at all ☐	Yes, a little ☐	Yes. They had to stop work completely ☐
Have you incurred any other costs because of your Parkinson's and anxiety this week?	Yes ☐		No ☐
If yes, please list them here.			

Appendix 9: OBtAIN-PD Parkinson’s & Anxiety information sheet (Chapter 5)

OBtAIN-PD

OBtAIN-PD information sheet (Parkinson’s & Anxiety)
V.1 30.09.2022
IRAS ID: 318175

Parkinson’s and Anxiety

People with Parkinson’s may be more prone to feeling anxious than other people due to the brain chemicals involved in Parkinson’s. Living with a long-term condition can be stressful, and combined with the chemical brain changes in Parkinson’s, this may mean people with Parkinson’s are more prone to anxiety than other people.

What are the main symptoms of anxiety?

Anxiety can cause both psychological and physical symptoms. Some of the psychological symptoms can be:

- Having a sense of impending doom, panic, danger, or dread.
- Trouble concentrating.
- Trouble thinking about anything other than the present worry.
- Still feeling worried once the situation has passed.

There are also physical symptoms of anxiety. These can include:

- Feeling restless, tense, or nervous.
- Sweating.
- Dizziness.
- Feeling breathless, or rapid breathing (hyperventilation).
- A racing heart (palpitations).
- Trembling.
- Stomach cramps, nausea, and indigestion.

When people become anxious for long periods of time, this can affect their life and cause feelings of hopelessness. It may affect things like their work and social life.

How does anxiety affect people with Parkinson’s?

In Parkinson's, anxiety is likely caused by a combination of things like changes in brain chemicals, stressful life events, and genetics (i.e., a family history of anxiety). The concerns and worries of living with a long-term condition like Parkinson's can also contribute to anxiety.

Some people with Parkinson's experience anxiety when their medications wear 'off'. Taking the medication can improve their anxiety symptoms but they can come back before the next dose is due. This is called 'wearing off'.

Anxiety can make people with Parkinson's experience the following:

- Their tremor might get worse.
- They might experience more 'freezing' when they walk. This means that they are at a greater risk of falling over.
- They might feel stiffer and find it harder to move.

How can I manage my anxiety?

Regular physical activity can help you to feel less anxious. If you feel that you would like to learn more about this, ask your occupational therapist for the information sheet called 'Physical Activity and Exercise'.

Eating a healthy, balanced diet can also help manage the symptoms of anxiety. If you would like to learn more about this, please ask your occupational therapist for the information sheet called 'Diet and Nutrition'.

Sleep is important for your physical and mental health. If you would like to learn more about this, please ask your occupational therapist for the information sheet called 'Sleep Hygiene'.

The OBtAIN-PD intervention is designed to help you manage your anxiety and take part in the things that you want to do. Your occupational therapist will work with you to develop a goal and help you to come up with a plan to work on this. They will help you to come up with this plan yourself using an approach called 'coaching' to help empower you.

Appendix 10: OBtAIN-PD information sheets (Chapter 5)

OBtAIN-PD
OBtAIN-PD information sheet (Diet and Nutrition)
V.1 30.09.2022
IRAS ID: 318175

Diet and Nutrition

If you have Parkinson's, there is no particular diet that you should follow unless you have been prescribed one by a registered healthcare professional. It is recommended to you maintain as healthy a diet as possible.

The general rules for following a healthy diet are:

- Eat a varied diet, that is do not eat a few of the same foods all the time.
- Eat at least five portions of fruit and vegetables a day.
- Eat regular meals.
- Make sure to drink plenty of fluids.
- Eat healthy portions of food (avoid eating too much in one sitting).
- Eat the right balance of carbohydrates (carbs), proteins, and fats.

If you are worried about your diet, your occupational therapist can help you to look at the choices you are making. If they feel it is needed, they might refer you to a dietitian.

Food and medication

When you take your medication should always be discussed with your consultant, GP, or Parkinson's nurse.

Some people with Parkinson's can feel sick after taking their medication. Having a simple snack like a plain cracker can help with this. You may find that taking your medication with water can help to reduce the sick feeling.

For some people with Parkinson's, protein (found mainly in meat, fish, eggs, pulses, and dairy) may interfere with the effects of their levodopa medication. It is generally advised that you should take your Parkinson's medication 30-45 minutes before meals.

If you want to review the timing of your medication to reduce the impact on your life and mealtimes, you should see your consultant, GP, Parkinson's nurse, or ask to be referred to a dietitian.

You should not stop eating protein completely as it is important to help your body recover and fight infection.

Should I buy special cutlery?

The physical symptoms of Parkinson’s can make it more difficult for you to get food or drink to your mouth. There are many types of adapted cutlery and utensils available that might be able to help you.

Special cutlery can help you if you have reduced grip, muscle weakness, or a tremor. This cutlery might have special handles or be shaped differently.

Special cups and mugs can help you to prevent spills when you are drinking. These cups and mugs may have extra handles, be shaped differently, or have a lid.

There are special plates available that can be helpful, particularly if you find it difficult to get food on your cutlery. These plates can help keep food warmer if it takes you a long time to eat, you can also get plates with high lips to stop spills, or non-slip mats to stop plates sliding around.

There are other aids available that can help with things like opening tins, bottles, and jars.

Your occupational therapist can help to advise you on the right equipment for your needs. They might refer you to a place called the ‘Independent Living Centre’ if you need more specialist advice.

Swallowing problems

Some people with Parkinson’s may find that they have problems swallowing when they are eating or drinking.

If you notice any problems with your swallowing (such as coughing when you eat or drink, finding it hard to start swallowing so food stays in your mouth, or find it difficult to keep food and drink in your mouth) then it is very important that you talk to your GP as soon as possible.

They can refer you to a speech and language therapist who will be able to give you specialist advice.

Physical Activity and Exercise

There is now lots of research evidence that shows that being active can help manage the symptoms of Parkinson's. Being physically active has a range of positive benefits both physically and mentally, including on anxiety.

How can physical activity and exercise help me?

It is easier to live well with Parkinson's if you are more physically active. Research shows that being more active can be as important as your medication in helping to manage your Parkinson's symptoms. The current recommendation is that being active for 2.5 hours a week can help to manage symptoms.

Regular physically activity will help to improve your strength, balance, and posture. It can also help with sleep, tiredness, your mood, and your mental health (including anxiety).

The activities that you can do might be affected by your current Parkinson's symptoms. Your occupational therapist can help you to work out what you might be able to do, or can refer you on to someone who can.

What about exercise?

Exercise is an activity that is performed to specifically improve physical fitness and overall wellness. Examples of exercise can include things like boxing, weightlifting, and exercise classes. There might be Parkinson's exercise classes in your area, if you would prefer to exercise with other people with Parkinson's.

Get active doing something that you enjoy

The right physical activity is different for everyone. Being active is nearly always most effective when you push yourself and get out of breath.

Whatever activity you decide to do, it is important to do it regularly. If you enjoy the physical activity that you are doing then you are more likely to keep doing it.

Some people do not like the idea of doing exercise. There are lots of other activities that you could do to help you be more active. Examples of these activities could be:

- Gardening
- Walking/ hiking
- Dancing
- Housework
- Playing with children/ grandchildren

Your occupational therapist can help you to identify activities that you enjoy that could be used as regular physical activity. They may refer you to another professional if you need more specific advise, such as your GP who might be able to supply you with a gym prescription.

Sleep Hygiene

Sleep is a naturally occurring and essential process for human beings. It is important for both physical recovery, mental restoration, and processing of memories.

It is important to get enough sleep and rest. Restful periods help the brain to refresh and cleanse itself. This helps us to absorb and process new information better.

The NHS recommends that adults need seven to nine hours of sleep per night. The amount of sleep that you need is individual to you and can be dependent on a range of other factors, like how much physical activity you do. Having a consistent cycle of sleeping and being awake is very important

When sleeping, fluid flows through the brain that removes waste products that are associated with conditions like Parkinson's. Falling and staying asleep at night can be more difficult if you have Parkinson's. 'Sleep hygiene' is the term used to describe good sleep habits.

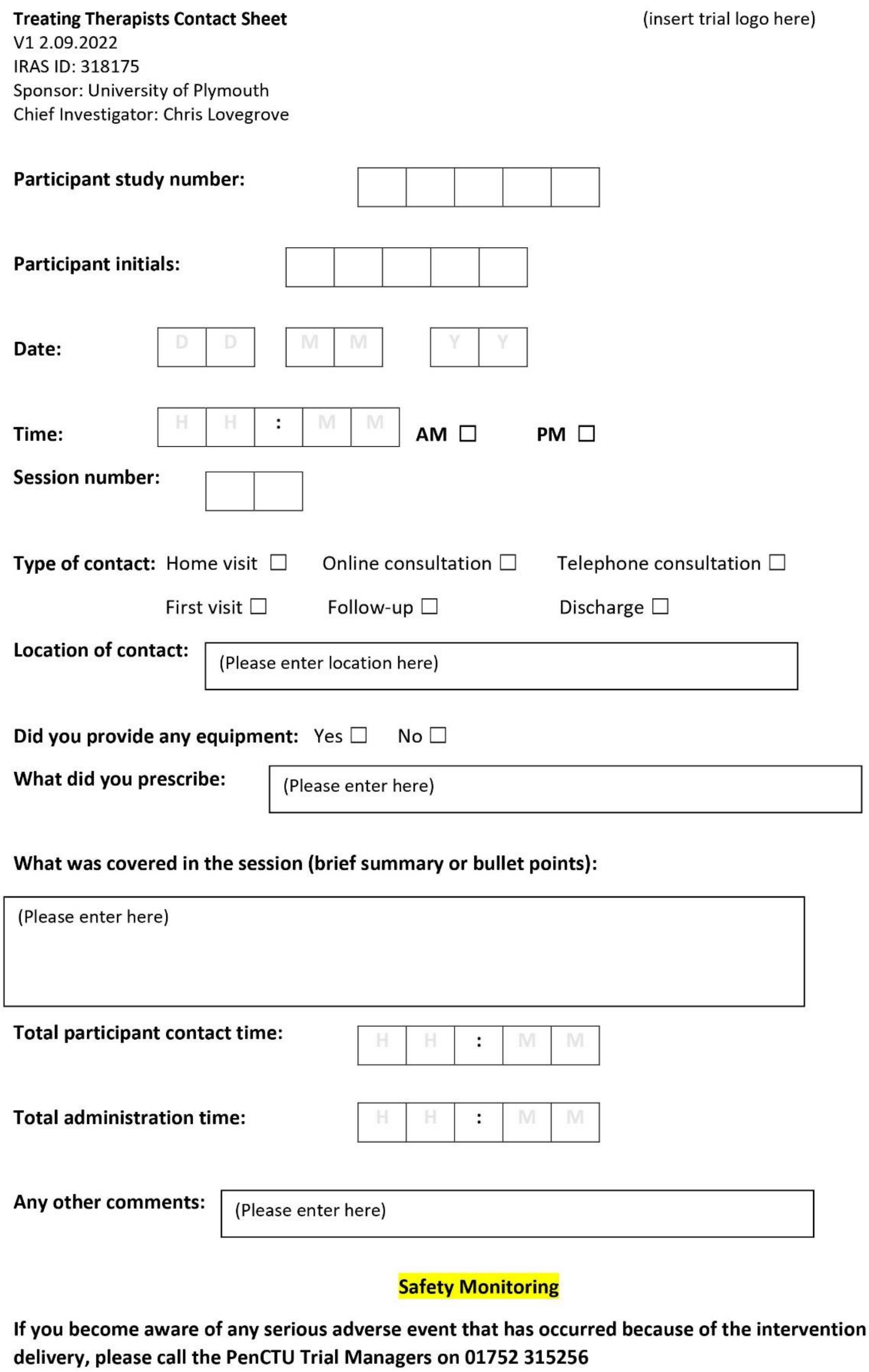
Sleep hygiene involves doing things to promote good sleep and avoiding things that interfere with your sleep. Below are some examples of sleep hygiene that you can use to help you. You may want to discuss these with your occupational therapist:

- **Try to keep to a regular routine-** try to stick to a regular pattern of bed times and waking up.
- **Avoid caffeine before you go to bed-** it is important to not drink too much caffeine during the day, and you may consider using decaffeinated drinks.

- **Avoid smoking-** Nicotine is a stimulant like caffeine and the effects are similar. Avoid smoking around bedtime or during the day, even if it feels like it relaxes you.
- **Get regular exercise-** but try to avoid vigorous exercising within two hours of going to bed as the effects of this may make it harder to fall asleep. Regular exercise can help to improve certain sleep problems.
- **Use your bedroom mainly for sleeping-** Keeping your bedroom for sleep can help your mind to associate it with activities that lead to sleep. Try to avoid things like watching television or using electronic devices with screens in bed.
- **Keep your bedroom calm and comfortable-** avoid excessively hot or cold temperatures as this may disturb your sleep and make you restless. Keep your curtains or blinds closed to reduce light coming into the room. You might want to try an eye mask if this is difficult.
- **Try to relax before going to bed-** If you are in a relaxed mindset before you go to bed, then you may find it easier to drift off to sleep. Other things that might help you relax could be taking a warm bath or shower, listening to soothing music, meditating, reading, or trying relaxation exercises.
- **Don’t stay in bed if you cannot sleep-** if you can’t fall asleep within 20 minutes of going to bed or you wake early and can’t get back to sleep, get out of bed and try a relaxing activity until you become drowsy.

You might have some other ideas that you might want to discuss with your occupational therapist. They can help you to identify specific issues and help you to come up with your own solutions to address them.

Appendix 11: OBtAIN-PD therapist contact form (Chapter 5)



Treating Therapists Contact Sheet
V1 2.09.2022
IRAS ID: 318175
Sponsor: University of Plymouth
Chief Investigator: Chris Lovegrove

(insert trial logo here)

Participant study number:

Participant initials:

Date: D D M M Y Y

Time: H H : M M **AM** ☐ **PM** ☐

Session number:

Type of contact: Home visit ☐ Online consultation ☐ Telephone consultation ☐

First visit ☐ Follow-up ☐ Discharge ☐

Location of contact: (Please enter location here)

Did you provide any equipment: Yes ☐ No ☐

What did you prescribe: (Please enter here)

What was covered in the session (brief summary or bullet points):

(Please enter here)

Total participant contact time: H H : M M

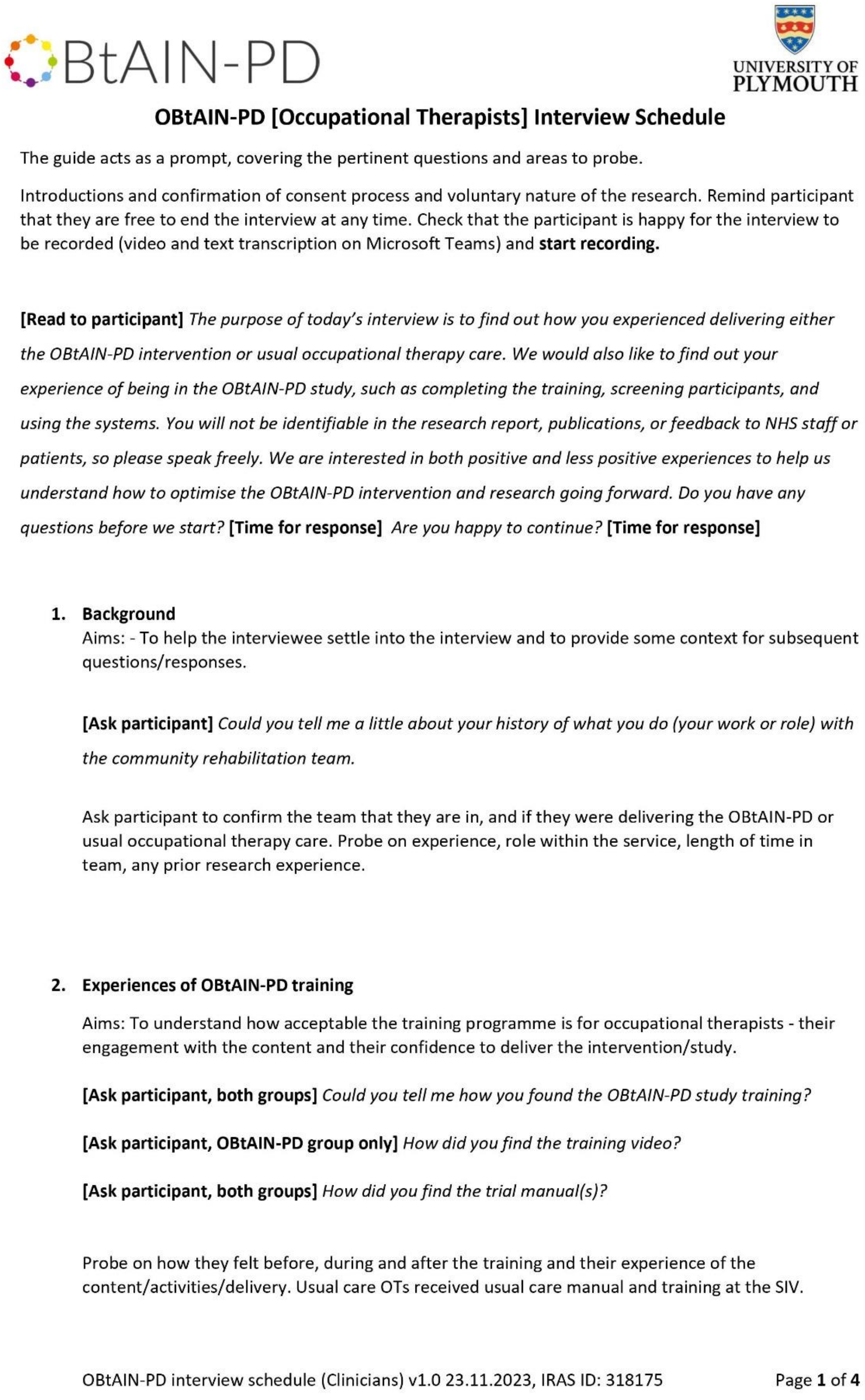
Total administration time: H H : M M

Any other comments: (Please enter here)

Safety Monitoring

If you become aware of any serious adverse event that has occurred because of the intervention delivery, please call the PenCTU Trial Managers on 01752 315256

Appendix 12: OBtAIN-PD clinician interview schedule (Chapter 5)



OBtAIN-PD

UNIVERSITY OF PLYMOUTH

OBtAIN-PD [Occupational Therapists] Interview Schedule

The guide acts as a prompt, covering the pertinent questions and areas to probe.

Introductions and confirmation of consent process and voluntary nature of the research. Remind participant that they are free to end the interview at any time. Check that the participant is happy for the interview to be recorded (video and text transcription on Microsoft Teams) and **start recording.**

[Read to participant] *The purpose of today's interview is to find out how you experienced delivering either the OBtAIN-PD intervention or usual occupational therapy care. We would also like to find out your experience of being in the OBtAIN-PD study, such as completing the training, screening participants, and using the systems. You will not be identifiable in the research report, publications, or feedback to NHS staff or patients, so please speak freely. We are interested in both positive and less positive experiences to help us understand how to optimise the OBtAIN-PD intervention and research going forward. Do you have any questions before we start?* **[Time for response]** *Are you happy to continue?* **[Time for response]**

1. **Background**

   Aims: - To help the interviewee settle into the interview and to provide some context for subsequent questions/responses.

   [Ask participant] *Could you tell me a little about your history of what you do (your work or role) with the community rehabilitation team.*

   Ask participant to confirm the team that they are in, and if they were delivering the OBtAIN-PD or usual occupational therapy care. Probe on experience, role within the service, length of time in team, any prior research experience.

2. **Experiences of OBtAIN-PD training**

   Aims: To understand how acceptable the training programme is for occupational therapists - their engagement with the content and their confidence to deliver the intervention/study.

   [Ask participant, both groups] *Could you tell me how you found the OBtAIN-PD study training?*

   [Ask participant, OBtAIN-PD group only] *How did you find the training video?*

   [Ask participant, both groups] *How did you find the trial manual(s)?*

   Probe on how they felt before, during and after the training and their experience of the content/activities/delivery. Usual care OTs received usual care manual and training at the SIV.

OBtAIN-PD interview schedule (Clinicians) v1.0 23.11.2023, IRAS ID: 318175 Page **1** of **4**

OBtAIN-PD clinicians received usual care AND OBtAIN-PD manual, SIV, plus a training video.

[If participant delivered OBtAIN-PD, ask this] *Could you tell me how you found the OBtAIN-PD intervention training?*

[If participant delivered OBtAIN-PD, ask this] *How confident were you in delivering the OBtAIN-PD?*

Probe on how they felt before, during and after the training and their experience of the content/activities/delivery.

3. Experiences of delivering OBtAIN-PD/ usual occupational therapy care

Aims: To explore aspects of delivery – what worked, what didn't work so well, delivery challenges, how challenges were overcome etc.

[Ask participant] *Could you tell me how delivery of [the OBtAIN-PD/ usual occupational therapy care] went for you?*

Probes: whether experiences changed over time (beginning, middle and end), what worked, what was challenging, how they overcame these.

[Ask participant] *Could you tell me if there were any staffing issues with delivering [the OBtAIN-PD/ usual occupational therapy care]?*

[Ask participant] *How do you think the intervention was for the client?*

Probes: whether they also delivered usual care, whether the commitment to delivering OBtAIN-PD took them away from other duties, and, if so, the impact.

[Ask participant] *What factors do you think influenced the outcome of the intervention?*

Probes: client factors (such as health, confusion, other stresses, willingness), intervention factors (design, access to materials), own factors (belief in intervention, experience levels)

[Ask participant] *Could you tell me how you think the participants responded to [the OBtAIN-PD/ usual occupational therapy care]?*

Probes: levels of engagement, attrition

[Ask all participants] *How did you find recruiting to the study?*

[Ask participant if their team did not recruit any participants] *Could you tell me why you think your team didn't recruit participants?*

Probes: what could be done to help improve recruitment

4. **Acceptability of Trial Processes**

Aims: To understand facilitator experience of being involved in the trial.

[Ask participant] *Could you tell me how you felt about being involved in the trial?*

Probes: quality of interactions with colleagues/researchers, were there any fears/concerns/issues and were they were sufficiently allayed.

[Ask participant] *How did you feel about the screening process for participants?*

Probes: whether they did this, when they completed the forms and how much of a burden these were. What was it like talking about the trial with potential participants?

[Ask participant] *How did you find using the electronic system for recording the interventions?*

Probes: whether they did this, when they completed the online forms and how much of a burden these were. Were there any problems, if so what was it like getting help. Were the issues rectified.

5. Contamination

Aims: To ascertain if occupational therapists who also deliver usual care import aspects of OBtAIN-PD

[Ask participant if they delivered usual care] *Do you have any sense of what was involved in OBtAIN-PD? Did you use any of this in delivering usual care?*

Probe: how did they find out about it, did they get access to materials, did they use it at all.

Reinforce that there is no repercussion and not about blame.

[Ask participant if they delivered OBtAIN-PD] *Did you draw upon aspects of the OBtAIN-PD when you delivered usual care? If so, what were they?*

Probe: which aspects did they use and why they chose these. Did they discuss the intervention with colleagues from other teams. Were they advised by colleagues to do anything different, and did they do this. Key components of OBtAIN-PD include; bespoke goal setting sheets, bespoke information sheets (Parkinson's and anxiety, sleep, exercise, or diet & nutrition), the OBtAIN-PD manual to structure conversations (e.g. used specific prompts from the manual).

6. Suggestions for improving the OBtAIN-PD intervention/ study

Aim: To support the optimisation of the OBtAIN-PD intervention and research programme.

[Ask participant] *What would you change about the OBtAIN-PD study?*

Probes: why these refinements would help

[Ask participant if they delivered OBtAIN-PD] *What would you change about the OBtAIN-PD intervention?*

Probes: why these refinements would help

[Ask participant] *What would you change about training or resources to help you deliver [intervention]?*

Probe: why these refinements would help

[Ask participant] *Have you any comments/thoughts about how training could be improved?*

[Ask participant] *Would you like to share anything else about your experiences?*

Thank the participant for their time and for sharing their experiences in the interview. State that you will now stop the recording and transcription.

STOP THE RECORDING NOW BEFORE PROCEEDING.

After recording has stopped, please ask the participant if they have any further questions or comment. If the participant offers something that might be valuable, or something else has come to mind, ask them for permission to restart the recording and transcription. Ask them to repeat what they just told you and thank them again for their time and stop the recording/transcription.

Tell the participant that if anything comes to mind following the interview, they can email this to the interviewer. Ask the participant if they would be willing to comment on a summary of the analysis. Thank the participant for their time.