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Inspiratory muscle training for people with Parkinson's disease: a protocol for a mixed methods randomised controlled trial

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ABSTRACT

Introduction Inspiratory muscle weakness is a known consequence of Parkinson's disease and could be a potential contributor to the dyspnoea experienced by many people living with the condition. Inspiratory muscle training is effective in improving inspiratory muscle strength and reducing dyspnoea in other chronic diseases. However, inspiratory muscle training has received little attention in people with Parkinson's disease, and it is unclear how this training affects inspiratory muscle strength, dyspnoea and quality of life.

Methods and analysis This mixed methods, randomised controlled trial will recruit 50 participants with idiopathic Parkinson's disease who will be randomly allocated to either the experimental group, for 8 weeks, or the control group. Inspiratory muscle strength (maximum inspiratory pressure) will be the primary outcome. The secondary outcomes include motor experience of daily living (Movement Disorder Society-Unified Parkinson's Disease Rating Scale part II), rate of perceived exertion (modified Borg Scale), exercise capacity (6-minute walk test) and quality of life (39-item Parkinson's Disease Questionnaire). Quantitative data will be analysed using descriptive statistics. Semi-structured interviews will be conducted with participants who underwent inspiratory muscle training. Inductive reflexive thematic analysis will be used to explore the participants' experiences of inspiratory muscle training and its impact on dyspnoea, activities of daily living and overall quality of life.

Trial registration number ACTRN12622000097741.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Individuals with Parkinson's disease experience dyspnoea and reduced inspiratory muscle strength. Inspiratory muscle training has proven feasible and effective in other populations, such as those with spinal cord injury and stroke.

WHAT THIS STUDY ADDS

⇒ This robust randomised controlled trial features concealed allocation, assessor blinding and intention-to-treat analysis, setting a new standard in methodological rigour for this area of research.

⇒ The findings will provide evidence on whether inspiratory muscle training improves inspiratory muscle strength, while reducing dyspnoea and improving quality of life.

⇒ By capturing the details of medication use and other exercises that are not part of the trial intervention, this study maps the factors that are important for understanding outcomes.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The results may inform clinical guidelines for managing dyspnoea in Parkinson's disease and support integration of inspiratory muscle training into standard care practice.

INTRODUCTION

There is growing evidence that Parkinson's disease (PD) can lead to respiratory muscle weakness.[1 2] Several studies have identified substantial inspiratory muscle weakness,[3–5] as indicated by the maximal inspiratory pressure (MIP) being significantly lower than predicted values,[1 2 6–8] which is detectable in more than 40% of people with PD.[3 4 9] The potential contribution of inspiratory muscle weakness to respiratory system dysfunction in PD is not well understood.[10] In people with other conditions such as chronic obstructive pulmonary disease (COPD), inspiratory muscle weakness contributes to increased risk of respiratory infection, reduced exercise tolerance and dyspnoea.[11 12] While dyspnoea is a multifactorial symptom,[13] improvement of MIP has been correlated with decreased dyspnoea in people with PD.[5] Given the prevalence of inspiratory muscle weakness[3 4 9] and its potential contribution to dyspnoea,[14] a strength training programme targeting the inspiratory muscles could increase strength and potentially reduce dyspnoea.

Improving inspiratory muscle strength has shown benefits in various conditions, including COPD, following mechanical ventilation in the intensive care unit, as well

as in athletic and healthy populations.[15–17] While inspiratory muscle training (IMT) is feasible and effective across numerous patient groups,[15 18] including those with critical illness,[19 20] it has received little attention in people with PD.[21] Evidence of the benefits of IMT in other neurological conditions such as multiple sclerosis,[22 23] stroke[24] and neuromuscular diseases[25] includes reduced dyspnoea and fewer respiratory complications. Despite the distinct underlying pathology in PD, this weakness may be modifiable through exercise, and its potential to improve strength, reduce dyspnoea and enhance quality of life through IMT deserves further consideration.

A systematic review published in 2020[26] found insufficient evidence to change clinical practice in regards to respiratory muscle training in PD. The lack of studies, low participant numbers and substantial heterogeneity of training protocols and outcome measures make it difficult to know the effectiveness of respiratory muscle training for people with PD.[21 26] Only one study focused purely on IMT and described its effect on dyspnoea.[5] However, this study had a moderate risk of bias due to a lack of sample size calculation, poorly defined eligibility criteria, no concealed allocation, a lack of presentation of between-group differences with 95% CIs and exclusion of data from participants who were less than one-third adherent. While expiratory muscle training appears to be promising in improving measures of maximal expiratory pressure, swallowing function and phonation,[27 28] the efficacy of IMT alone in improving strength remains poorly understood.

An observational study led by our team found that IMT is feasible and acceptable to people with PD and is associated with improved inspiratory muscle strength (under review). A randomised trial is now required to determine the efficacy of IMT in improving inspiratory muscle strength in people with PD. The potential benefits of such training could include not just increasing muscle strength but also reducing dyspnoea, improving exercise capacity and enhancing overall quality of life in PD. However, a first step is an adequately powered study to ascertain whether or not IMT can effectively increase inspiratory muscle strength, before exploring the impact on more complex patient-centred outcomes.

There are limited studies exploring barriers and facilitators to IMT from the perspectives of people living with PD. We need to understand the values and perspectives of people with PD regarding IMT as a potentially compelling, widely available, treatment option. Therefore, combining the qualitative aspect into a randomised controlled trial (RCT) is reasonable to enrich the trial.

The following protocol outlines the process by which we intend to answer the following questions:

1. Do people with PD have clinically relevant weakness of the inspiratory muscles (defined as <60% of predicted values)?
2. Does IMT improve inspiratory muscle strength compared with usual care for PD?
3. Does IMT appear to improve dyspnoea, activities of daily living, exercise capacity and overall quality of life compared with usual care for PD?
4. What are the participants' experiences with the intervention and perception of outcomes, and what are the associated implications for the interpretation of the RCT results?

METHODS AND ANALYSIS

Design and setting

This mixed-methods, 2-arm single-centre assessor-blind RCT will be conducted in a metropolitan region of Australia from March 2022 to December 2025. People diagnosed with idiopathic PD who meet the eligibility criteria will be randomised to the experimental or control group (figure 1). The study will be conducted at the University Parkinson's Clinic. The clinic provides evidence-based group physiotherapy classes to people with PD, focusing on mobility, balance, skill-based training and everyday activities. Participants typically attend group classes one time per week for 1 hour.

Participants

Community-dwelling people diagnosed with idiopathic PD will be invited to participate in the study. The research team will obtain written informed consent from all eligible participants on entry to the study.

Demographic and clinical information will be collected using a questionnaire, including questions on sociodemographic variables (eg, sex, age, education level) as well as clinical predictor variables (eg, PD medication, other medical conditions, smoking status). The level of disease severity will be determined by the Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) part III: Motor Examination[29] and Hoehn and Yahr Scale.[30]

Inclusion criteria

1. ≥18 years of age;
2. Experienced trouble with their breathing (eg, walking, climbing stairs, carrying heavy objects or performing household chores).
3. Able to walk independently with or without usual walking aids around the community.

Exclusion criteria

1. Substantial cognitive impairment (Mini-Mental State Exam <24).
2. Uncontrolled arrhythmias; severe COPD; uncontrolled hypertension; symptomatic peripheral artery disease; unstable angina.
3. Other neurological conditions (ie, neuromuscular diseases).
4. Completed IMT within the last 6 months.
5. Medical conditions which would preclude or interfere with the assessment or the training programme.

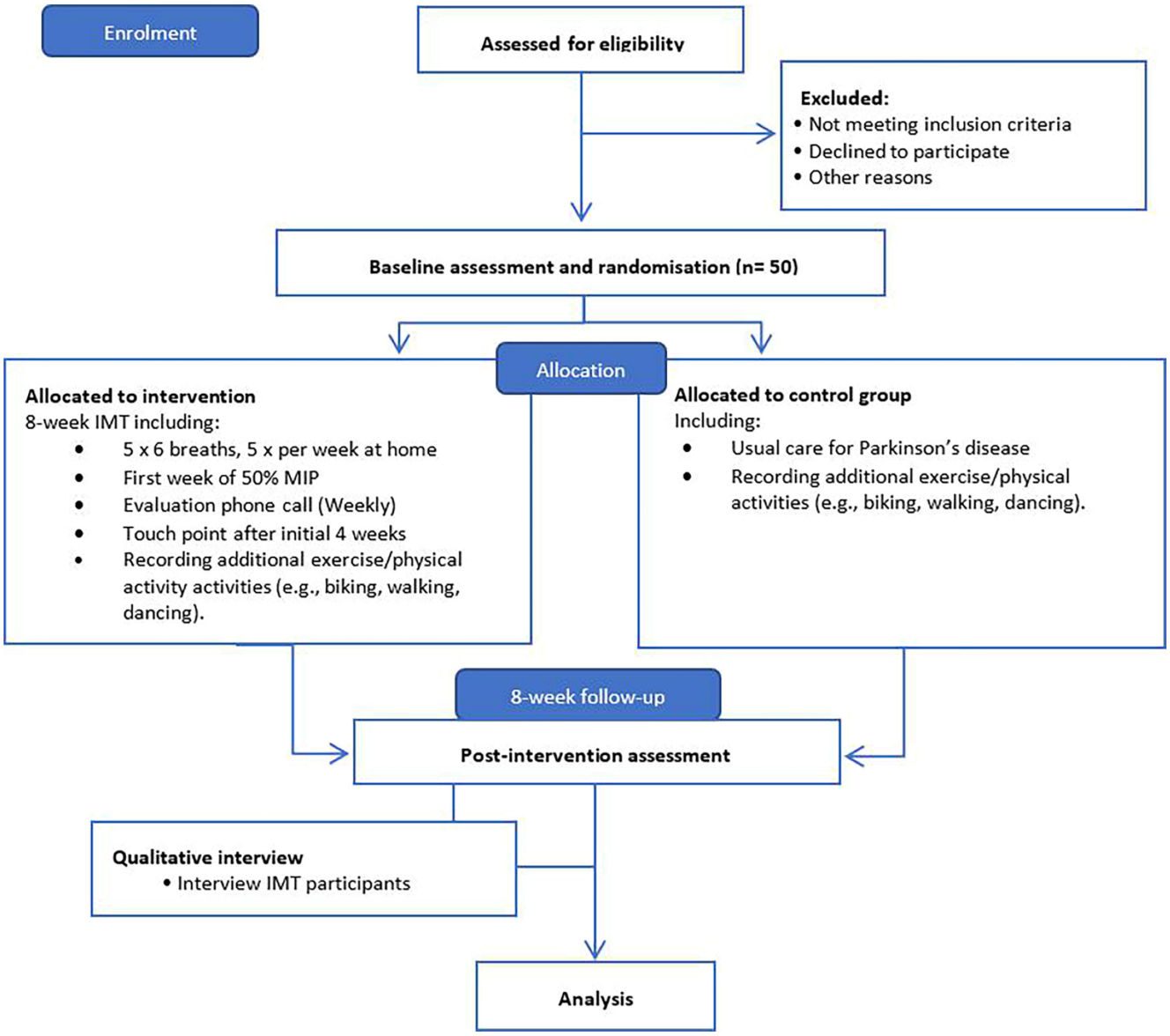

Figure 1 Flow of participants through the study. IMT, inspiratory muscle training.

Experimental group

Inspiratory Muscle Training

IMT will be performed using the POWERBreathe Medic plus inspiratory muscle trainer (PowerBreathe Medic plus, Southam, UK). The training parameters are based on a previous feasibility and acceptability study led by our research group (unpublished data, 2021) and are consistent with evidence-based IMT training guidelines in patients with chronic lung disease, which recommend that high-intensity interval training is well-tolerated and optimises outcomes.[31 32] Participants will initially breathe through inspiratory resistance (POWERbreathe IMT device) at a resistance equal to 50% of their MIP during their first week. Training will be five sets of six inspirations each session, performed 5 days a week for 8 weeks (figure 2). One training session will take <15 min. Participants will be instructed on how to perform the training by a researcher specifically trained in IMT (JFBM), and they will be instructed to conduct IMT during the 'on' phase of medication—that is, when their PD medication is effectively managing motor symptoms. This will be a home-based training, in which the therapist will contact the patient via telephone call weekly to discuss their progress and prescribe the resistance of the IMT. After the first week, the resistance will be set at the highest tolerable intensity that allows the participant to just complete the sixth breath in each set. After the initial 4 weeks, participants will attend an appointment (in person or online video) to discuss their progress, review their technique and clarify any issues concerning the training programme.

Control group

Those randomised to the control group will experience usual care for PD, which typically consists of multidisciplinary care and group exercise classes.[33]

Figure 2 Inspiratory muscle training.

Monitoring medication and exercise

Throughout the 8 weeks, changes in levodopa equivalent dosage and other exercise that is not part of the trial intervention will be monitored and recorded via weekly telephone calls. Exercise includes but is not limited to attending physiotherapy exercise classes and activities within the community, such as biking, walking and dancing. Participants allocated to both groups will be asked to record any exercise in a diary.

Outcome measures

All outcome measures will be conducted at the University Parkinson's Clinic and collected at baseline and after 8 weeks (<10 days post completion of intervention) while participants are in the 'on' phase of their usual PD medication. Assessors, blinded to group allocation, will collect all outcome measures, using a standardised protocol and the same research-grade equipment. The schedule of enrolment, interventions and assessments is displayed in table 1.

Primary outcome

The primary outcome is inspiratory muscle strength. Inspiratory muscle strength will be measured as MIP (cmH_2O), performed according to the guidelines of the American Thoracic Society and European Respiratory Society.[34] This technique requires the person to maximally inhale from residual volume into a handheld pressure manometer and sustain the effort for more than 1 s. The person is coached to ensure adequate lip seal around the mouthpiece and achieve maximum voluntary effort. The effort is repeated until at least three measurements have <20% variability between them.[34] The device used to perform MIP testing is a portable MicroRPM Respiratory Pressure meter (CareFusion, San Diego, California, USA). Such handheld devices demonstrated reliability and validity.[35] The values obtained will be recorded (cmH_2O), and scores will be normalised for sex and age, according to Evans and Whitelaw,[36] the highest value being considered for statistical analysis.

Using the method as outlined by Evans and Whitelaw,[36] reference MIP will be calculated and baseline MIP for each participant will be presented as a percentage of their reference MIP. Inspiratory muscle weakness was defined a priori as <60%.[37] It should be noted that this equation is designed for people <70 years; however, reference values for people >70 years have not been defined.

Secondary outcomes

The secondary outcomes include activities of daily living, exercise capacity (distance completed in the 6-minute walk test, 6MWT), dyspnoea (modified Borg Scale) and quality of life (39-item Parkinson's Disease Questionnaire, PDQ-39).

Motor experiences of daily living

The MDS-UPDRS part II will be used for the assessment of motor experiences of daily living activities. [29]The MDS-UPDRS section II: Motor Experiences of Daily Living has 13 patient-based items. Each item is scored from 0 (normal) to 4 (severe), with higher scores indicating increased disability.[29] The MDS-UPDRS is valid and reliable in community settings as well as in research.[29]

Exercise capacity

The 6MWT is a practical and common measure of exercise capacity.[38] The test is a self-paced, submaximal test of exercise capacity and has been found to be reliable and of clinical utility in guiding rehabilitation for people with moderate PD.[39–41] The 6MWT will be conducted in a quiet gym area with a flat 15–20 m walkway marked off at 1-metre intervals and cones placed at each end.[38 42] To reflect the intensity of exercise performed, heart rate, blood pressure (mmHg), peripheral oxygen saturation (SpO2) and leg fatigue using a modified Borg scale[43] will be measured pretest, on immediate completion of the test and after 6 min in the sitting position. Only one trial will be administered. The distance walked during the test will be recorded for statistical analysis, recorded to the nearest metre.

Table 1 Schedule of enrolment, interventions and assessments

	Study period					
	Enrolment	Allocation	Post allocation		Closed out	
Time point*	**-t_1**	**0**	**t_1**	**t_2**	**t_3**	**t_4**
Enrolment:						
Eligibility screen	x					
Eligibility confirmation	x					
Participant information	x					
Informed consent		x				
Allocation		x				
Interventions:						
IMT			⟷	⟷		
Usual care			⟷	⟷		
Assessments:						
Demographics, medical history, MDS-UPDRS III		x				
MDS-UPDRS II		x			x	
MIP		x			x	
6MWT		x			x	
PDQ-39		x			x	
Qualitative data						x

*t1 = prior to allocation; t0 = time zero, at baseline; t1 = time 1, day after preintervention assessment; t2 = time 2, completion 8-week intervention period; t3 = time 3, post-training assessment; t4 = time 4, individual interviews within 30 days.
MDS-UPDRS, Movement Disorder Society-Unified Parkinson's Disease Rating Scale; MIP, maximal inspiratory pressure; 6MWT, 6-minute walk test; PDQ-39, 39-item Parkinson's Disease Questionnaire.

Dyspnoea (shortness of breath)

Dyspnoea will be assessed using a modified Borg scale (rating of perceived exertion, 0–10 categorical scale),[43] which has acceptable reliability and validity in patients in people with PD[44] and is commonly used during 6MWT.[38] The scale ranges from 0 (no dyspnoea) to 10 (maximal dyspnoea).[43] Dyspnoea will be measured pretest, on immediate completion of the test and after 12 min in the sitting position.

Health-related quality of life

Health-related quality of life will be assessed using the PDQ-39,[45] scored from 0 to 100, with higher scores indicating worse health-related quality of life. The PDQ-39 is the most widely used PD-specific health-related quality of life questionnaire. The PDQ-39 is reliable, valid, responsive, acceptable and feasible as the tool for assessing the impact of PD on health-related quality of life.[46 47]

Participant experiences and perception

Qualitative data will be collected from a subset of experimental group participants who have agreed to undertake an interview within 1 month of completion of IMT.

This study will use semi-structured interviews with open-ended questions following Hoffman *et al*.[48] and van de Wetering-van Dongen *et al*.[49] Questions will be adapted to reflect participants' experiences with the trial intervention, the related dyspnoea, activities of daily living and overall quality of life outcomes and factors that influence these views (online supplemental material 1). Interviews will be conducted by a person not involved with intervention delivery. The semi-structured interviews will be conducted in a quiet, private room, audio-recorded and transcribed verbatim.

Data analysis

Data will be analysed using intention-to-treat analysis with carry forward analysis for missing data. All participants who complete the baseline assessment, including those who did not complete training, will be included in the analysis. Descriptive statistics will be performed and presented as mean (±SD) or median (IQR) and 95% CIs. It is anticipated that for variables with parametric distribution, the paired t-tests will be used to assess within-group changes. Mixed linear models will be used to assess the between-group difference of the changes between enrolment and follow-up measures. A 95% CI will be used to establish any differences, and a p value <0.05 will be indicative of a statistically significant difference between groups (two-tailed). If the supposition of normality is not met, pairwise comparisons between groups will be

performed using a nonparametric test, as appropriate, for independent samples or dependent samples. All analyses will be done using either SPSS or R 3.6.1.

The sample size calculation for the two-arm randomised controlled trial was calculated a priori for the primary outcome measure (MIP). Based on a study of inspiratory muscle strength in older outpatients with COPD,[50] we selected a 17 cmH_2O change level as the minimum clinically important difference (MCID). This decision was made as the MCID in MIP scores has not been established in PD. Data obtained from our feasibility study (under review) was used to calculate the appropriate sample size where there was a 17cm H2O change in MIP. Pre-intervention MIP was 69 cmH_2O and the post-treatment MIP was 86 cmH_2O. Therefore, to detect a 17 cmH_2O change in MIP with a power of 80% at a two-tailed significance level of 0.05, 50 participants are required, allowing a 15% dropout rate, with 25 in each group.

The interviews will be analysed using reflexive thematic analysis, as described by Braun and Clarke.[51–53] The analysis will be based on two sources of data, transcribed interviews and field notes. The process will involve several stages, including data familiarisation, coding, generating initial themes, reviewing, defining and naming themes and producing the report.[51] To increase the credibility of our findings and encourage reflective practice, a summary of the qualitative analysis process and results will be reviewed and discussed with all research team members (eg, once general themes are identified). Interview transcripts will also be submitted to the participants to confirm the accuracy of content.

Patient and public involvement

The results and detailed participant feedback via questionnaires provided during a feasibility study conducted by our team directly informed the design of this trial. For example, as the duration of measurements and the time required to attend appointments were identified as a potential burden to participants, this trial was designed to minimise the number of scheduled measurement appointments. Furthermore, prioritisation of patient-centred outcome measures (dyspnoea, quality of life) is lacking in previous studies. All participants had the option to receive trial results.

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Competing interests The authors declare that there are no competing interests.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Ethics approval This study involves human participants and the University of Canberra Human Research Ethics Committee approved this study (HREC-9268) Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available.

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