

Title: Trunk exercises improve gait symmetry in Parkinson disease: A blind phase II randomised-controlled trial

Short Title: Trunk-specific exercises improve gait symmetry in PD

Authors: Ryan P. Hubble PhD^{a*}, Geraldine Naughton PhD^b, Peter A. Silburn PhD, FRACP^c,
Michael H. Cole PhD^{a*}

Affiliations: a. Australian Catholic University, School of Exercise Science, Banyo, Queensland, AUSTRALIA

b. Australian Catholic University, School of Exercise Science, Fitzroy, Victoria, AUSTRALIA

c. Asia-Pacific Centre for Neuromodulation, Queensland Brain Institute, The University of Queensland, Brisbane, Queensland, AUSTRALIA

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Correspondence: Dr Ryan P. Hubble

Department of Kinesiology

Wesley College

120 North State Street

Dover, DE 19901

UNITED STATES OF AMERICA

Dr Michael H. Cole

School of Exercise Science

Australian Catholic University

P.O. Box 456

Virginia, Queensland, 4014

AUSTRALIA

Email Address: ryan.hubble@wesley.edu

michael.cole@acu.edu.au

Telephone: +1 302 212 7300

+61 7 3623 7674

Facsimile:

+61 7 3623 7650

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ABSTRACT

Objective: Deficits in step-to-step symmetry and trunk muscle activations have been linked to falls in Parkinson's disease (PD). Given such symptoms are poorly managed with anti-parkinsonian medications, alternate therapies are needed. This blind phase II randomised-controlled trial sought to establish whether exercise can improve step-to-step symmetry in PD.

Design: Twenty-four PD patients with a falls history completed baseline assessments of symptom severity, balance confidence, mobility and quality of life. Step-to-step symmetry was assessed by deriving harmonic ratios from three-dimensional accelerations collected for the head and trunk. Patients were randomly assigned to either 12-weeks of exercise and falls prevention education or falls prevention education only. Both groups repeated the baseline tests 12- and 24-weeks following the initial assessment. The Australian and New Zealand Clinical Trials Registry number is ACTRN12613001175763.

Results: At 12-weeks, the Exercise group had statistically significant and clinically relevant improvements in anterior-posterior step-to-step trunk symmetry. In contrast, the Education group recorded statistically significant and clinically meaningful reductions in medial-lateral and vertical step-to-step trunk symmetry at 12-weeks.

Conclusion: Given that step-to-step symmetry improved for the Exercise group and declined for the Education group post-intervention, active interventions appear more suited to increasing independence and quality of life for people with PD.

Keywords: Exercise, Parkinson Disease, Accident Prevention, Gait

INTRODUCTION

Postural instability is one of the most disabling symptoms of Parkinson's disease (PD) and contributes to falls in this population. Unfortunately, these symptoms are poorly managed by current pharmacological and surgical interventions,¹ which emphasises the need for more effective alternative therapies for improving the overall management of these patients. Exercise-based interventions are known to improve many motor symptoms and clinical measures of balance, mobility and falls risk in people with PD.^{2,3} However, despite the proven efficacy of exercise-based interventions for improving the clinical symptoms of PD, there is currently conflicting evidence regarding whether these methods are capable of reducing the rate and number of falls in PD populations. For example, some research has reported a significant reduction in the number and rate of falls experienced by people with PD following an exercise-based intervention,⁴ while others have reported no significant change in these outcomes.³ Despite these inconsistencies, a recent systematic review and meta-analysis of 8 randomised controlled trials has added important weight to this debate; indicating that although exercise does not reduce the number of fallers in the PD population, it is effective at reducing the rate of falls experienced by each individual.⁵

During locomotion, the maintenance of equilibrium relies upon one's ability to produce smooth and rhythmic movements of the head and trunk, which collectively comprise almost 60% of the body's mass.⁶ While clinical assessments of axial motor symptoms have been shown to provide some insight into the effects of the disease on one's ability to safely ambulate, the majority of the tests that assess postural stability, trunk rigidity and gait disability rely on Likert scales, which appears to make them less sensitive to subtle changes in function.⁷ To improve the assessment of postural stability during dynamic activities, researchers have started using lightweight wearable sensors to examine gait stability⁸⁻¹⁰ and muscle activation¹¹ in

people with PD. Specifically, scientists have used such devices to measure the medial-lateral (side-to-side), anterior-posterior (front-to-back) and vertical (up and down) movement patterns of the head, trunk and pelvis during walking to assess disease-related changes in gait stability. Of the measures reported, the harmonic ratio (HR) is one of the more common⁸⁻¹⁰ and, in the context of walking, provides a measure of the step-to-step symmetry of segmental accelerations.¹² Higher HRs describe improved step-to-step symmetry and are typically considered to represent a more stable gait pattern. The HR has previously been used to identify differences in movement symmetry between PD patients and controls,^{9,10} PD freezers and non-freezers,¹³ and PD patients who have a history of falling and those who have not previously fallen.^{8,9} Interestingly, recent research has shown that these deficits in segmental control are accompanied by specific alterations in the activation patterns of the superficial trunk muscles.¹¹ Specifically, people with PD who prospectively reported falling had greater peak and baseline levels of erector spinae activity during walking compared with age-matched controls.¹¹ Interestingly, these differences in baseline activity were shown to be significant predictors of the medial-lateral pelvis, trunk and head displacement¹¹ that has been linked with future falls in previous research.^{14,15} The authors argued that the increased baseline activation of the erector spinae may have been indicative of an underlying dysfunction of the deeper and more fatigue-resistant muscles involved in postural control (i.e. multifidus, transverse abdominus).

Given the altered trunk muscle activations exhibited by PD fallers have been linked to larger and less symmetrical head^{11,14,15} and trunk¹¹ movements, it is possible that exercises that target trunk mobility and endurance may assist with improving the step-to-step symmetry of head and trunk movements in this population. Therefore, it was the purpose of this phase II randomised controlled trial to determine whether a 12-week intervention incorporating both exercise and falls prevention education was more effective than falls prevention education

alone at improving gait symmetry in people with PD. It was hypothesised that the Exercise group would have improved step-to-step symmetry following the intervention, while participants in the Education group would exhibit no improvements in gait symmetry following the 12-week intervention period.

METHODS

Participants

This phase II randomised-controlled trial was developed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.¹⁶ Individuals from a metropolitan neurology clinic diagnosed with idiopathic PD, based on the UK Brain Bank Criteria¹⁷ were sent a letter outlining the details of the study inviting them to volunteer. Prospective participants were initially screened over the telephone and were excluded if they had; i) an inability to ambulate independently; ii) uncontrolled hypertension; iii) a prescription for psychotropic medications; iv) significant limitations due to osteoporosis; v) orthopaedic surgery within the previous year; vi) serious neck, shoulder or back injuries (including spinal fusions); vii) received deep brain stimulation (DBS) surgery for symptom management; viii) a neurological condition other than PD; or ix) no history of falls or near misses within the past year. For the purposes of 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.³ Similarly, near misses were defined as events during which an individual felt that they were going to fall but did not.³ The study's protocol¹⁸ was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12613001175763) and approved by the University's Human Research Ethics Committee (2013 223Q). The recruitment and assessment of all participants was completed between February 2014 and December 2015 and all volunteers provided written informed consent in accordance with the Declaration of Helsinki.

On the basis of an a-priori sample size calculation using medial-lateral trunk harmonic ratios recorded for people with PD during walking,¹⁰ it was determined that a minimum of 11 participants was required per group to confidently report any significant changes in the step-to-step symmetry of trunk motion (diff=0.05, SD=0.04, Cohen's $d=1.25$, Power=80%, $p=0.05$).

Clinical Measures

Prior to randomization, participants completed a battery of baseline assessments including the; i) Addenbrooke's cognitive examination (ACE); ii) Bailey-Lovie high contrast visual acuity test; iii) Timed Up and Go test; iv) Activities-specific Balance Confidence scale; v) 39-item Parkinson's Disease Questionnaire (PDQ-39); vi) Part III of the Unified Parkinson's Disease Rating Scale (UPDRS III); vii) Hoehn & Yahr stage score; and viii) Schwab & England Activities of Daily Living Scale. Furthermore, participants completed a previously-developed questionnaire to collect details about their medical history (e.g. date of diagnosis) and prescription medication use. Using the information provided, it was possible to calculate each participant's levodopa equivalent daily dose using previously-described methods.¹⁹ All baseline measures were taken 1-2 hours following the patient's scheduled dose of anti-parkinsonian medication to ensure results were representative of similar tasks performed in the real world. Participants with significant visual (Bailey-Lovie high contrast visual acuity >0.30 logMAR) and/or cognitive (ACE score <82) impairment were excluded prior to baseline testing.

Gait Analysis

Following the clinical assessments, participants completed four walking trials separated by a rest break of at least 30 seconds along a 10-meter walkway at a self-selected pace. While

performing this task, head and trunk accelerations were measured at 1500 Hz using two microelectromechanical system (MEMS) three-dimensional accelerometers (Noraxon Inc., Scottsdale, AZ), which were statically-calibrated using previously-described methods.²⁰ To facilitate the assessment of head and trunk accelerations during walking, the accelerometers were firmly attached over the; i) occipital protuberance of the skull via a sport headband; and ii) the spinous process of the 10th thoracic vertebra (T10) using double-sided tape. Walking speed was measured using a pair of Speedlight timing gates positioned 6-meters apart (SWIFT Performance Equipment, Alstonville, Australia).

In addition to the acceleration patterns of the head and trunk, bilateral activation of the thoracic and lumbar erector spinae was measured using surface electromyography. The skin overlying the muscles of interest was prepared with an abrasive gel (NuPrep; Weaver & Company, Aurora, CO) and cleaned thoroughly with isopropyl alcohol to improve myoelectric signal quality. Where necessary, excessive body hair was removed with a razor prior to skin abrasion to improve signal quality and to enhance electrode adhesion. After skin preparation, four pairs of silver/silver chloride pre-gelled surface electrodes (AMBU Blue Sensor, Ballerup, DK; 34 mm diameter, 10 mm² sensing area) were placed with a centre-to-centre inter-electrode distance of 34 mm over the thoracic (5 cm lateral to the T10 spinous process) and lumbar (2 cm lateral to the L3 spinous process) erector spinae.¹¹ Raw electromyogram (EMG) data were collected at a rate of 1500 Hz using wireless transmitters containing integrated pre-amplifiers (gain: 500, common mode rejection ratio: >100 dB, input impedance: >100 M Ω). To facilitate synchronisation of head and trunk accelerations with trunk muscle activations, both datasets were wirelessly telemetered to a Telemetry DTS belt receiver and to a laptop running the MyoResearch XP software (Noraxon Inc., Scottsdale, AZ).

To allow for inter-group and inter-day comparisons, trunk muscle activity was expressed as a percentage of the peak activation recorded for each muscle during three maximum voluntary isometric contractions (MVC).¹¹ To perform the MVC tasks, participants were required to lie prone/prostrate on a padded table with their hips flexed and their feet on the floor with a Velcro strap placed over the lower torso to secure them to the table for safety. During each maximal effort, the patients simultaneously extended both hips to raise their legs to a horizontal position (i.e. 180°) at which point their movements were actively resisted by the researcher. This method was chosen in preference to the traditional Biering-Sørensen test to limit the potential difficulties that older participants may have with this more complex movement pattern.²¹ Participants were verbally encouraged by the researchers and the maximum value recorded for each muscle during the three trials was used for normalisation of electromyography data collected for that muscle during the walking trials.

Randomisation and Blinding

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) that was generated by a team member who was not involved in participant allocation or assessment (GAN). To minimise the risk of bias and to eliminate the potential for inter-rater reliability issues, all clinical assessments were conducted by an experienced movement disorders scientist who was blinded to participant group assignment (MHC). A flow diagram of participant recruitment and group assignment is represented in Figure 1.

Insert Figure 1 about here

Interventions

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. The use of an exercise-based intervention is supported by systematic evidence, which demonstrates that exercise is one of the best method for reducing falls risk in older adults.²² In contrast, previous research has reported little to no evidence regarding the efficacy of falls prevention education strategies with respect to their capacity to reduce falls risk in ageing populations.²² As such, those assigned to receive exercise and falls prevention education comprised the treatment group, while those receiving the falls prevention education represented the placebo group. As both groups received the same falls prevention education, it was possible to discriminate the changes resulting from the exercise-based intervention from those related to the education program.

During the 12-week intervention, participants in the Education group received a weekly multi-disciplinary educational brochure that explained how factors, such as exercise, nutrition and/or sleep quality may influence their risk of falling. The education brochures provided a combination of written and illustrative materials and were developed using information freely-available from community-based support groups. Participants assigned to the Exercise group received the same weekly education brochures, but also completed a 12-week exercise program aimed at improving trunk mobility and endurance. This program involved one supervised 90-minute session each week with a trained Exercise Scientist in groups of up to three participants. This exercise program was designed to conform with current recommendations for exercise-based interventions that target stability^{23,24} and was informed by programs previously-described for older adults²⁵ and people with PD.²⁶ 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 endurance and stability 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 in-depth description of the specific endurance and mobility tasks involved in the exercise-based intervention has been previously published elsewhere.¹⁸ Participants were reassessed 12- and 24-weeks following the baseline assessment, 1-2 hours following their scheduled dose of anti-parkinsonian medication, to ensure a fair comparison with baseline assessments. Where possible, the 12-week follow-up assessment was scheduled to occur within one week of the participants completing their allotted intervention.

Data Analyses

Primary Outcome: Gait step-to-step symmetry

Raw accelerations were transformed to a horizontal-vertical orthogonal coordinate system to remove the effect of gravity from the anterior-posterior (AP) and medial-lateral (ML) axes of the sensors.²⁰ After transformation, accelerations were low-pass filtered using a bi-directional fourth-order Butterworth filter, with a cut-off frequency of 30 Hz.⁸ The time series of the filtered AP, ML and vertical (VT) head and trunk accelerations were then divided into individual gait cycles by identifying the peaks in VT trunk accelerations, which coincide with heel contact.⁸⁻¹⁰ The AP, ML and VT HRs were then calculated for 6 successive gait cycles within each walking trial, with the average AP, ML and VT HRs of these gait cycles used for further analysis.

Secondary Outcome: Muscle Function

To evaluate trunk muscle function, the raw EMGs were initially processed with an adaptive filter to attenuate any influence of the electrocardiogram on the trunk EMGs.¹¹ Data

were then full-wave rectified and low-pass filtered using a fourth-order Butterworth filter with a 20 Hz cut-off frequency. The root mean square (RMS) method was then used to process the rectified and filtered EMGs over consecutive 50 millisecond windows (i.e. 75 samples) with a 74-sample overlap. All processed EMGs were then normalised by expressing them as a percentage of the peak activation recorded during the MVC trials.

The secondary outcomes were calculated for three successive gait cycles for each leg (i.e. 6 gait cycles total), which were taken from the middle of the trial to minimise the influence of acceleration and deceleration at the beginning and end of the trial. For the assessment of muscle function, the three gait cycles completed for each leg produced eight peaks of muscle activity (i.e. 4 left and 4 right footfalls yield 3 left and 3 right gait cycles; 1 peak per footfall). The eight peaks derived from the left- and right-side thoracic and lumbar erector spinae muscles (i.e. 16 peaks per vertebral level) were subsequently averaged; yielding a single peak value for each vertebral level during each walking trial. Similarly, to evaluate the extent to which the superficial trunk muscles ‘switched off’ between strides, the minimum EMG amplitude between successive heel contacts (i.e. within the seven troughs between the eight activation peaks) was determined.¹¹ Similar to the methods used for the peak activation data, the 7 troughs for the left- and right-side thoracic and lumbar erector spinae (i.e. 14 troughs per vertebral level) were averaged to represent the minimum activation of these muscle group during each walking trial. All EMG processing was performed using the MyoResearch XP software (MR 3.6.20), while custom programs developed in Matlab R2015b (The Mathworks, Natick, MA) were used to identify peaks and troughs in the processed EMGs and to transform and process the raw accelerations.

Statistical Analysis

The one-way analysis of variance (ANOVA) procedure was used to compare the groups at baseline for differences in continuous demographic variables (e.g. age), while the Chi-square test was used to compare groups for categorical outcomes (e.g. gender). Where the assumptions of normality (Shapiro-Wilks test) or homogeneity of variance (Levene's test) were violated, the non-parametric Kruskal-Wallis test was used to compare the continuous measures.

To determine the efficacy of the two 12-week interventions, the analyses were based on a modified intention to treat approach.²⁷ 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.²⁸ Linear mixed model analyses were conducted to determine whether the trunk-specific exercise program was more effective than the education program at improving the step-to-step symmetry of head and trunk movements and muscle activation. These models included two repeated factors (Day; 3 levels; Trial; 4 levels), one fixed factor (Group; 2 levels) and 2 covariates (levodopa equivalent daily dose and walking speed). Walking speed and levodopa equivalent daily dose were both included as covariates, as they were significantly correlated with the primary and secondary outcomes. Furthermore, it is well known that walking speed influences accelerations^{8,9} and trunk muscle activations¹¹ and that levodopa significantly improves some motor symptoms in PD.^{1,29} When a significant Group*Day interaction was identified, the Tukey's Least Significant Difference (LSD) post-hoc procedure was used to identify where the differences lay.

To provide insight into the clinical meaningfulness of any changes in step-to-step symmetry, muscle activations and/or the clinical rating scales, the minimal detectable change (MDC) for each measure was also derived. The MDC score represents the minimum change in a particular outcome measure that would be considered to result in a meaningful change in patient function and, hence, provides useful information regarding the clinical importance of the reported findings. All statistical analyses were completed with Statistical Product and Service Solutions (SPSS v21.0) and the level of significance was set at $p < 0.05$.

RESULTS

Study Population Retention and Compliance

Of the 24 participants assessed at baseline, 22 completed the 12-week intervention and two withdrew citing changes in circumstances that made them unable to commit to the project. Comparison of the remaining 22 patients at baseline indicated that the Exercise and Education groups did not differ with respect to measures of cognition, vision, neurological function or mobility. However, individuals in the Exercise group had a greater body mass index (BMI) at baseline than the Education group (Table 1).

Insert Table 1 about here

While 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; $p = 0.49$), four participants (two Exercise; two Education) 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 patients, two reported having recently undergone DBS surgery, one was unavailable to complete the follow-up, and one was not contactable via telephone or email. As such, the 24-week data for

these four participants were imputed from the 12-week assessment using the LOCF method. Average participant compliance for the exercise sessions was 90%, with individual compliance ranging from 8 (67%) to 12 (100%) of the 12 supervised sessions. Participants reported no discomfort or adverse effects associated with either intervention.

Primary Outcome: Step-to-Step Symmetry

Statistical comparison of the two groups indicated that they did not differ with respect to the step-to-step symmetry of head and trunk movements at baseline. The linear mixed model analyses indicated no significant main effects for Group, but significant Group*Day interactions were reported for AP ($p=0.038$) and VT ($p=0.004$) head movements and AP ($p<0.001$), ML ($p=0.003$) and VT ($p=0.024$) trunk movements. Pairwise comparisons revealed that the Exercise group demonstrated improved step-to-step symmetry for VT head movements ($p=0.009$) and AP trunk movements ($p<0.001$) at 12-weeks compared with baseline. Furthermore, at 24-weeks, improvements in the step-to-step symmetry of AP head movements ($p=0.040$) and AP trunk movements ($p<0.001$) were evident compared with baseline values, while AP head movements were also better at this time point, relative to the 12-week assessment ($p=0.011$).

In contrast, the post-hoc analyses indicated that the Education group exhibited poorer step-to-step symmetry, with respect to AP ($p=0.005$) and VT ($p=0.035$) head movements and AP ($p=0.049$), ML ($p<0.001$) and VT ($p<0.001$) trunk movements at 12-weeks relative to the baseline measures. Additionally, step-to-step symmetry of VT trunk movements ($p=0.024$) was reduced at 24-weeks compared with baseline, while the step-to-step symmetry of ML trunk movements was improved at 24-weeks compared with the 12-week assessment ($p=0.010$).

When assessing the clinical importance of the significant improvements/declines in the step-to-step symmetry of head movements reported for the groups (via the MDC score), it was determined that the recorded changes were not substantial enough to be considered clinically meaningful. Despite this, the improved step-to-step symmetry of AP trunk movements recorded for the Exercise group at 12- and 24-weeks was not only statistically significant, but sufficiently large to be considered clinically important. Similarly, the reduced step-to-step symmetry of ML and VT trunk movements in the Education group at 12-weeks was substantial enough to be considered a clinically important change (Table 2).

Insert Table 2 about here

Secondary Outcomes: Trunk Muscle Activation and Clinical Outcomes

At baseline, participants assigned to the Education group exhibited significantly greater peak activations for the lumbar erector spinae, but otherwise did not differ from those in the Exercise group with respect to the other secondary outcomes. Analysis of the trunk muscle activations of the two groups identified significant Group*Day interactions for peak (thoracic: $p < 0.001$; lumbar: $p = 0.032$) and trough (thoracic: $p < 0.001$; lumbar: $p = 0.010$) erector spinae activity. Post-hoc analyses indicated that peak activation of the thoracic erector spinae was increased at 12-weeks relative to the baseline assessment for the Exercise group ($p = 0.026$). In contrast, thoracic erector spinae activity within the troughs was significantly reduced at baseline ($p = 0.039$) and 12-weeks ($p = 0.049$), relative to the 24-week assessment, while the lumbar erector spinae exhibited less activation in the troughs at 12-weeks, relative to baseline ($p = 0.011$). Nevertheless, despite the statistical significance of these outcomes, the MDC values indicated that the recorded changes in trunk muscle activation for the Exercise group were insufficient to be deemed clinically meaningful.

For the Education group, the pairwise comparisons revealed that peak activation of the thoracic and lumbar erector spinae was significantly reduced at 12-weeks (thoracic: $p<0.001$; lumbar: $p=0.008$) and 24-weeks (thoracic: $p<0.001$; lumbar: $p<0.001$) compared with baseline. Furthermore, peak activation of the lumbar erector spinae was significantly reduced at 24-weeks relative to the 12-week assessment for those patients in the Education group ($p=0.010$). With respect to the minimum activation levels of the thoracic erector spinae, participants in the Education group demonstrated significantly reduced activation during the 12- ($p<0.001$) and 24-week ($p<0.001$) assessments compared with baseline. Similarly, lumbar erector spinae activation within the troughs was significantly reduced at the 24-week time point compared with the baseline ($p<0.001$) and 12-week ($p<0.001$) assessments for these patients. In spite of the large number of changes recorded in erector spinae activation for the Education group, only the reduction observed in peak lumbar erector spinae activation between the baseline and 24-week assessments and the changes in minimum levels of activation were sufficiently large to be considered clinically important (Table 2).

Unlike the analyses conducted for step-to-step symmetry and trunk muscle activation, statistical analysis of the clinical scores identified no significant Group*Day interactions (Table 3); suggesting that neither intervention led to a measurable change in the clinical outcomes.

Insert Table 3 about here

DISCUSSION

This phase II randomised-controlled trial represents the first study to examine the efficacy of a 12-week trunk-specific exercise program for improving step-to-step symmetry in

people with PD. The results support the hypothesis that trunk-specific exercises may improve (or at the very least, maintain) step-to-step symmetry of trunk movements and trunk muscle function in this population. These outcomes are commensurate with previous research, which demonstrated improvements in step-to-step symmetry of VT trunk movements in people with mild cognitive impairment following a 6-month multi-component exercise program.³⁰ Also, these results extend existing knowledge by suggesting that measures of step-to-step symmetry, such as the harmonic ratio, may be suitable for assessing subtle changes in postural control during dynamic tasks, such as walking. The lack of significant changes in step-to-step symmetry between the 12- and 24-week assessments for the Exercise group also suggests that the benefits of the weekly exercise program may be retained for up to 12-weeks following the cessation of the training regime. In contrast, the findings presented for the Education group suggest that, without specifically focusing on maintaining mobility and core strength, the step-to-step symmetry of trunk movements may decline in as little as 12 weeks. These findings should be considered with some caution, however, as the poorer step-to-step symmetries reported for the Education group at 12-weeks had generally returned to near baseline values by the 24-week assessment. Collectively, these findings tend to suggest that the exercise-based intervention was more effective than the education-based intervention at improving gait symmetry in people with PD. However, it should be reiterated that the mode of delivery used for the education intervention required participants to be proactive and to seek guidance and/or additional information, if needed. As such, it is possible that the efficacy of such an approach could be improved if it were delivered in a more structured and closely-monitored fashion.

The reported changes in step-to-step symmetry were complemented by changes in trunk muscle function. Specifically, the Education group experienced significant and clinically-meaningful declines in the step-to-step symmetry of trunk movements at 12-weeks that were

matched with declines in peak and minimum levels of erector spinae activity at 12- and/or 24-weeks. However, it should be noted that the Education group exhibited significantly greater peak activation of the lumbar erector spinae at baseline compared with the Exercise group. Furthermore, despite the peak activation of this muscle group reducing over the 24-week period of the study, its level of activation at the 24-week time point was not dissimilar to that reported for the Exercise group. Nevertheless, considering the erector spinae are bilaterally activated around initial heel contact to control the forward flexion moment experienced by the trunk,³¹ it may be argued that the reduced peak thoracic erector spinae activation may have contributed to the poorer trunk control exhibited by the Education group at 12 weeks. Support for this notion was provided by the results presented for the Exercise group, who exhibited significant (although not clinically meaningful) improvements in trunk muscle function following the intervention. Considering these results in conjunction with the improved AP symmetry of head and trunk movements during the 12- and 24-week tests, it could be argued that the improved trunk muscle function exhibited by the Exercise group served to resist the large anteriorly-directed torque imposed upon the body at heel contact.³¹ Collectively, these results seem to provide evidence to suggest that a targeted exercise program may assist with maintaining trunk muscle function in people with PD, which has important implications for clinical practice.

As with any study, there are a number of potential limitations that should be considered when interpreting these outcomes. First, a slow rate of recruitment resulted in a relative small sample size (from a statistical perspective). While the comparisons reported for the primary outcome measure were supported by an a-priori power calculation, the generalizability of these findings to a larger cohort is unknown. Second, an ancillary aim of this project was to evaluate whether three weekly exercise sessions offered greater improvements in gait symmetry and trunk muscle function than one weekly exercise session.¹⁸ However, difficulties with

participant recruitment and retention made it necessary to discard this secondary aim and focus on the primary aim. Given the encouraging outcomes of this study, future research might seek to establish whether increasing the frequency of this exercise program offers greater improvements in step-to-step symmetry and/or has the potential to reduce the rate of falls in people with PD. It should also be noted that the design of this study meant that participants in the Exercise group received a higher treatment dose than the Education group over the 12-week intervention period (i.e. 12 x 90-minute exercise sessions = 1080 additional minutes). As such, while one could argue that the improvements in AP head and trunk step-to-step symmetry resulted from the targeted trunk muscle exercises, it is possible that these improvements were attributable to the greater level of activity of the Exercise group over this period. Finally, 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.

In conclusion, the results presented suggest that by performing as little as one focussed exercise session per week it may be possible to improve or, at the very least maintain, step-to-step symmetry in people with PD. Such improvements in function are likely to have significant implications for an individual's self-confidence and independence, which ultimately should contribute to an improved quality of life. Given these findings, exercises that target trunk muscle function should be considered when developing an exercise program that seeks to improve balance and reduce falls risk in people with PD.

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FIGURE LEGENDS

Figure 1: Summary of the number of participants contacted, screened, assessed and randomised to each group for the purposes of this study.