

BMJ Open Trunk muscle exercises as a means of improving postural stability in people with Parkinson's disease: a protocol for a randomised controlled trial

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ABSTRACT

Introduction: Exercise has been shown to improve clinical measures of strength, balance and mobility, and in some cases, has improved symptoms of tremor and rigidity in people with Parkinson's disease (PD). However, to date, no research has examined whether improvements in trunk control can remedy deficits in dynamic postural stability in this population. The proposed randomised controlled trial aims to establish whether a 12-week exercise programme aimed at improving dynamic postural stability in people with PD; (1) is more effective than education; (2) is more effective when training frequency is increased; and (3) provides greater long-term benefits than education.

Methods/design: Forty-five community-dwelling individuals diagnosed with idiopathic PD with a falls history will be recruited. Participants will complete baseline assessments including tests of cognition, vision, disease severity, fear of falling, mobility and quality of life. Additionally, participants will complete a series of standing balance tasks to evaluate static postural stability, while dynamic postural control will be measured during walking using head and trunk-mounted three-dimensional accelerometers. Following baseline testing, participants will be randomly-assigned to one of three intervention groups, who will receive either exercise once per week, exercise 3 days/week, or education. Participants will repeat the same battery of tests conducted at baseline after the 12-week intervention and again following a further 12-week sustainability period.

Discussion: This study has the potential to show that low-intensity and progressive trunk exercises can provide a non-invasive and effective means for maintaining or improving postural stability for people with PD. Importantly, if the programme is noted to be effective, it could be easily performed by patients within their home environment or under the guidance of available allied health professionals.

Trial registration number: The protocol for this study is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613001175763).

INTRODUCTION

Prospective studies indicate that the incidence of falls are much greater for people

Strengths and limitations of this study

- This study has been designed as a randomised controlled trial, which is currently considered the best methodological approach for evaluating the efficacy of a specific intervention.
- The proposed study will be the first to assess whether dynamic postural stability during walking can be improved or maintained in people with Parkinson's disease who regularly perform specific exercises to improve trunk mobility and endurance.
- This study seeks to assess changes in static and dynamic balance using continuous measures rather than graded clinical tests that are based on Likert scales, as these may be more sensitive for detecting improvements in postural stability for this patient group.
- While it would be important to examine whether improvements in postural stability are associated with a reduction in falls, the large sample size required to achieve this goal (approximately 120 participants per group) is prohibitive.
- Owing to the nature of the chosen intervention, the findings may only be applicable to patients who experience mild-to-moderate symptoms and are healthy enough to perform the exercises. As such, alternate interventions may be necessary for individuals who present with more advanced symptoms.

with Parkinson's disease (PD) than for age-matched controls, with up to 68% of people with PD falling at least once each year and up to 50% of these individuals experiencing recurrent falls.^{1 2} The increased falls risk in this population is compounded by an increased risk of injury, as differences in the postural responses of people with PD place them at a greater risk of sustaining a significant fall-related injury than age-matched controls.³ Falls and fall-related injuries often lead to a fear of falling, reduced mobility, poorer muscle strength and loss of independence, all of which ultimately influence

an individual's mortality, morbidity and quality of life.⁴ Biomechanical research involving healthy younger adults⁵ has shown that the trunk segment plays an important role in modulating gait-related oscillations and maintaining head stability; an important goal of the human postural control system. However, the increased axial rigidity that is evident in people with PD⁶ significantly impairs the trunk's capacity to attenuate these movement-related forces, which inadvertently reduces head stability and impairs the clarity of the visual and vestibular information used in balance control. In the early stages of the disease, the symptoms of PD are typically managed using any number of antiparkinsonian medications. However, these medications are unfortunately not always effective at improving symptoms of axial rigidity⁶ and often lead to undesirable side effects including dopamine-induced dyskinesias or motor fluctuations that have the potential to increase the risk of falls in people with PD. As such, there is a clear need for alternative therapies that can be easily implemented, have low running costs and have the potential to improve postural control, segmental mobility and falls risk in this population.

It is important for individuals to be able to effectively control their body's segments to maintain postural stability and limit the risk of falling during both static and dynamic activities of daily living. Older adults demonstrate poorer postural stability during tasks requiring dynamic postural control (eg, walking and turning), which can place them at an increased risk of falling.⁷ Age-related declines in dynamic postural control may be further exacerbated with the presence of PD, which would exacerbate the decreased balance and higher falls rate evident in this population.^{1 8 9}

Given that the head and trunk comprise 60% of the overall mass of the body,¹⁰ it seems reasonable to suggest that one's ability to precisely coordinate trunk movements would contribute significantly to attenuating movement-related oscillations and maintaining postural stability during these activities. An examination of segmental stability for different regions of the upper body in a healthy population showed that trunk movements were smaller than those of the head and neck during walking.¹¹ However, separate research suggests that the trunk has a more irregular movement pattern than the head during gait.⁵ The authors argued that the trunk may serve to attenuate forces during dynamic tasks to stabilise the head, and preserve the quality of the visual and vestibular feedback required for postural control. If an individual has increased axial rigidity⁶ and is unable to adequately control the trunk segment during dynamic tasks, then the exaggerated movements of the trunk may have a direct impact on head stability and overall balance.

A common method used to evaluate head and trunk stability during dynamic tasks is the harmonic ratio (HR), which provides a measure of the stability of gait-related accelerations by evaluating the stride-to-stride regularity

of the harmonics within the acceleration signal.¹² Walking patterns that produce higher HRs will be characterised by a more regular acceleration profile over successive gait cycles (ie, less stride-to-stride variability); hence, the gait pattern is deemed to be more stable.¹³ People with PD who fall are known to have increased mediolateral (ML) and anteroposterior (AP) movements of the trunk during sitting,¹⁴ less regular pelvic movements (lower HRs)¹⁵ and increased ML head movement during gait.^{1 16} Collectively, these studies suggest that some of the falls experienced by people with PD may be related to a reduced capacity for these individuals to adequately coordinate the body's segments during dynamic tasks. As such, there is a clear need to evaluate the efficacy of different non-invasive interventions aimed at maintaining and/or improving trunk mobility and control to improve postural stability in this population. To date, few studies have investigated the efficacy of different non-invasive methods for improving balance and reducing falls risk in this high-risk population.^{17–21}

It is widely recognised that exercise is an effective means of maintaining or improving cardiovascular and musculoskeletal health, both of which are critical for preserving physiological functioning and independence. Furthermore, some modes of exercise have been shown to be effective at improving standing balance,^{22 23} symptoms of anxiety and depression^{24 25} and reducing fall rates²⁶ and risk of falling^{22 27} in otherwise healthy individuals. A number of previous studies have also provided evidence to support the short-term benefits of exercise for improving clinical measures of mobility,^{15 17 28–30} postural stability,^{15 17 28–30} quality of life,³¹ cognitive function^{31 32} and symptom severity in people with PD.^{29 30} Current evidence suggests that when programmes include more challenging balance exercises, they may offer greater benefits for balance and mobility.¹⁷ For example, tai chi is a specific form of exercise known to challenge the balance system. Previous research has shown tai chi can improve measures of static postural stability in people with PD.³³ However, it is important to note that the results of a recent systematic review suggest that other forms of exercise may also provide similar benefits to balance in this population.³⁴

While this systematic evidence supports that exercise improves clinical measures of balance, mobility and disease severity, many of the improvements did not achieve a level that would be considered a minimally clinically important change. Furthermore, most of the balance and mobility assessments used in previous studies have relied on Likert scales to assess function, which may limit their ability to discriminate between people with PD who fall and those who do not. As such, it is possible that the incorporation of biomechanical measures of dynamic postural stability may improve our capacity to accurately detect improvements or declines in balance for this population, which would facilitate better identification of patients who are at a higher risk of falling. However, the investigators are unaware of any

previous research that has investigated whether exercise can improve quantitative measures of dynamic postural stability in people with PD. A possible explanation for this may be that such a study would require the use of complex measuring equipment that is typically only available in a laboratory setting, making it a higher order of investigation and difficult to assess in a clinical environment.

As such, the proposed randomised controlled trial aims to establish whether a 12-week exercise programme aimed at improving dynamic postural stability in people with PD; (1) is more effective than education; (2) is more effective when training frequency is increased; and (3) provides greater long-term benefits than education. It is hypothesised that the both exercise programmes will improve dynamic postural stability more than education, however training at an increased frequency will yield better improvements for the people with PD.

METHODS

The proposed randomised controlled trial will be conducted in 2014/2015 and seeks to improve the mobility and endurance of the trunk and its supporting musculature. This study protocol was developed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.³⁵

Participants

Forty-five participants diagnosed with idiopathic PD, based on the UK Brain Bank Criteria³⁶ and who have a history of two or more near-misses and/or one fall or more in the previous 12 months will be recruited from: (1) neurology clinics, (2) community support groups, (3) and a pre-existing database of people with PD who have expressed an interest in participating in research. Prospective participants will be sent an information letter outlining the details of the study and inviting them to contact a member of the research team if they are interested in participating in the research. On contacting a member of the research team, prospective participants will be screened to ensure that they all meet the requirements of the study and, if they are deemed eligible for inclusion, a time will be scheduled to conduct the baseline assessments. Participants will be excluded if they: (1) are unable to stand and walk independently without the use of a walking aid, (2) have any significant visual (Bailey-Lovie high-contrast visual acuity >0.30 logMAR) or cognitive impairment (Addenbrooke's cognition examination score <82), (3) have uncontrolled hypertension, (4) are taking psychotropic medications, (5) have any significant limitations due to osteoporosis, (6) have had any orthopaedic surgery within the previous year, (7) have any serious neck, shoulder or back injuries; including spinal fusions, or (8) have received deep brain stimulation surgery to manage their symptoms. For the purposes of this study, a fall will be defined as 'any coming to the ground or lower level not as the result of a

major intrinsic event or overwhelming hazard' and a near miss will be defined as 'an event on which an individual felt that they were going to fall but did not actually do so'.¹⁸ All volunteers will be asked to provide written informed consent in accordance with the Declaration of Helsinki prior to participation in the study.

To determine a suitable sample size, a power calculation was completed based on the HR, the primary measure of this study. The sample size was calculated using ML head accelerations from a previous study that assessed differences in dynamic postural stability in PD compared with healthy controls using the HR.³⁷ On the basis of this calculation, it was concluded that a minimum of 11 participants per group is needed to confidently report any significant changes in dynamic postural stability (diff=0.05, SD=0.04, Cohen's $d=1.25$, Power=80%, $p=0.05$). Given the longitudinal nature of the research, 15 individuals will be recruited per intervention group to accommodate a 25% rate of attrition. The experimental procedures for this study have been approved by the Australian Catholic University Human Research Ethics Committee. To ensure participants are assessed under similar conditions during each testing session, all procedures will be scheduled to start within 1–2 h of the participants taking their medication. This will ensure the participants are comfortable and safe during the assessments and that the results are representative of how the individuals might perform such tasks in the real world.

Clinical measures

Individuals who provide consent to participate in this study will be asked to attend an initial session at the Australian Catholic University (Brisbane) during which a series of baseline assessments will be performed. This battery of tests will include clinical assessments of: (1) cognitive function (Addenbrooke's Cognitive Examination (ACE)),³⁸ (2) visual acuity (Bailey-Lovie high-contrast visual acuity³⁹), (3) disease severity (Unified Parkinson's Disease Rating Scale (UPDRS), the modified Hoehn & Yahr (H&Y) scale,⁴⁰ the Schwab & England Activities of Daily Living Scale⁴¹ and the PD Gait and Falls Questionnaire (PD-GFQ)⁴²), (4) fear of falling (Activity-specific Balance Confidence Scale⁴³), (5) mobility (Timed Up and Go⁴⁴) and (6) quality of life (Parkinson's disease questionnaire 39 (PDQ-39)).⁴⁵ The PD-GFQ is a 16-item tool that assesses the extent of any falls and gait difficulties experienced by people with PD and incorporates six questions that are summed to give the freezing of gait (FOG) score.⁴² The ACE was selected to assess cognitive function, as it incorporates the Mini Mental State Examination and has been shown to have high sensitivity and specificity for detecting dementia (cut-off <82 gives 82% sensitivity and 100% specificity). The other assessments were selected as they have been shown to be both reliable and valid,^{38 46–49} and have been used previously to assess individuals with PD.^{15 50}

Postural stability measures

To evaluate dynamic postural stability, participants will be asked to walk along a 10 m walkway at a comfortable self-selected pace for four trials and will be offered a rest break between trials to minimise the risk of fatigue. While completing this task, movement patterns of the head and trunk will be measured using two microelectromechanical system three-dimensional accelerometers (Noraxon Inc, Scottsdale, Arizona, USA) sampling at a rate of 500 Hz. Prior to testing, the accelerometers will be statically calibrated using the methods described previously.⁵¹ Calibration involves aligning each sensing axis of the accelerometer perpendicular to a horizontal surface to determine a conversion factor that describes gravitational acceleration (1 gravitational unit or 1 g). Following static calibration, an accelerometer will be firmly attached over the occipital protuberance of the skull via a sport headband and another will be attached directly to the skin using double-sided tape over the spinous process of the 10th thoracic vertebra (T10). To detect gait events, such as heel strike and toe off during the gait cycle, two pressure-sensitive footswitches (Noraxon Inc) will be placed bilaterally under the calcaneus, the distal end of the first phalange and the distal end of the first and fifth metatarsals of the foot.

Static postural stability will be assessed while participants are standing quietly on a portable force plate that is sampling data at an effective rate of 200 Hz (Advanced Mechanical Technology Inc, USA). Participants will complete two 30 s trials that will involve standing as still as possible for each of the following conditions: (1) on a firm surface with eyes open, (2) on a firm surface with eyes closed, (3) on a foam surface with eyes open and (4) on a foam surface with eyes closed. Before start of each trial, participants will be asked to look straight ahead at a cross that will be placed on the wall at eye level with their arms resting at their sides and their feet 10 cm apart. Measurements derived from the force plate data will include: peak RMS displacement of the centre of pressure and postural sway velocity in the AP and ML directions.

In addition to the acceleration profiles that will be collected for the head and trunk, muscle activation patterns for the thoracic and lumbar erector spinae will be measured at 1500 Hz using a wireless Noraxon surface electromyography (EMG) system (Noraxon Inc). In healthy individuals, the erector spinae muscles show a phasic increase in activation just after heel-contact to counter forward trunk flexion during walking.⁵² The erector spinae muscles were chosen for evaluation because individuals with PD are known to have decreased trunk muscle performance than age-matched controls,⁵³ which may influence their capacity to control trunk motion during walking. Prior to applying the surface electrodes over the muscles of interest, the skin will be prepared with an abrasive gel (Nuprep; Weaver Company, Aurora, Colorado, USA), and then cleaned thoroughly with an isopropyl alcohol wipe to minimise

impedance at the electrode-skin interface and improve clarity of the myoelectric signal.⁵⁴ For individuals with excessive hair over the muscles of interest, the area will be shaved in order to maximise the fidelity of the myoelectric signal and ensure the best possible adherence to the skin. After skin preparation, four pairs of Ag/AgCl pregelled surface electrodes (AMBU Blue Sensor, Ballerup, DK; 34 mm diameter, 10 mm² sensing area) will be placed with a centre-to-centre interelectrode distance of 34 mm. Specifically, these electrode pairs will be placed bilaterally 5 cm lateral to the spinous process of the T10 vertebral body and 2 cm lateral to the spinous process of the third lumbar (L3) vertebral body.⁵⁵

To facilitate comparisons between the different testing dates and the different participant groups, the EMG data will be normalised to the muscle activity levels recorded for the participants during a maximal voluntary contraction (MVC) of the erector spinae. To perform the MVC, the participants will lie prone/prostrate on a padded table with their hips flexed and their feet on the floor. The participant will then be asked to complete three practice trials to learn the movement before performing three maximal efforts that involve simultaneously extending both hips to raise the legs to a horizontal position to activate the erector spinae muscle group. A restraining force will be applied to the legs of the participants to make sure that their legs remain horizontal (180°) while performing the test to produce the MVC. This method was chosen in preference to the traditional Biering-Sorensen test, due to the potential difficulties that older participants may have with this movement.⁵⁵

All data collection will be performed using the MyoResearch XP software to ensure that the data from the different systems remain synchronised. Participants will be re-tested using the assessments outlined above: (1) after the 12-week intervention to establish the immediate effects of the exercise programme on postural stability and (2) 12 weeks after the completion of the intervention to evaluate the retention of any benefits over the longer term (ie, 24 weeks following baseline). The battery of assessments and the time points at which they will be taken are summarised in [table 1](#) and the flow of recruitment, data collection and follow-up procedures are outlined in [figure 1](#).

Data analyses

Data from the raw accelerations will be low-pass filtered using a bi-directional fourth order Butterworth filter with a cut-off frequency of 30 Hz.⁵⁶ Measurements derived from the accelerometry data will include: (1) peak acceleration (root mean square (RMS)) and (2) HR, both of which will be calculated for the AP, ML and vertical (VT) axes of the head and trunk accelerometers separately. The HR has been used previously to evaluate dynamic postural instability in people with PD^{15 37} and will be used in this study to provide an indication of how

Table 1 The primary, secondary and tertiary outcomes measures and the time points at which they will be assessed during the study

Outcome measures		Baseline (week 0)	Postintervention (week 12)	Final assessment (week 24)
Primary outcome measure				
Dynamic postural stability	Harmonic ratio (AP, ML, VT)	X	X	X
Secondary outcome measures				
Static postural stability	Peak RMS displacement (AP, ML)	X	X	X
	Sway velocity (AP, ML)	X	X	X
Bilateral trunk muscle function	Peak RMS activity (ES at T10 and L3 levels)	X	X	X
Tertiary outcome measures				
Disease severity	UPDRS III	X	X	X
	FOGQ	X	X	X
	ABC scale	X	X	X
	Schwab and England Activities of daily living	X	X	x
	PDQ-39	X	X	X
Other variables	Intervention compliance	X	X	x
	Adverse events	X	X	X
	Daily levodopa equivalents	X	X	X
	International physical activity questionnaire		X	X
Screening measures				
Cognitive function	Addenbrooke's cognitive examination	X		
Visual function	Bailey-Lovie high-contrast visual acuity	X		

ABC Scale, Activities-Specific Balance Confidence Scale; AP, anteroposterior; ES, erector spinae; FOGQ, Freezing of Gait Questionnaire; ML, mediolateral; PDQ-39, Parkinson's Disease Questionnaire 39; UPDRS III, Motor Subscale of Unified Parkinson's Disease Rating Scale; VT, Vertical.

well the movement patterns of the head and trunk are controlled during normal gait.

Raw EMG data will be high-pass filtered at 100 Hz to remove heart rate artefact from the signal and then full-wave rectified and low-pass filtered (4th order Butterworth filter) at 20 Hz.⁵⁷ Following filtering of the data, the RMS of the muscle activity throughout the walking trials will be calculated over a 50 ms⁵⁷ moving average window, with a 25 ms overlap.⁵⁵ To facilitate comparisons between participants and across testing days, the activation levels of the trunk muscles will be normalised to the peak RMS amplitude of the muscle activity recorded during the MVC trials. The peak normalised RMS muscle activities derived from three complete gait cycles for each leg from each of the four trials (n=12 gait cycles per leg) will then be averaged and these data will be used for all subsequent analyses.

Randomisation and blinding

After completion of the baseline assessments, participants will be randomised using a computerised random number generator (block size=3) in a 1:1:1 ratio to one of the three intervention groups: (1) exercise 1 day/week, (2) exercise 3 days/week or (3) education. To minimise the possibility of introducing issues related to inter-rater reliability and/or biasing the outcomes, the clinical assessments will be conducted by an individual who is trained to administer the tests, but who will not be

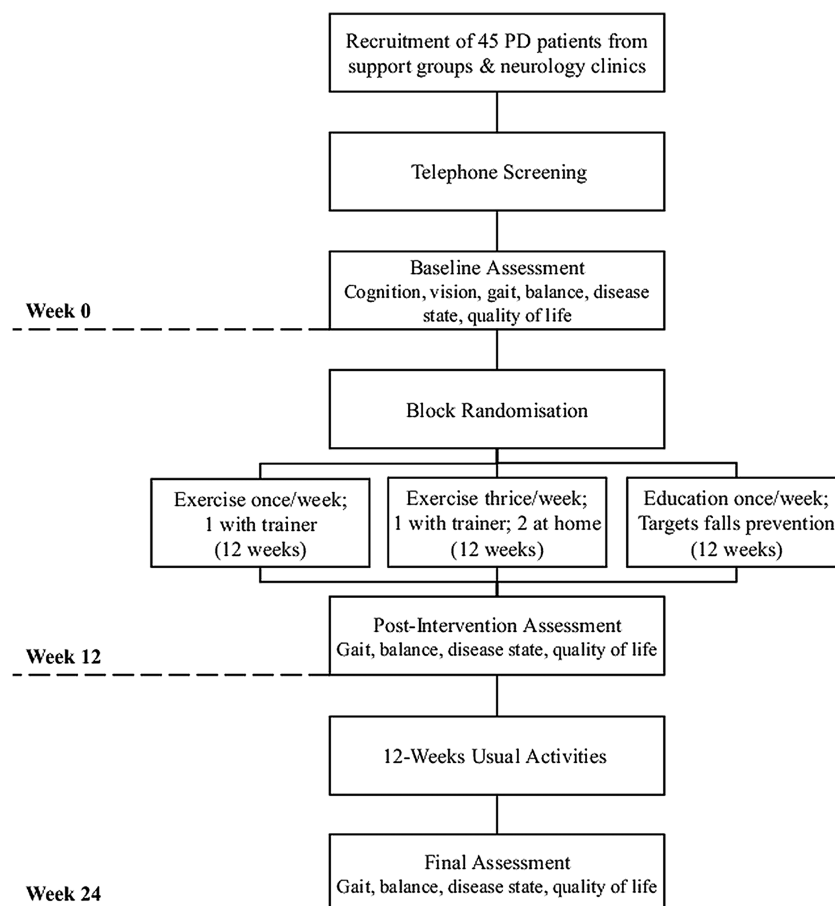
involved with the recruitment and allocation of participants to intervention groups and will also be blinded to intervention status. Furthermore, another member of the research team responsible for processing and analysing the data related to the assessment of static and dynamic postural stability will recruit and assign participants to intervention groups, however will be blinded to the group allocation of the participants during data analysis.

Intervention

At baseline, all participants will receive a 10–15 min one-off presentation outlining the evidence that supports exercise as an effective means of improving movement and postural stability in people with PD. Participants in the education group will be encouraged to continue their day-to-day lives, as usual, but will receive a weekly multidisciplinary education package that will include a health tip that will explain how, for example, exercise, nutrition and/or sleep quality may influence their falls risk and quality of life. The education group represents what would normally be seen in everyday life, with the education brochures created using scientific evidence drawn from pre-existing research and freely-available information sheets produced by government and not-for-profit organisations.

Participants assigned to the exercise groups will complete a low-level supervision, 12-week exercise programme aimed at improving trunk mobility and

Figure 1 Study outline. Flow chart depicting the order of recruitment and testing procedures for the outlined study.



endurance, which will involve one supervised session each week with a trained Exercise Scientist at the University. The group exercising once per week will receive the intervention during the weekly supervised session, while the group exercising three times per week will be asked to complete the protocol at home on two other days of the week, for a total of three training days per week. The exercise programme consists primarily of exercises that have previously been used in two different exercise-based interventions involving older adults⁵⁸ and people with PD,⁵⁹ that focused on improving trunk muscle strength and endurance. Importantly, the programme was designed to conform to the current recommendations for best clinical practice with respect to the implementation of exercise-based interventions for improving postural stability.^{27 33 60} Specifically, the programme includes movements focusing on improving trunk mobility, exercises that target muscular strength and endurance, tasks that aim to develop balance under challenging situations (ie, on an unstable surface) and ambulating over different terrains in a real-world environment. The programme will progress in complexity to accommodate individuals with different physical capabilities. The primary movements used for the programme are outlined in table 2. Hold times for the endurance exercises begin at 5 s and repetitions begin at 10 or as many as achievable by the participant. In addition, as the participant progresses in the programme, a round

and flat air filled disc will be incorporated to create an unstable surface and create a balance challenging environment during the exercises. For the walking portion of the programme, this will be completed on an outdoor walking path that specifically incorporates varying degrees of incline and decline, stairs and multiple surface types to simulate walking during activities of daily living. The various challenges offered by this walking course will serve to improve the participants' capacity to safely and effectively ambulate in predictable and unstable real-world environments.

To facilitate monitoring of activity levels during the 12-week intervention and the 12-week sustainability periods, all participants will be asked to record their weekly activity levels using the International Physical Activity Questionnaire (IPAQ)⁶¹ during these periods. The IPAQ is a questionnaire that has been shown to be both a valid and reliable tool for quantifying activity levels in different populations.^{62 63} In addition, compliance to the intervention protocol and any adverse events will also be monitored and reported by the researchers.

Statistical analysis

Continuous data will first be checked for normal distribution and, where applicable, log transformation will be applied to the data. To assess for any significant differences between the groups with respect to the continuous demographic variables (eg, age, height, weight,) a one way

Table 2 Summary of the specific tasks, repetitions and progressions for each of the exercises

Task	Movement	Repetitions/progression
Trunk mobility Warm-up	Lateral bends	10 to the left 10 to the right
	Torso rotations	10 to the left 10 to the right
	Small arm circles	10 forward 10 backward
	Large arm circles	10 forward 10 backward
	Torso rotations with high and low reaching	10 reaching up to left, down to right 10 reaching up to right, down to left
		Increase difficulty of exercise by: ► Increased hold times ► Movement complexity ► Introduce unstable support surface
Trunk endurance	Abdominal hollowing	
	Side bridging	
	Front bridging	
	Bird dog	
Mobility	Walking over surfaces of varying incline/decline, density and up and down stairs	8–10 min of walking on an outdoor walking path
Active cool down	Hamstring stretch	2 sets of 20 s holds
	Quadriceps stretch	2 sets of 20 s holds
	Gastrocnemius/soleus stretch	2 sets of 20 s holds
	Triceps stretch	2 sets of 20 s holds
	Pectoral stretch	2 sets of 20 s holds

analysis of variance (ANOVA) will be used, while the χ^2 test will be used to identify any significant differences in the frequency of categorical data (eg, gender, Hoehn & Yahr scale). If a significant difference is found from the ANOVA, the Tukey's honestly significant difference test will be used to perform post hoc comparisons among the three groups. If the assumptions of normality (Shapiro-Wilks test) or homogeneity of variance (Levene's test) are still violated after log transformation, the non-parametric Kruskal-Wallis testing will replace the ANOVA. Analysis of the outcome measures for static and dynamic postural stability will be based on intention to treat principles. To assess the acute (12 weeks) and long-term (24 weeks) effects of the intervention on measures of postural stability, a repeated measures analysis of covariance (RM-ANCOVA) will be conducted, with the baseline value for each outcome measure and disease severity entered as covariates. To determine covariates, variables of age and disease severity will be graphed in relation to baseline measures of postural stability to identify any linear relationships. All statistical analyses will be completed in the Statistical Package for the Social Sciences (SPSS V.21.0) and the level of significance will be set at $p < 0.05$.

DISCUSSION

For people with PD, the increased risk of falls and fall-related injuries has the potential to significantly influence an individual's psychological, physiological and socioeconomic state; ultimately impacting their quality of life. Although oral medications are known to improve many of the motor and non-motor symptoms associated with PD, late-stage symptoms such as gait difficulties and postural instability are not always responsive to this

therapeutic intervention.⁶⁴ As postural instability and gait difficulties contribute significantly to the high risk of falls in patients with PD, there is a strong need for further research examining additional non-invasive interventions that target the improvement of segmental control and postural alignment in this population.

To date, a number of studies have demonstrated that an exercise intervention can improve strength,^{65 66} measures of static postural stability⁶⁷ and motor symptoms^{17 28 68} in people with PD. In contrast, a separate study reported no significant improvements in self-reported disability or clinical measures of balance, mobility or quality of life for people with PD following a 6-week home-based exercise intervention.¹⁸ Although these clinical tests have been widely used to assess falls risk in people with PD, they may lack the sensitivity to provide real insight into the falls risk of this population. Specifically, it has been shown that the Tinetti Balance and Gait Assessment, Berg Balance Scale, Timed Up and Go, Functional Reach and Physiological Profile Assessment (PPA) of falls risk achieve only moderate sensitivities (65–69%), specificities (62–69%) and accuracies (53–68%) when predicting prospective falls for people with PD.⁵⁰ Continuous biomechanical measures, such as those provided by force platforms and accelerometers may help to resolve this problem by increasing the sensitivity of outcome measures to more accurately detect changes in motor performance.

From the perspective of maintaining balance, the trunk is believed to play an important role in maintaining head stability during dynamic tasks. During walking, forces are transmitted upwards from the feet following heel contact, which requires the legs, trunk and neck to act as shock absorbers to attenuate the load and maintain smooth

movement patterns for the head.⁵ However, individuals with PD are known to have deficits in trunk control and trunk muscle function,⁵³ which may impair their capacity to perform this role and increase their risk of falling. The findings of previous research tend to support this notion, indicating that people with PD who fall have greater ML head movement while walking on firm¹ and compliant¹⁶ surfaces and poorer pelvic control¹⁵ during unconstrained gait. As such, interventions aimed at improving trunk muscle functioning may help to improve postural stability and reduce falls for individuals with PD.

The intervention for this study was specifically developed to achieve this goal and will incorporate a series of safe and progressive exercises that were adapted from two previous studies examining the effects of exercise on balance and trunk muscle performance. The findings of these studies demonstrated that progressive exercises targeting improvements in the function of the deeper trunk muscles were effective in improving clinical measures of balance in older women who were at a high risk of falling.⁵⁸ Similar exercises, when combined with aerobic exercises and stretching, were shown to significantly improve the strength and mobility of the trunk muscles in individuals with PD, but the authors did not report whether these improvements were associated with any changes in postural stability.⁵⁹

As with any study of this nature, there are a number of limitations that have the potential to influence the outcomes of the proposed exercise-based intervention. First, to ensure the comfort and safety of the participants throughout the data collection and exercise (if applicable) sessions, participants will complete the baseline, follow-up and training sessions while on-medication. As such, it is possible that dopamine-induced side effects of the medication may influence their performances on some of the laboratory and/or clinical assessments. However, details regarding medications will be collected and participants will be asked to report any changes in medications during the study period. If differences are identified between the groups with respect to disease duration, disease severity or medications, these variables will be entered as covariates in the statistical model. Second, the sample size for this study may seem small compared with other studies that have used exercise-based interventions to reduce falls in older adults⁶⁹ or people with PD.¹⁸ However, as supported by the presented power calculation, the target sample size of 15 participants per group is adequate to detect differences in our chosen primary outcome measure and will accommodate an attrition rate of 25%.

In conclusion, there is a growing body of evidence to suggest that regular exercise has the potential to reduce the risk of falling in people with PD¹⁷ and may even help to reduce the number of falls experienced by some individuals.¹⁸ This study will be the first to examine whether a 12-week training programme aimed at improving trunk mobility and endurance has the potential to improve measures of postural stability in this population. If found to be effective, this training programme will provide a

safe and inexpensive exercise-based therapy option that will help to maintain and/or improve postural stability and ultimately contribute to improving quality of life for people with Parkinson's disease.

Contributors RPH and MHC designed the study, obtained funding and completed extensive preparation to develop the study protocol. MHC will oversee the execution of the study and will be responsible for administering the clinical tests and assisting with recruitment of participants. RPH will be responsible for the day-to-day management of the study, data collection, data analysis and interpretation of the findings. GAN provided important assistance with the development of the study protocol and will be responsible for participant allocation. PAS will be involved in assisting with participant recruitment and with the interpretation of the clinical relevance of the study's outcomes. RPH and MHC developed the initial draft of this manuscript and all authors contributed to the refinement and finalisation of the submitted manuscript.

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Competing interests None.

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