Title: Trunk exercises improve quiet standing balance in people with Parkinson disease: A randomised-controlled trial

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Abstract

Background and Purpose: Trunk control is important for maintaining balance, hence deficient trunk control may contribute to balance problems in people with Parkinson disease (PD). Unfortunately, this deficit is poorly managed with pharmacological therapies, emphasizing the need for alternative therapies for these patients. This randomized controlled trial sought to examine the effects of a 12-week trunk-specific exercise-based intervention on balance in people with PD.

Methods: Twenty-four people with PD and with a history of falls completed assessments of motor symptom severity, balance confidence, mobility, quality of life and quiet standing balance. Participants were then randomized to receive either 12-weeks of exercise or education and reassessed after 12 and 24 weeks.

Results: Linear mixed model analyses showed no significant changes in clinical outcomes following the intervention. However, during quiet standing, sway area on a foam surface without vision was reduced for the Exercise group at 12- (-6.9±3.1 cm; 95% CI=-13.1 to -0.7; p=0.029; d=0.66) and 24-weeks (-7.9±3.1 cm; 95% CI=-14.1 to -1.7; p=0.013; d=0.76). Furthermore, the Exercise group demonstrated reduced sway variability at 12- (-0.2±0.1 cm; 95% CI=-0.4 to 0.0; p=0.042; d=0.62) and 24-weeks in the medial-lateral direction (-0.2±0.1 cm; 95% CI=-0.4 to 0.0; p=0.043; d=0.62). No changes in quiet standing balance were recorded for the Education group.

Discussion and Conclusions: The results of this study suggest that exercise-based interventions targeting trunk strength, endurance and mobility may be effective for improving quiet standing balance in people with PD. However, additional research is needed to determine whether these improvements are sufficient to reduce falls risk. **Video Abstract available** for more insights from the authors (see Video, Supplemental Digital Content 1).

Keywords: Parkinson disease; Motor Control; Falls; Quality of Life, Standing Balance

Introduction

The maintenance of an upright posture is often modelled as an inverted pendulum, in which balance is facilitated via fine adjustments to the mechanical stiffness of the body.[1,2] These adjustments in mechanical stiffness are largely influenced by muscle contractions and ultimately result in a continuous sequence of corrective movements that serve to maintain the centre of mass (i.e. the body's balancing point) over the base of support (i.e. the feet). During quiet stance, it is generally considered that the postural corrections exhibited by an individual are produced via one of two primary strategies; namely the 'ankle' and 'hip' strategies.[3] The corrective movements produced via the 'ankle' strategy involve the body rotating as a relatively rigid mass about the ankle joint and rely upon the coordinated activation of the lower limb, pelvic and trunk muscles.[3] In contrast, the corrective movements that characterise the 'hip' strategy are produced by hip and pelvic movements that are primarily controlled by muscles surrounding the hips, pelvis and trunk.[3] While both of these strategies require effective control of the muscles responsible for ankle (ankle strategy only), knee, hip and trunk motion, the relative importance of the trunk segment is highlighted by its significant contribution to the body's mass (≈50%[4]).

During quiet stance, co-activation of the thoracic erector spinae, superficial lumbar multifidus and internal oblique muscles increases the mechanical stiffness of the trunk segment, which serves to limit unwanted motion and preserve trunk control.[5] The importance of adequate mechanical stiffness to balance control has previously been demonstrated in a large prospective study involving community-dwelling older adults, which showed that those who exhibited increased postural stiffness during balancing tasks were at a significantly lower risk of falling.[1] However, it is important to consider that the relationship between postural stiffness and balance control is not linear, but rather takes the form of inverted U-shape. Given this understanding, it can be surmised that while an increase in postural stiffness may initially improve balance

control, further increases in stiffness may be detrimental. Evidence for this complex relationship has been provided in previous studies demonstrating that atypical increases in trunk stiffness negatively impact an individual's balance and overall risk of falls.[6,7]

Unusually high levels of trunk stiffness are not common in the general population, but such symptoms can be prominent in people with Parkinson disease (PD) who experience symptoms of axial rigidity[8-10] and reduced trunk muscle strength[11] compared with healthy aged-matched controls. Symptoms of axial rigidity are suggested to impair an individual's capacity for lateral balance control, as responses to laterally-directed perturbations require more input from the trunk and hip muscles (i.e. the 'hip' strategy) than perturbations from an anterior-posterior direction, which typically rely on the 'ankle' strategy.[12] Specifically, people with PD who experience these symptoms may have difficulty with the timing and scaling of effective corrective movements, which would ultimately increase their risk of overbalancing and falling.

In addition to axial rigidity, concomitant deficits in muscle strength means that people with PD would be more likely to experience premature muscle fatigue, which has been shown to significantly impair balance control during standing balance assessments.[13] It is worth noting, however, that deficits in trunk mobility and strength affect much more than balance control in people with PD, as those who exhibit an impaired ability to recruit their trunk muscles are also less stable during gait[14] and less capable of performing common activities of daily life (e.g. rising from a chair, negotiating stairs).[15] Given the importance of the trunk to balance control and the performance of activities of daily living, it is possible that therapies seeking to improve the strength, endurance and/or mobility of these structures may assist with preserving independence and reducing the risks that contribute to the high-rate of falls in this population.[16-18]

Levodopa and deep brain stimulation are commonly used to manage the motor and non-motor symptoms of PD, but are known to be relatively ineffective at managing the symptoms that affect balance.[19] As such, researchers have sought to determine whether other therapies, such as exercise-based interventions, may benefit people with PD who experience such symptoms. In recent years, exercise-based interventions have been shown to reduce the incidence of falls[20,21] and improve clinical measures of mobility,[22-26] balance,[22-26] quality of life,[21,27] cognition,[27,28] and motor symptom severity[24,25] in people with PD. Furthermore, exercise-based interventions targeting the trunk muscles have been shown to significantly improve superficial trunk muscle activations in healthy older adults[15] and trunk muscle strength in people with PD.[29] Importantly, the likely benefits of an exercise-based intervention appears to be contingent on the level of disability of the patient at the commencement of the program, as research shows that while targeted exercise-based interventions can reduce the incidence of falls in patients with milder symptoms, they are less effective for those who are more severely affected.[30]

Collectively, the literature suggests that exercise-based interventions may improve trunk mobility, trunk strength and balance in people with PD who have mild symptom severity. However, there is currently a paucity of research directly assessing the potential link between trunk-specific exercise-based interventions and improvements in balance in this clinical population. Therefore, it was the primary aim of this randomized, controlled trial to establish whether a 12-week trunk-specific exercise-based intervention that incorporated falls prevention education was more effective than falls prevention education alone at improving balance in people with PD. A secondary aim of this study was to determine whether the same 12-week exercise-based intervention could improve clinical measures of mobility, balance confidence, quality of life, levodopa equivalent daily dose, motor symptom severity, disease stage, disability or freezing of gait in the PD population. It was hypothesized that the

participants assigned to the Exercise group would exhibit improvements in the balance and clinical measures following the intervention, while those assigned to the Education group, receiving the falls prevention education, would show no improvements after the 12-week intervention.

Methods

Participants

The study protocol[31] was developed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines[32] and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613001175763). Individuals from a metropolitan neurology clinic who were diagnosed with idiopathic PD, based on the UK Brain Bank Criteria[33] were sent an information sheet that outlined the details of the study and invited them to contact the research team if they wished to volunteer. Prospective participants were initially screened over the telephone and were excluded if they had: 1) an inability to walk independently; 2) uncontrolled hypertension; 3) a prescription for psychotropic medications; 4) significant limitations due to osteoporosis; 5) orthopaedic surgery within the previous year; 6) serious neck, shoulder or back injuries (including spinal fusions); 7) received deep brain stimulation (DBS) surgery for symptom management; 8) a neurological condition other than PD; or 9) reported no history of falls or near misses in the past year. For this study, a fall was defined as a coming to the ground or lower level not as the result of a major intrinsic event or overwhelming hazard.[34] Similarly, near misses were defined as events during which an individual felt that they were going to fall but did not.[34]

On the basis of an *a priori* power calculation completed using a previous study comparing balance in PD fallers and non-fallers,[35] it was determined that a minimum of 11 participants per group would be required to confidently report significant changes (Cohen's d

= 1.10, Power = 80%, p = 0.05). Of the 683 prospective participants contacted, 571 did not respond, 19 declined to participate and 68 did not meet the inclusion criteria (Figure 1). Following telephone screening, the remaining 25 people with PD were invited to the Biomechanics Laboratory at the Australian Catholic University to complete some further screening and, if eligible, the baseline assessments. During this assessment, participants were screened for significant visual (Bailey-Lovie high contrast visual acuity >0.30 logMAR[36]) or cognitive impairment (Addenbrooke's Cognition Examination (ACE)[37] total score <82), which resulted in the exclusion of one participant who recorded an ACE score of 68. The recruitment and assessment of all participants was completed between February 2014 and December 2015. All experimental procedures were approved by the Australian Catholic University's Human Research Ethics Committee (2013 223Q) and each volunteer gave written informed consent in accordance with the Declaration of Helsinki to participate.

*****INSERT FIGURE 1 ABOUT HERE*****

Primary Outcomes: Standing Balance

Eligible participants completed two 30-second standing balance trials that involved standing as still as possible under each of the following conditions: i) on a firm surface with eyes open, ii) on a firm surface with eyes closed, iii) on a foam surface with eyes open and iv) on a foam surface with eyes closed. While performing the balance task, participants stood with their arms resting at their sides and their feet 10 cm apart while visually focusing on a cross that was placed at eye level 40 cm in front of them. Center of pressure was measured at 200 Hz by a portable force plate (Advanced Mechanical Technology Inc., USA) to provide insight into each participant's quiet standing balance during the trials. The use of force plates to assess standing balance has become widely accepted in many laboratory and clinical settings and is likely

influenced by their good to excellent test-retest reliability[38,39] and their capacity to measure the subtle balance changes that contribute to falls in people with PD.[40]

Using the center of pressure data, outcome measures that included the 95% elliptical sway area, sway velocity and the variability of anterior-posterior and medial-lateral sway patterns (as determined using the standard deviation) were calculated using commercial software (BioAnalysis; Advanced Mechanical Technology, Watertown MA, USA). The selection of these outcomes was guided by previous research which has reported differences in these measures for people with PD relative to controls[41-43] and for PD fallers compared with non-fallers.[40]

Secondary Outcomes: Clinical Measures

Prior to attending the testing session, participants were asked to complete a series of self-report questionnaires that examined; i) balance confidence (Activity-specific Balance Confidence Scale[44,45]), ii) quality of life (39-item Parkinson Disease Questionnaire[46]); iii) freezing of gait (Freezing of Gait Questionnaire[47]); and iv) prescription medication use. Using this information, each participant's levodopa equivalent daily dose was calculated using previously-described methods.[48] During the testing session, mobility was assessed via the Timed Up-and-Go test[49], while motor symptom severity (Part III of the Unified Parkinson Disease Rating Scale[50]), disease stage (modified Hoehn & Yahr scale[51]) and disability (Schwab & England Activities of Daily Living Scale[52]) were assessed by an experienced movement disorders scientist blinded to the participants' group assignment (MHC). All assessments of physical performance and motor symptom severity were conducted 1-2 hours following the participant's scheduled dose of anti-parkinsonian medication to ensure results were representative of real-world performance.

Randomization and Blinding

This study was designed to be a parallel group randomized controlled trial. After baseline assessment, participants were assigned by a member of the research team (RPH) to one of two 12-week intervention groups using a random allocation sequence (block size=2; 1:1 ratio). This random allocation sequence was generated by a member of the research team who was not involved in participant recruitment, assessment or group allocation (GAN). The researcher who conducted the instrumented quiet standing balance assessments (RPH) was not blinded to the participants' group allocation. However, the scientist who completed the clinical tests of motor symptom severity, disease stage and disability (MHC) was blinded to the participants' group allocation to minimise the risk of bias during these assessments

Intervention

Participants were randomly assigned to receive either 12-weeks of falls prevention education or 12-weeks of exercise and falls prevention education and were required to commence their assigned intervention within a week of completing the baseline assessments. It is important to acknowledge that an ancillary aim of this project was to evaluate whether three weekly exercise sessions led to greater improvements in clinical outcomes and/or quiet standing balance than one weekly exercise session.[31] However, the prospect of potentially needing to complete the exercise-based intervention three times per week led to difficulties with participant recruitment, which made it necessary to narrow the focus to the stated aims. Participants randomized to the Education group were encouraged to continue their day-to-day lives, but received a weekly pack of printed multi-disciplinary education materials that included health tips explaining how lifestyle (e.g. exercise) and/or condition-related issues (e.g. poor sleep quality) can influence their risk of falling and overall quality of life. The education brochures were specifically created by the research team using information drawn from pre-existing research and information that is freely-available online via government and not-for-

profit organizations (see Appendix Falls Prevention Education Materials, Supplemental Digital Content 2).

Participants assigned to the Exercise group also received the weekly education brochures, but completed a supervised exercise-based intervention aimed at improving trunk strength, endurance and mobility. The Exercise group attended one supervised session each week with a trained exercise scientist. The program included trunk-specific exercises used previously for older adults[53] and people with PD[29] and was designed to conform to current recommendations for implementing exercise-based interventions that target improved balance.[20,54,55] In short, the exercise-based intervention comprised three parts; i) a warm-up focusing on trunk mobility exercises to improve range of motion; ii) an exercise routine focusing on the strength and endurance of the trunk muscles (multifidus, erector spinae, obliques, transverse abdominus, rectus abdominus); and iii) a cool-down involving stretching and walking in a real-world environment. An overview of the trunk exercise program is provided in Table 1.

The exercise-based intervention was designed to accommodate individuals with varying degrees of symptom severity and the starting intensity was individualized for each participant based on their physical capacity at the time of the first session. The participants' progress was reviewed during each session and, where necessary, the intensity of their program was incrementally increased to ensure that it remained suitably challenging. For the endurance exercises, static hold times began at 5 seconds and were progressed in 5-second increments. Furthermore, as the participants progressed with the program, standing on a round and flat air-filled disc was incorporated into the exercises to create an unstable surface and a balance-challenging condition. Given that systematic evidence suggests that exercise-based interventions are well suited to reducing falls risk in older adults,[56] those assigned to receive exercise and falls prevention education comprised the treatment group. In contrast, given there

is little to no evidence regarding the efficacy of falls prevention education strategies with respect to their capacity to reduce falls risk in ageing populations,[56] those receiving the falls prevention education represented the placebo group. Additional information about the education and exercise-based interventions has been published previously.[31]

*****INSERT TABLE 1 ABOUT HERE*****

Immediately following the completion of the 12-week intervention, all participants were re-assessed using the same tests completed at baseline. Additionally, participants were invited to complete a 24-week follow-up assessment to assess the long-term retention of any improvements. During this 12-week retention period, participants in the Exercise group were advised that they were no longer required to perform the exercise-based intervention, but should not specifically refrain from performing any of the activities that they would normally perform as part of their daily lives. Adherence to the intervention protocol and any adverse events were also monitored and reported.

Statistical Analysis

To determine the efficacy of the two 12-week interventions, the analyses were based on a modified intention to treat approach.[58] In accordance with this approach, two participants who withdrew from the study after randomization were excluded from the analyses, as they did not receive treatment and, hence, were unable to contribute meaningful data regarding the efficacy of the interventions. Furthermore, when participants who completed the 12-week intervention were unable to return for follow-up testing, their data were imputed using the last observation carried forward (LOCF) method. To assess for changes between groups at 12- and 24-weeks compared with baseline, linear mixed model analyses were used (baseline vs. 12

weeks, baseline vs. 24-weeks, 12 weeks vs. 24-weeks). These models included multiple repeated factors (Day: 3 levels; Vision: 2 levels; Surface: 2 levels; Trial: 2 levels), one fixed factor (Group: 2 levels) and 2 covariates (levodopa equivalent daily dose and age). Levodopa equivalent daily dose and age were added as covariates into the model to be controlled for as levodopa improves motor symptoms[59] and standing balance is influenced by age.[60] If a significant interaction was found, the Tukey's Least Significant Difference test was used to perform post-hoc comparisons. All data analyses were conducted using Statistical Product and Service Solutions (SPSS v.21, New York, USA) with significance set at $p<0.05$.

Results

Study Population, Retention and Adherence

Two participants withdrew from the study before completing the 12-week exercise program citing their inability to commit the time required. As such, these participants were not re-assessed at the 12- (post-intervention) or 24-week (retention) time points and their data were not included in the subsequent analyses. Statistical comparisons of the remaining participants in each group indicated that the groups did not differ significantly with respect to demographics or their performance on the clinical assessments of cognition, vision, mobility, balance confidence or quality of life at baseline (Table 2). Among the 11 individuals completing the 12-week exercise-based intervention, adherence to the exercise program was 90%, on average, with the individual rates of adherence ranging from 8 (67%) to 12 (100%) of the 12 supervised sessions. Participants reported no discomfort or adverse effects associated with either intervention.

All 22 participants were reassessed at 12-weeks (mean 12-week follow-up time: Exercise = 94.6 ± 2.0 days, Education = 92.1 ± 3.0 days; $p = 0.49$), but four participants (Exercise=2; Education=2) did not complete the 24-week follow-up (mean 24-week follow-up

time: Exercise = 188.6 ± 7.0 days, Education = 186.4 ± 7.4 days; p = 0.84). Of these participants, two underwent deep brain stimulation surgery for their symptoms, one was unable to be contacted and one was unable to complete the 24-week assessment until 32-weeks after the baseline assessment. As such, the 24-week data for these four participants were imputed from the 12-week assessment using the LOCF method.

*****INSERT TABLE 2 ABOUT HERE*****

Primary Outcomes: Standing Balance

The statistical analyses returned significant Group*Day*Surface*Vision interactions for 95% elliptical area (Figure 2a), sway velocity (Figure 2b), anterior-posterior sway variability (Figure 2c) and medial-lateral sway variability (Figure 2d). Pairwise comparisons indicated that, while standing on the foam surface, both groups exhibited significantly increased sway area, sway velocity and sway variability when their eyes were closed compared with open during all three testing sessions. Similarly, when vision was occluded, participants in the Exercise and Education groups demonstrated increased sway area, sway velocity and sway variability on the foam surface compared with the firm surface on all three testing days.

*****INSERT FIGURE 2 ABOUT HERE*****

Post-hoc analyses between the baseline, 12-week and 24-week sessions revealed that, while standing on the foam surface without vision, participants in the Exercise group had a reduced 95% elliptical sway area at both the 12- (-6.9±3.1 cm; 95% CI=-13.08 to -0.71; p=0.029; d=0.66) and 24-week (-7.9±3.1 cm; 95% CI=-14.13 to -1.72; p=0.013; d=0.76) time points compared with the baseline values (Figure 2a). Furthermore, under these conditions, the

Exercise group had less variable medial-lateral sway patterns at the 12- (-0.2±0.1 cm; 95% CI=-0.42 to -0.01; p=0.042; d=0.62) and 24-week (-0.2±0.1 cm; 95% CI=-0.42 to -0.01; p=0.043; d=0.62) time points compared with baseline values (Figure 2d). In contrast to the changes exhibited by the Exercise group over the 24-week study period, participants in the Education group reported no significant changes in any of the balance outcomes between the baseline, 12-week and 24-week assessments.

Secondary Outcomes: Clinical Measures

The results of the linear mixed model analyses revealed that neither intervention led to a significant change in mobility, balance confidence, quality of life, levodopa equivalent daily dose, motor symptom severity, disease stage, disability or freezing of gait at the 12- or 24-week time points.

Discussion

The purpose of this randomized, controlled trial was to evaluate whether a 12-week trunk-specific exercise-based intervention could improve quiet standing balance and/or clinical measures of mobility, balance confidence, quality of life, freezing of gait, motor symptom severity, disease stage, or disability. The outcomes of this study demonstrated that the exercise-based intervention did not lead to significant improvements in any of the clinical measures, which was commensurate with the findings of several previously-described exercise-based interventions spanning 8-weeks,[26,34] 10-weeks,[61] and 6-months.[22] However, given that separate research has shown that exercise-based interventions are capable of improving clinical measures of balance,[22-26] quality of life,[27] and motor symptom severity[24,25] in people with PD, it was anticipated that the Exercise group would exhibit an improvement in these measures following the 12-week period. However, in interpreting these findings, it should be

acknowledged that the cohort assessed in this study was generally comprised of early stage PD patients (Hoehn and Yahr) who presented with mild to moderate motor symptoms (Unified Parkinson's Disease Rating Scale), a low fear of falling (Activities-specific Balance Confidence) and a mild level of disability (Schwab and England). Given the relatively good level of function exhibited by these participants at Baseline, it is possible that they had only a limited capacity to improve on these specific outcomes following the interventions. As such, when working with similar cohorts in the future, it may be necessary to adopt more challenging clinical assessments of physical function, balance and/or mobility to identify any underlying deficits and to clinically monitor the efficacy of a specific intervention.

In contrast to the clinical tests, the assessments of balance during quiet stance revealed that the 12-week trunk-specific exercise program led to significant improvements in some balance measures. Specifically, those who received the exercise-based intervention demonstrated reductions in the 95% elliptical sway area and sway variability in the medial-lateral direction when completing the most challenging condition (i.e. standing on a foam surface without vision). Similar improvements in balance have been reported for people with PD following other exercise-based interventions;[20,62] however, null findings have also been reported.[22,63,64] he null findings reported in previous research may be attributable, at least in part, to the relatively predictable conditions under which these studies examined balance (i.e. standing on a firm surface with eyes open). As highlighted by the post-hoc analyses in the current study, irrespective of group, all measures of balance worsened when somatosensory and/or visual feedback were impaired. Furthermore, the balance improvements exhibited by the Exercise group following the intervention were only evident during the most challenging balance task. Similar findings have been reported in separate research evaluating the efficacy of exercise-based interventions, with improved balance only evident during tasks involving reduced proprioceptive and/or visual feedback.[65,66]

Despite the improvements in medial-lateral sway variability, it was interesting to note that there was no significant change in anterior-posterior sway variability at the 12- or 24-week time points. A possible explanation for this finding could be the relative importance of the trunk muscles to the two primary strategies that are used to produce the corrective movements involved in maintaining an upright posture. As outlined previously, responses to laterally-directed perturbations require more input from the trunk and hip muscles than perturbations from an anterior-posterior direction.[12] However, the symptoms of PD, which can include increased axial rigidity and trunk muscle weakness, are known to significantly impair postural control in the frontal plane.[12] Similarly, flexed truncal postures have been shown to be associated with poorer balance and mobility in people with PD.[67] As such, it seems reasonable to suggest that by targeting an improvement in trunk mobility and trunk muscle strength and endurance via the exercise-based intervention, it was possible to reduce this impairment and improve medial-lateral balance control. However, given that these improvements were only evident during the most challenging balance task, it seems that subtle changes in balance may not be easily detected when assessments are performed under less-challenging conditions. As such, it is recommended that clinical assessments of balance be sufficiently difficult to challenge the body's postural control system, so as to expose any underlying impairment.

Limitations

The results of this study should be considered in light of a number of limitations. First, due to the difficulties experienced with participant recruitment, it was not feasible to determine the potential efficacy of a more regular exercise-based intervention. As such, in spite of the encouraging outcomes reported in this study, there is a need for further research aimed at establishing whether increasing the frequency of this exercise program offers greater improvements in quiet standing balance and/or has the potential to reduce the rate of falls in

people with PD. Second, as a randomized controlled trial, the sample size was relatively small. While the comparisons reported for the outcomes derived from the posturography assessment were supported by an a-priori power calculation, the generalisability of these findings to a larger cohort is unclear. Third, while every effort was made to ensure that patients were assessed at a similar time of day for each testing session, logistical constraints meant that some participants had to be tested at a different time of the day for one or more of the follow-up sessions. Although this may have influenced the reported outcomes, care was taken to ensure that participants were tested 1-2 hours following a scheduled dose of anti-parkinsonian medication to minimise the influence of any motor fluctuations that patients may experience throughout the medication cycle. Fourth, given the longitudinal nature of this project, the potential impact of any changes in a participant's anti-parkinsonian medication needs to be considered. It is well recognised that levodopa can significantly improve a participant's symptoms;[59] hence any changes to the frequency, dose and/or type of medication was carefully monitored. On the basis of this process, it was noted that during the 24-week period that followed the baseline assessment, 25% of those in the Education group and 36% of those in the Exercise group reported at least one change to their prescription medications. Nevertheless, statistical comparison of the participants' levodopa daily equivalents at the three time points indicated no significant increase or decrease in the levodopa equivalent daily doses being taken by participants in the two groups. Also, as one's interactions with their healthcare providers can influence their response to treatment, it could be argued that the improved balance outcomes for the Exercise group may have been attributable, at least in part, to the greater interaction that they shared with the study staff. Finally, despite participants in the Exercise group not being required to perform the exercise program between the 12- and 24-week assessments), their prior involvement in the exercise-based intervention may have led to a more active lifestyle during this period. As such, it should be considered that the improvements

reported for the Exercise group at 24-weeks (compared with Baseline) may not be evident for patients who return to a sedentary lifestyle following a similar program.

Conclusions

This study demonstrated that a 12-week trunk-specific exercise program can lead to improvements in select measures of quiet standing balance under challenging sensory conditions in individuals with Parkinson disease who have mild to moderate disease severity. However, there were no improvements in measures of mobility, balance confidence, symptom severity, disability, or quality of life. Further research is needed to determine whether a similar program of higher intensity and/or longer duration in a larger cohort of patients can lead to improvements in measures of activity, participation and/or falls risk.

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Author Roles

Authors RH and MC were involved with the research project conception, organization and execution, statistical analysis design, execution and review and critique, and the manuscript review and critique. Author RH was responsible for writing the first draft of the manuscript. Author PS was involved with the organization of the project and the review and critique of the manuscript. Author GN was involved with the review and critique of the manuscript.

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Figure Legends

Figure 1: Flow diagram illustrating the recruitment and randomisation processes

Figure 2: Estimated Marginal Means (+1 SEM) for the; a) 95% elliptical area; b) sway velocity; c) anterior-posterior sway variability; and d) medial-lateral sway variability measured during the posturography assessments completed by the Exercise and Education groups on the firm and foam surfaces with eyes open and eyes closed. **Note:** * indicates a statistically significant ($p<0.05$) difference between testing days within a group.

List of supplemental digital content

SDC1: Video Abstract

SDC2: Appendix Falls Prevention Education Materials

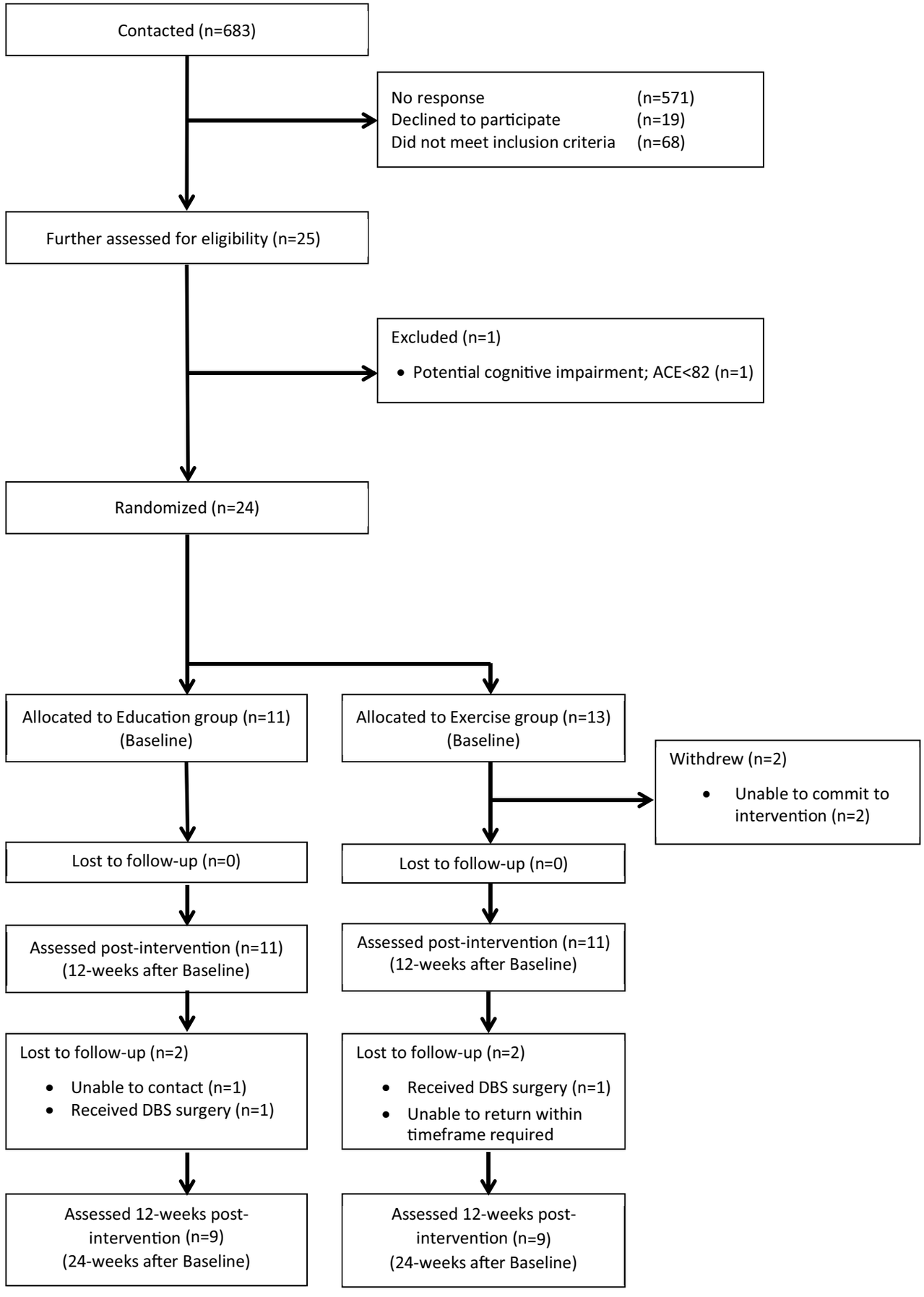
Table 1: Outline of exercise program

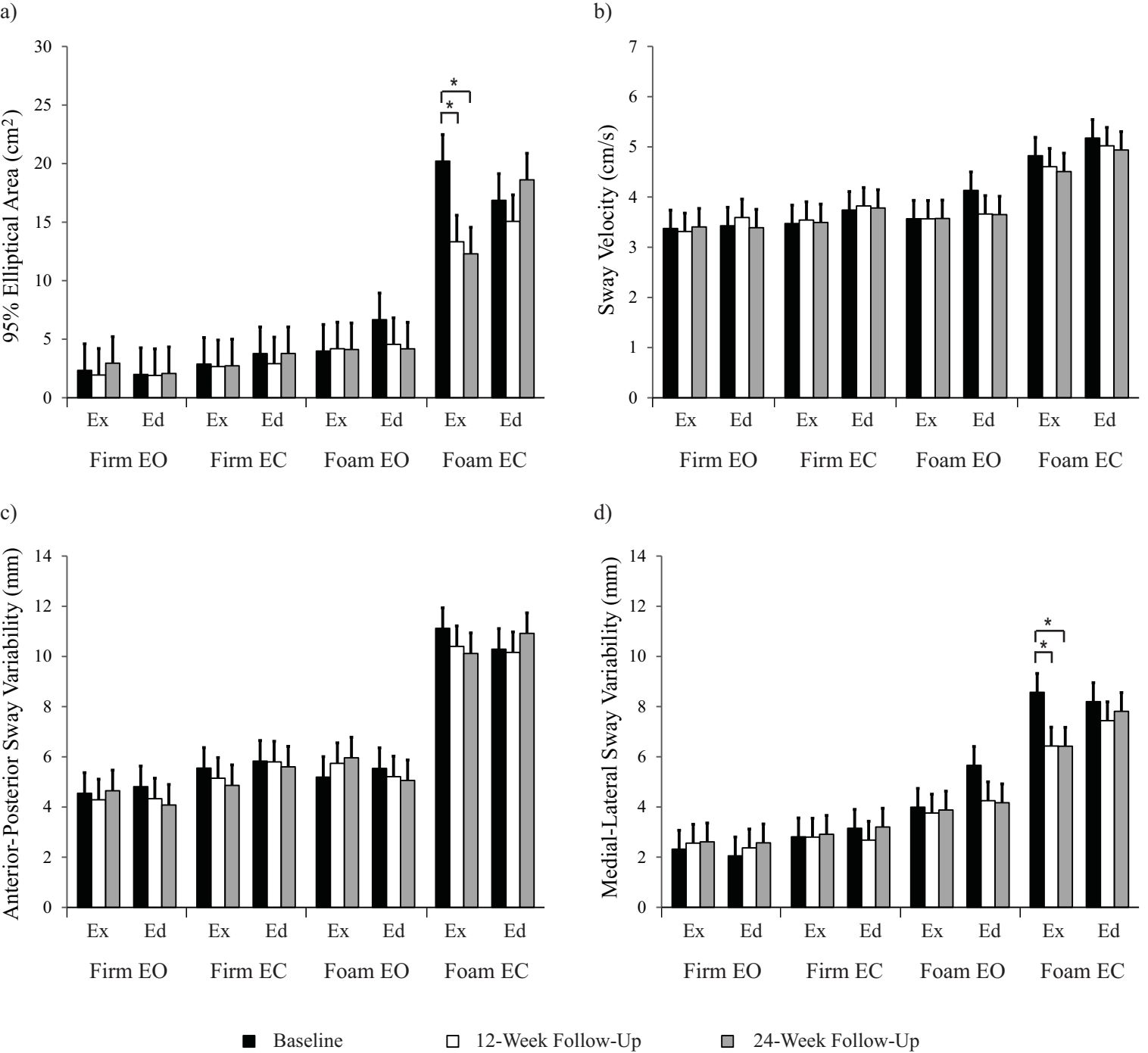
Task	Movement	Sets	Repetitions/ Duration/Progression		Rationale
Warm Up	Small arm circles	1	10 forward & backward		During dynamic tasks, the coordination of pelvic and trunk movements is vital to maintaining stability. However, the symptoms of axial rigidity that are often present in people with PD lead to an increase in trunk stiffness and a tendency for en-bloc movements of the upper body segment[10]. The warm-up exercises seek to prepare the patients for the more physically challenging aspects of the session, while also
	Large arm circles	1	10 forward & backward		
	Lateral bends	1	10 to the left & right		
	Torso rotations	1	10 to the left & right		
	Torso rotations w/ high and low reaching	1	10 reaching up to left, down to right		
			Time Progression	**Difficulty Progression**	
Exercise	Abdominal hollowing	3	Increased from a 5- to 20-second hold time in 5-second increments.	Seated Double leg pelvic bridge Single leg pelvic bridge Single leg pelvic bridge; foot on stability disc	Given that dysfunction of the trunk muscles has been shown to be predictive of the excessive head, trunk and pelvis motion linked to falls in people with PD[14], the exercises were chosen to improve the strength and endurance of deeper trunk muscles. Specifically, these exercises targeted the transversus abdominus, the internal obliques and the multifidus, which are collectively known to be important for stabilising the spine during static and dynamic activities[57].
	Side bridging	3	Increased from a 5- to 20-second hold time in 5-second increments.	Leaning against wall On floor with knees on ground On floor with knees off ground On floor with feet on stability disc	
	Front bridging	3	Increased from a 5- to 20-second hold time in 5-second increments.	Leaning against wall On floor with knees on ground On floor with knees off ground On floor with feet on stability disc	
	Bird dog	3	Increased from a 5- to 20-second hold time in 5-second increments.	Single arm Single leg Alternate arm & leg Alternate arm & leg; knees on stability disc	
Active Cool Down	Hamstring stretch	2	20-second hold per side		The active cool down was incorporated to allow participants to actively recover from the more physically exerting component of the program. The short walking component incorporated into this phase sought to improve the patients' mobility and their capacity to safely navigate real-world environments. Although systematic evidence suggests that walking programs may not be effective at reducing falls risk, they are known to have important benefits for general health and physical function[55]
	Quadriceps stretch	2	20-second hold per side		
	Gastrocnemius stretch	2	20-second hold per side		
	Triceps stretch	2	20-second hold per side		
	Pectoral stretch	2	20-second hold per side		
	Walking	1	8-10 minutes involving stair ascent/descent and walking over surfaces of varying incline/decline and density in an outdoor environment		

Table 2: Demographics and scores for the clinical baseline assessments completed by the entire PD cohort and the Exercise and Education sub-groups.

	All (n = 22) Mean ± SD / N	Education (n = Mean ± SD / N	Exercise (n = 11) Mean ± SD / N	Tes	Sig. (p)
Demographics					
Gender (Male)	15 (68.2%)	8 (72.7%)	7 (63.6%)	3	0.65
Age (years)	65.4 ± 5.7	67.5 ± 5.8	63.3 ± 4.9	2	0.08
Height (cm)	170.6 ± 7.7	171.6 ± 7.7	169.7 ± 8.0	1	0.58
Mass (kg)	80.0 ± 20.3	78.6 ± 23.9	81.4 ± 17.0	1	0.76
Body Mass Index (kg/m^2)	27.2 ± 5.5	26.3 ± 5.9	28.2 ± 5.1	1	0.42
Cognition & Vision					
Addenbrooke's Cognitive Exam	91.5 ± 6.8	92.3 ± 5.4	90.6 ± 8.1	1	0.58
High Contrast Visual Acuity (LogMAR)	0.01 ± 0.1	0.04 ± 0.1	-0.02 ± 0.1	1	0.09
Mobility, Balance Confidence & Quality of Life					
Timed Up and Go (s)	9.3 ± 1.6	9.87 ± 1.7	8.85 ± 1.9	1	0.31
Activities-specific Balance Confidence (%)	80.8 ± 20.4	78.4 ± 26.0	83.3 ± 13.8	1	0.77
39-Item Parkinson Disease Questionnaire	22.7 ± 11.6	24.1 ± 11.2	21.3 ± 12.2	1	0.49
Neurological Examination					
Disease Duration (years)	6.7 ± 5.0	7.0 ± 5.0	6.5 ± 5.2	2	0.84
Unified Parkinson Disease Rating Scale (Part III)	19.4 ± 13.0	21.5 ± 11.7	17.3 ± 14.4	2	0.31
Hoehn & Yahr Stage Score	1.9 ± 0.6	2.0 ± 0.7	1.8 ± 0.6	3	0.50
Schwab & England Activities of Daily Living Scale	82.5 ± 8.8	81.0 ± 10.0	84.1 ± 7.7	2	0.34
Gait and Falls Questionnaire	10.7 ± 11.6	12.8 ± 13.5	8.6 ± 9.4	1	0.60
Freezing of Gait Score	5.3 ± 5.5	6.0 ± 5.9	4.6 ± 5.2	1	0.78
Retropulsion Test	0.4 ± 0.7	0.6 ± 0.7	0.6 ± 0.7	1	0.27
Levodopa Daily Equivalent Dose (mg)	716.5 ± 427.7	868.2 ± 475.7	564.8 ± 327.6	1	0.10
Dopamine Agonists	5 (22.7%)	3 (27.3%)	2 (18.2%)	3	0.61
Catechol-O-Methyl Transferase Inhibitors	8 (36.4%)	3 (27.3%)	5 (45.5%)	3	0.38
Monoamine Oxidase Inhibitors	8 (36.4%)	6 (54.5%)	2 (18.2%)	3	0.08
Benzodiazepines	1 (4.5%)	1 (9.1%)	0 (0.0%)	3	0.31

Note: Test 1 = One-way analysis of variance; Test 2 = Mann-Whitney U test; Test 3 = Chi-square test


Contacted (n=683)
No response (n=571)
Declined to participate (n=19)
Did not meet inclusion criteria (n=68)
Further assessed for eligibility (n=25)
Excluded (n=1)
Potential cognitive impairment; ACE<82 (n=1)
Randomized (n=24)
Allocated to Education group (n=11) (Baseline)
Allocated to Exercise group (n=13) (Baseline)
Withdrew (n=2)
Unable to commit to intervention (n=2)
Lost to follow-up (n=0)
Lost to follow-up (n=0)
Assessed post-intervention (n=11) (12-weeks after Baseline)
Assessed post-intervention (n=11) (12-weeks after Baseline)
Lost to follow-up (n=2)
Unable to contact (n=1)
Received DBS surgery (n=1)
Lost to follow-up (n=2)
Received DBS surgery (n=1)
Unable to return within timeframe required
Assessed 12-weeks post-intervention (n=9) (24-weeks after Baseline)
Assessed 12-weeks post-intervention (n=9) (24-weeks after Baseline)


a)
95% Elliptical Area (cm2)
30
25
20
15
10
5
0
*
*
b)
Sway Velocity (cm/s)
7
6
5
4
3
2
1
0
c)
Anterior-Posterior Sway Variability (mm)
14
12
10
8
6
4
2
0
d)
Medial-Lateral Sway Variability (mm)
14
12
10
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*
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Ex
Ed
Firm EO
Firm EC
Foam EO
Foam EC
Baseline
12-Week Follow-Up
24-Week Follow-Up