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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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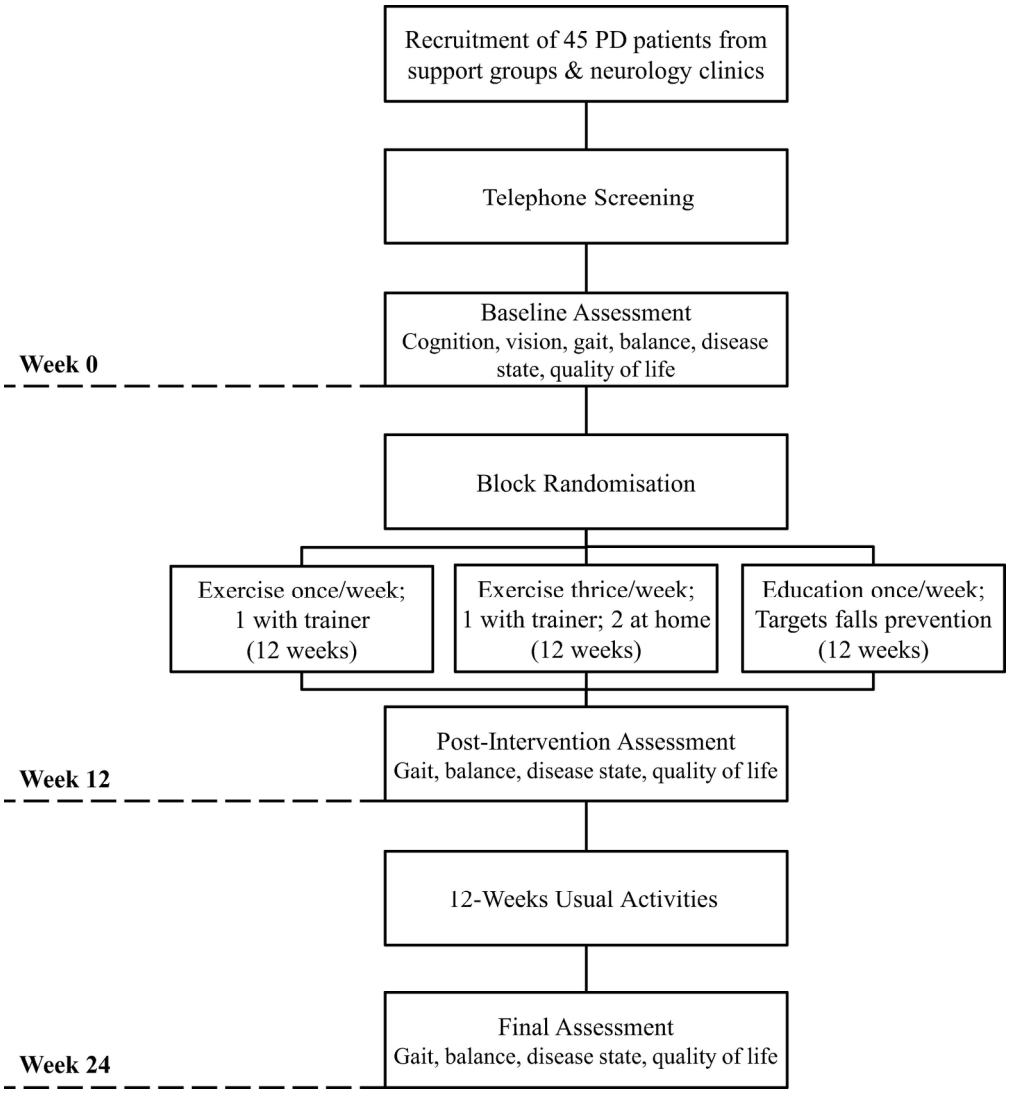

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
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Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-12
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Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	14

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Results			
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	13b	For each group, losses and exclusions after randomisation, together with reasons	NA
Recruitment	14a	Dates defining the periods of recruitment and follow-up	NA
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Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	NA
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	NA
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	NA
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	NA
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Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	NA
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	26

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Title: 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: During walking, the trunk is important for dynamic postural stability as it attenuates forces ascending from the feet to ensure the visual and vestibular systems are unperturbed. People with Parkinson's disease (PD) who fall demonstrate less regular head and trunk movements during walking, suggesting that this compensatory strategy may be different in these individuals. Evidence shows that exercise can improve clinical measures of strength, balance and mobility, and in some cases, can improve symptoms of tremor and rigidity in individuals with PD. Despite this, it remains unclear whether improvements in trunk control can correct postural stability deficits in this population. The proposed randomised controlled trial will evaluate the effects of a 12-week intervention aimed at improving trunk mobility and endurance on postural stability in people with PD.

Methods and Analysis: Forty-five individuals diagnosed with idiopathic PD with a history of falls or multiple near misses will be recruited. At baseline, participants will complete tests of cognition, vision, disease severity, fear of falling, mobility and quality of life. Postural stability under static conditions will also be assessed while standing on a force platform and three-dimensional accelerometers on the head and trunk will assess dynamic stability during walking. Following baseline testing, participants will be randomly-assigned to one of three intervention groups; i) exercise once per week; ii) exercise thrice per week; iii) education. Participants will repeat the tests conducted at baseline after the 12-week intervention and following a 12-week sustainability period.

Ethics and Dissemination: This study has received ethics approval from the Australian Catholic University Human Research Ethics Committee (Approval #2013 223Q). The

findings of this study will be disseminated via peer-reviewed articles published in clinical and movement science journals and conference presentations.

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

Study Strengths and Limitations:

- 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.
- This 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 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 sie required to achieve this goal (approximately 120 participants per group) is prohibitive.
- Due to the nature of the chosen intervention, the findings may only be applicable to patients who experience mild to moderate symptoms that are healthy enough to perform the exercises. As such, alternate interventions may be necessary for individuals who present with more advanced symptoms.

Keywords: Postural stability, trunk, exercise, accelerometry, randomised-controlled trial

INTRODUCTION

Parkinson's disease (PD) is an age-related neurodegenerative disease, conservatively estimated to affect 64,000 Australians[1] and 6.3 million people worldwide.[2 3] The neurodegenerative changes associated with PD result in the loss of dopamine-producing neurons within the basal ganglia, which leads to the depletion of this important neurotransmitter and impairments in motor function.[4] After approximately 70% of the dopaminergic cells are lost, numerous motor symptoms can manifest including slowness of movement (bradykinesia), resting tremor and muscle rigidity.[5] With progression of the disease, symptoms affecting postural stability and gait can also develop and may include a stooped or flexed trunk posture, decreased gait velocity and reduced arm swing while walking; all of which can reduce postural stability and increase the risk of falls.

Falls can be quite common for healthy older individuals, with 33% of people aged 65 years and over reportedly falling at least once within a 12-month period.[5 6] However, the incidence of falls is much greater for people with PD, with prospective studies indicating that up to 68% of people with PD will fall at least once each year and up to 50% of these individuals will experience recurrent falls.[7 8] 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.[9] 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.[10]

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 (e.g. walking and turning), which can place them at an

increased risk of falling.[11] 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.[7 12 13]

Given that the head and trunk comprise 60% of the overall mass of the body,[14] it seems reasonable to suggest that one's ability to precisely coordinate trunk movements would contribute significantly to 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.[15] However, separate research suggests that the trunk has a more irregular movement pattern than the head during gait.[16] The authors argued that the trunk may serve to attenuate forces during dynamic tasks to stabilize the head, and preserve the quality of the visual and vestibular feedback required for postural control. If an individual was 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.

People with PD who fall are known to have increased medial-lateral (ML) and anterior-posterior (AP) movements of the trunk during sitting[17], less regular pelvic movements[18] and increased ML head movement during gait.[7 19] 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.[20-24]

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, exercise has been shown to be effective in improving standing balance[25], symptoms of anxiety and depression[26] and reducing falls rates[25 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[18 20 28 29], postural stability[18 20 28 29] and symptoms of severity in people with PD.[29] Current evidence suggests that when programs include more challenging balance exercises, they may offer greater benefits for balance and mobility.[20] 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.[30] 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.[29]

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.[29] 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 continuous 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 and continuous 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 program aimed at improving trunk mobility and endurance in people with PD; i) is more effective than education at improving dynamic postural stability; ii) is more effective at improving dynamic postural stability when training frequency is increased; and iii) provides greater long-term benefits to dynamic postural stability than education over a 12-week period. It is hypothesized that the exercise program will produce greater benefits to dynamic postural stability than education, and increased training 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.[31]

Participants

Forty-five participants diagnosed with idiopathic PD, based on the UK Brain Bank Criteria[32] 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: i) neurology clinics, ii) community support groups, iii) and a pre-existing database of people with PD who have expressed an interest to participate in research. Participants will be excluded if they: i) are unable to stand and walk independently without the use of a walking aid, ii) have any significant visual (Bailey-Lovie

high contrast visual acuity > 0.30 logMAR) or cognitive impairment (Addenbrooke's cognition examination score <82), iii) have uncontrolled hypertension, iv) are taking psychotropic medications, v) have any significant limitations due to osteoporosis, vi) have had any orthopaedic surgery within the previous year, vii) have any serious neck, shoulder or back injuries; including spinal fusions, or viii) 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".[21]

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. All volunteers will be asked to provide written informed consent in accordance with the Declaration of Helsinki prior to participation in the study. The primary measure for this study is the calculation of a harmonic ratio. The sample size was calculated using mediolateral head accelerations from a previous study that assessed differences in dynamic postural stability between people with PD and healthy controls using a continuous measure known as the harmonic ratio.[33] 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.

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 to be performed. This battery of tests will include clinical assessments of: i) cognitive function (Addenbrooke's Cognitive Examination (ACE)[34]), ii) visual acuity (Bailey-Lovie high contrast visual acuity[35]), iii) disease severity (Unified Parkinson's Disease Rating Scale (UPDRS), the modified Hoehn & Yahr (H&Y) scale[36], the Schwab & England Activities of Daily Living Scale[37] and the PD Gait and Falls Questionnaire (PD-GFQ)[38]), iv) fear of falling (Activity-specific Balance Confidence Scale[39]), v) mobility (Timed Up and Go[40]) and vi) quality of life (Parkinson's disease questionnaire 39 (PDQ-39)).[41] The PD-GFQ is a 16-item tool that assesses falls and the extent of any gait difficulties experienced by people with PD and incorporates 6 questions that are summed to give the freezing of gait (FOG) score.[37] 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,[34 42-45] and have been used previously to assess individuals with PD.[18 46]

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 (MEMS) three-dimensional accelerometers (Noraxon Inc., Scottsdale, AZ) sampling at a rate of 500 Hz. Prior to testing, the accelerometers will be statically calibrated using the methods

described previously.[47] 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 1g). 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., Scottsdale, AZ) 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 second trials that will involve standing as still as possible for 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. Before commencement 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 (COP) 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., Scottsdale, AZ). In healthy individuals, the erector spinae muscles show a phasic increase in activation just after heel-contact to counter forward trunk flexion during walking.[48] The erector spinae muscles were chosen for evaluation because individuals with PD are known to

have decreased trunk muscle performance than age-matched controls,[49] 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, CO), and then cleaned thoroughly with an isopropyl alcohol wipe to minimise impedance at the electrode-skin interface and improve clarity of the myoelectric signal.[50] 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 pre-gelled surface electrodes (AMBU Blue Sensor, Ballerup, DK; 34 mm diameter, 10 mm^2 sensing area) will be placed with a centre-to-centre inter-electrode 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 3rd lumbar (L3) vertebral body.[51]

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.[51]

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)	Post-Intervention (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
Screening Measures				
Cognitive Function	Addenbrooke's Cognitive Exam	X		
Visual Function	Bailey-Lovie High-Contrast Visual Acuity	X		

Abbreviations: **AP** = Anteroposterior, **ML** = Mediolateral, **VT** = Vertical, **ES** = Erector Spinae, **UPDRS III** = Motor Subscale of Unified Parkinson's Disease Rating Scale, **FOGQ** = Freezing of Gait Questionnaire, **ABC Scale** = Activities-Specific Balance Confidence Scale, **PDQ-39** = Parkinson's Disease Questionnaire 39.

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: i) after the 12-week intervention to establish the immediate effects of the exercise program on postural stability and ii) 12-weeks after the completion of the intervention to evaluate the retention of any benefits over the longer term (i.e. 24-weeks following baseline). To ensure that participants are assessed under similar conditions on each of the testing days, all procedures will be scheduled to start within 1 to 2 hours of the participants taking their medication to ensure they are optimally-medicated. 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.

INSERT FIGURE 1 ABOUT HERE

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.[52] Measurements derived from the accelerometry data will include: i) peak acceleration (root mean square (RMS)) and ii) harmonic ratio, both of which will be calculated for the AP, ML and vertical (VT) axes of the head and trunk accelerometers separately. The harmonic ratio (HR) provides a measure of the stability of gait-related accelerations by evaluating the stride-to-stride regularity of the harmonics within the acceleration signals.[53] Walking patterns that produce higher HRs will be characterised by more a more regular acceleration profile over successive gait cycles (i.e. less stride-to-stride variability), hence, the gait pattern is deemed to be more stable.[54] The HR has been used previously to evaluate dynamic postural instability in people with PD[18 33] and will be used in this study to provide an indication of how 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.[55] Following filtering of the data, peak RMS muscle activity throughout the gait cycle will be calculated over a 50 ms[55] moving average window, with a 25 ms overlap.[51]

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: i) exercise one day per week, ii) exercise three days per week or iii) 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

All participants assigned to these groups will receive a 10-15 minute 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 multi-disciplinary 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 from research and information provided freely to the community.

Participants assigned to the exercise groups will complete a low-level supervision, 12-week exercise program aimed at improving trunk mobility and 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 program consists primarily of exercises previously used in two different exercise-based intervention studies involving older adults[56] and people with PD.[57] It has been designed to conform to the current recommendations for exercise-based interventions for stability[27 30 58] and will progress in complexity to accommodate individuals with different physical capabilities. The primary movements used for the program are outlined in Table 2. Hold times for the endurance exercises begin at five seconds and repetitions begin at 10 or as many as achievable by the participant. In addition, as the participant progresses in the program, 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 program, 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 both 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)[59] 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.[60 61] In addition, compliance to the intervention protocol and any adverse events will also be monitored and reported by the researchers.

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
Trunk Endurance	Abdominal Hollowing Side Bridging Front Bridging Bird Dog	Increase difficulty of exercise by: • Increased hold times • Movement complexity • Introduce unstable support surface
Mobility	Walking over surfaces of varying incline/decline, density and up and down stairs	8-10 minutes of walking on an outdoor walking path
Active Cool down	Walking	2 minutes (incline/decline
	Hamstring stretch	2 sets of 20 second holds
	Quadriceps stretch	2 sets of 20 second holds
	Gastrocnemius/ soleus stretch	2 sets of 20 second holds
	Triceps stretch	2 sets of 20 second holds
	Pectoral stretch	2 sets of 20 second holds

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 (e.g. age, height, weight,) a one way ANOVA will be used, while the Chi-square test will be used to identify any significant differences in the frequency of categorical data (e.g. 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 v21.0) 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 socio-economic 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.[62] 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[63 64], measures of static postural stability[65] and motor symptoms[20 28 66] 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.[21] 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.[46] 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.[16] However, individuals with PD are known to have deficits in trunk control and trunk muscle function[49], 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 firm[7] and compliant[19] surfaces and poorer pelvic control[18] 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.[56] 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.[57]

Separate studies have provided evidence to suggest that regular exercise has the potential to reduce the risk of falling in people with PD[20] and may even help to reduce the number of falls experienced by some individuals.[21] This study will be the first to examine whether a 12-week training program aimed at improving trunk mobility and endurance has the potential to improve continuous measures of static and dynamic postural stability in this population. If found to be effective, this training program will provide a safe and inexpensive exercised-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.

LIST OF ABBREVIATIONS USED

ANOVA = analysis of variance

AP = anterior-posterior

COP = centre of pressure

EMG = electromyography

H&Y = Hoehn & Yahr scale

IPAQ = International Physical Activity Questionnaire

MEMS = microelectromechanical system

ML = medial-lateral

MVC = maximal voluntary contract

PD = Parkinson's disease

RM-ANCOVA = repeated measures analysis of covariance

RMS = root mean square

UPDRS = Unified Parkinson's Disease Rating Scale

VT = vertical

COMPETING INTERESTS

None

AUTHORS' CONTRIBUTIONS

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.

AUTHORS' INFORMATION

None

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ENDNOTES

None

REFERENCES

1. Parkinson's Australia. Living with Parkinson's disease - 2011 update. Canberra, ACT: Deloitte Access Economics Pty Ltd. 2011
2. Baker MG, Graham L. The journey: Parkinson's disease. BMJ: British Medical Journal 2004;**329**(7466):611
3. Gassinger T, Litvan I. World Parkinson's Day International Symposium. Moving Along 2004;**6**(1):9
4. Hausdorff JM, Edelberg HK, Mitchell SL, Goldberger AL, Wei JY. Increased gait unsteadiness in community-dwelling elderly fallers. Archives of physical medicine and rehabilitation 1997;**78**(3):278-83
5. Lajoie Y, Gallagher S. Predicting falls within the elderly community: comparison of postural sway, reaction time, the Berg balance scale and the Activities-specific Balance Confidence (ABC) scale for comparing fallers and non-fallers. Archives of gerontology and geriatrics 2004;**38**(1):11-26
6. Lin MR, Wolf SL, Hwang HF, Gong SY, Chen CY. A randomized, controlled trial of fall prevention programs and quality of life in older fallers. Journal of the American Geriatrics Society 2007;**55**(4):499-506
7. Cole MH, Silburn PA, Wood JM, Worringham CJ, Kerr GK. Falls in Parkinson's disease: kinematic evidence for impaired head and trunk control. Movement disorders 2010;**25**(14):2369-78
8. Wood B, Bilclough J, Bowron A, Walker R. Incidence and prediction of falls in Parkinson's disease: a prospective multidisciplinary study. Journal of Neurology, Neurosurgery & Psychiatry 2002;**72**(6):721-25
9. Grimbergen YA, Munneke M, Bloem BR. Falls in Parkinson's disease. Current opinion in neurology 2004;**17**(4):405-15
10. Bloem BR, Hausdorff JM, Visser JE, Giladi N. Falls and freezing of gait in Parkinson's disease: a review of two interconnected, episodic phenomena. Movement Disorders 2004;**19**(8):871-84
11. Clark S, Rose DJ. Evaluation of dynamic balance among community-dwelling older adult fallers: a generalizability study of the limits of stability test. Archives of physical medicine and rehabilitation 2001;**82**(4):468-74
12. Goldberg A, Hernandez ME, Alexander NB. Trunk repositioning errors are increased in balance-impaired older adults. The Journals of Gerontology Series A: Biological Sciences and Medical Sciences 2005;**60**(10):1310-14
13. Grabiner MD, Donovan S, Bareither ML, et al. Trunk kinematics and fall risk of older adults: translating biomechanical results to the clinic. Journal of Electromyography and Kinesiology 2008;**18**(2):197-204
14. Winter DA. *Biomechanics and motor control of human movement*: John Wiley & Sons, 2009.

15. Cromwell R, Aadland-Monahan T, Nelson A, Stern-Sylvestre S, Seder B. Sagittal plane analysis of head, neck, and trunk kinematics and electromyographic activity during locomotion. The Journal of orthopaedic and sports physical therapy 2001;**31**(5):255
16. Kavanagh J, Barrett R, Morrison S. The role of the neck and trunk in facilitating head stability during walking. Experimental brain research 2006;**172**(4):454-63
17. Van der Burg J, Van Wegen E, Rietberg M, Kwakkel G, Van Dieën J. Postural control of the trunk during unstable sitting in Parkinson's disease. Parkinsonism & related disorders 2006;**12**(8):492-98
18. Latt MD, Lord SR, Morris JG, Fung VS. Clinical and physiological assessments for elucidating falls risk in Parkinson's disease. Movement disorders 2009;**24**(9):1280-89
19. Cole MH, Silburn PA, Wood JM, Kerr GK. Falls in Parkinson's disease: Evidence for altered stepping strategies on compliant surfaces. Parkinsonism & related disorders 2011;**17**(8):610-16
20. Allen NE, Canning CG, Sherrington C, et al. The effects of an exercise program on fall risk factors in people with Parkinson's disease: a randomized controlled trial. Movement disorders 2010;**25**(9):1217-25
21. Ashburn A, Fazakarley L, Ballinger C, Pickering R, McLellan LD, Fitton C. A randomised controlled trial of a home based exercise programme to reduce the risk of falling among people with Parkinson's disease. Journal of Neurology, Neurosurgery & Psychiatry 2007;**78**(7):678-84
22. Ebersbach G, Edler D, Kaufhold O, Wissel J. Whole body vibration versus conventional physiotherapy to improve balance and gait in Parkinson's disease. Archives of physical medicine and rehabilitation 2008;**89**(3):399-403
23. Morris M, Menz H, McGinley J, et al. Falls and mobility in Parkinson's disease: protocol for a randomised controlled clinical trial. BMC neurology 2011;**11**(1):93
24. Morris ME, Martin C, McGinley JL, et al. Protocol for a home-based integrated physical therapy program to reduce falls and improve mobility in people with Parkinson's disease. BMC neurology 2012;**12**(1):54
25. Barnett A, Smith B, Lord SR, Williams M, Baumand A. Community-based group exercise improves balance and reduces falls in at-risk older people: a randomised controlled trial. Age and Ageing 2003;**32**(4):407-14
26. Fox KR. The influence of physical activity on mental well-being. Public health nutrition 1999;**2**(3a):411-18
27. Sherrington C, Whitney JC, Lord SR, Herbert RD, Cumming RG, Close JC. Effective exercise for the prevention of falls: a systematic review and meta-analysis. Journal of the American Geriatrics Society 2008;**56**(12):2234-43
28. Lun V, Pullan N, Labelle N, Adams C, Suchowersky O. Comparison of the effects of a self-supervised home exercise program with a physiotherapist-supervised exercise program on the motor symptoms of Parkinson's disease. Movement disorders 2005;**20**(8):971-75
29. Tomlinson CL, Patel S, Meek C, et al. Physiotherapy intervention in Parkinson's disease: systematic review and meta-analysis. BMJ: British Medical Journal 2012;**345**
30. Li F, Harmer P, Fitzgerald K, et al. Tai chi and postural stability in patients with Parkinson's disease. New England Journal of Medicine 2012;**366**(6):511-19
31. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMC medicine 2010;**8**(1):18
32. Hughes AJ, Daniel SE, Kilford L, Lees AJ. Accuracy of clinical diagnosis of idiopathic Parkinson's disease: a clinico-pathological study of 100 cases. Journal of Neurology, Neurosurgery & Psychiatry 1992;**55**(3):181-84

33. Lowry KA, Smiley-Oyen AL, Carrel AJ, Kerr JP. Walking stability using harmonic ratios in Parkinson's disease. Movement disorders 2009;**24**(2):261-67
34. Mathuranath P, Nestor P, Berrios G, Rakowicz W, Hodges J. A brief cognitive test battery to differentiate Alzheimer's disease and frontotemporal dementia. NEUROLOGY-MINNEAPOLIS- 2000;**55**(11):1613-20
35. Bailey IL, Lovie J. New design principles for visual acuity letter charts. American journal of optometry and physiological optics 1976;**53**(11):740
36. Hoehn MM, Yahr MD. Parkinsonism: onset, progression, and mortality. Neurology 1998;**50**(2):318-18
37. Projection technique for evaluating surgery in Parkinson's disease. Third symposium on Parkinson's disease. Edinburgh: Livingstone; 1969.
38. Giladi N, Shabtai H, Simon E, Biran S, Tal J, Korczyn A. Construction of freezing of gait questionnaire for patients with Parkinsonism. Parkinsonism & related disorders 2000;**6**(3):165-70
39. Powell LE, Myers AM. The activities-specific balance confidence (ABC) scale. The Journals of Gerontology Series A: Biological Sciences and Medical Sciences 1995;**50**(1):M28-M34
40. Podsiadlo D, Richardson S. The timed" Up & Go": a test of basic functional mobility for frail elderly persons. Journal of the American geriatrics Society 1991;**39**(2):142
41. Peto V, Jenkinson C, Fitzpatrick R, Greenhall R. The development and validation of a short measure of functioning and well being for individuals with Parkinson's disease. Quality of Life Research 1995;**4**(3):241-48
42. Goetz CG, Poewe W, Rascol O, et al. Movement Disorder Society Task Force report on the Hoehn and Yahr staging scale: Status and recommendations The Movement Disorder Society Task Force on rating scales for Parkinson's disease. Movement disorders 2004;**19**(9):1020-28
43. Lovie-Kitchin JE. Validity and reliability of visual acuity measurements. Ophthalmic and physiological optics 1988;**8**(4):363-70
44. Martinez-Martin P, Gil-Nagel A, Morlán Gracia L, et al. Intermediate scale for assessment of Parkinson's disease. Characteristics and structure. Parkinsonism & related disorders 1995;**1**(2):97-102
45. Ramaker C, Marinus J, Stiggelbout AM, van Hilten BJ. Systematic evaluation of rating scales for impairment and disability in Parkinson's disease. Movement disorders 2002;**17**(5):867-76
46. Kerr G, Worringham C, Cole M, Lacherez P, Wood J, Silburn P. Predictors of future falls in Parkinson disease. Neurology 2010;**75**(2):116-24
47. Moe-Nilssen R. A new method for evaluating motor control in gait under real-life environmental conditions. Part 2: Gait analysis. Clinical Biomechanics 1998;**13**(4):328-35
48. Winter D, Yack H. EMG profiles during normal human walking: stride-to-stride and inter-subject variability. Electroencephalography and clinical neurophysiology 1987;**67**(5):402-11
49. Bridgewater KJ, Sharpe MH. Trunk muscle performance in early Parkinson's disease. Physical therapy 1998;**78**(6):566-76
50. Hewson D, Hogrel J-Y, Langeron Y, Duchene J. Evolution in impedance at the electrode-skin interface of two types of surface EMG electrodes during long-term recordings. Journal of Electromyography and Kinesiology 2003;**13**(3):273-79
51. Vera-Garcia FJ, Moreside JM, McGill SM. MVC techniques to normalize trunk muscle EMG in healthy women. Journal of Electromyography and Kinesiology 2010;**20**(1):10-16

52. Kavanagh J, Barrett R, Morrison S. Upper body accelerations during walking in healthy young and elderly men. Gait & posture 2004;**20**(3):291-98
53. Smidt GL, Arora JS, Johnston RC. Accelerographic analysis of several types of walking. American Journal of Physical Medicine & Rehabilitation 1971;**50**(6):285-300
54. Menz HB, Lord SR, Fitzpatrick RC. Acceleration patterns of the head and pelvis when walking on level and irregular surfaces. Gait & posture 2003;**18**(1):35-46
55. Robichaud JA, Pfann KD, Comella CL, Corcos DM. Effect of medication on EMG patterns in individuals with Parkinson's disease. Movement Disorders 2002;**17**(5):950-60
56. Hesari AF, Mahdavi S, Abadi MRH, Sangdevini M, Golpaigani M. Comparisons of berg balance scale following core stabilization training in women elderly. Annals of Biological Research 2012;**3**(3):1499-504
57. Bridgewater KJ, Sharpe MH. Trunk muscle training and early Parkinson's disease. Physiotherapy Theory and Practice 1997;**13**(2):139-53
58. Smania N, Corato E, Tinazzi M, et al. Effect of balance training on postural instability in patients with idiopathic Parkinson's disease. Neurorehabilitation and Neural Repair 2010;**24**(9):826-34
59. Booth ML, Ainsworth BE, Pratt M, et al. International physical activity questionnaire: 12-country reliability and validity. Medicine & Science in Sports & Exercise 2003;**195**(9131/03):3508-1381
60. Hagstromer M, Oja P, Sjostrom M. The International Physical Activity Questionnaire (IPAQ): a study of concurrent and construct validity. Public health nutrition 2006;**9**(6):755-62
61. Hallal PC, Victora CG. Reliability and validity of the international physical activity questionnaire (IPAQ). Med Sci Sports Exerc 2004;**36**(3):556
62. Ferraye MU, Debû B, Fraix V, et al. Effects of pedunculopontine nucleus area stimulation on gait disorders in Parkinson's disease. Brain 2010;**133**(1):205-14
63. Crizzle AM, Newhouse IJ. Is physical exercise beneficial for persons with Parkinson's disease? Clinical Journal of Sport Medicine 2006;**16**(5):422-25
64. Goodwin VA, Richards SH, Taylor RS, Taylor AH, Campbell JL. The effectiveness of exercise interventions for people with Parkinson's disease: A systematic review and meta-analysis. Movement disorders 2008;**23**(5):631-40
65. Hirsch MA, Toole T, Maitland CG, Rider RA. The effects of balance training and high-intensity resistance training on persons with idiopathic Parkinson's disease. Archives of physical medicine and rehabilitation 2003;**84**(8):1109-17
66. Jöbges EM, Spittler-Schneiders H, Renner C, Hummelsheim H. Clinical relevance of rehabilitation programs for patients with idiopathic Parkinson syndrome. II: Symptom-specific therapeutic approaches. Parkinsonism Relat Disord 2007;**13**(4):203-13

Figure Legend

Title: Study outline

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

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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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Title: 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

Background: 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 program aimed at improving dynamic postural stability in people with PD; i) is more effective than education; ii) is more effective when training frequency is increased; and iii) 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 three days per 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 Parkinson's disease. Importantly, if the program 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: The protocol for this study is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613001175763).

Strengths and Limitations to 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.
- Due 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.

Keywords: Parkinson, Posture, Exercise, Stability, Acceleration

INTRODUCTION

Prospective studies indicate that the incidence of falls are much greater for people with 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 adults[5] 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 PD[6] 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 anti-parkinsonian medications. However, these medications are unfortunately not always effective at improving symptoms of axial rigidity[6] 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 (e.g. 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 stabilize the head, and preserve the quality of the visual and vestibular feedback required for postural control. If an individual has increased axial rigidity[6] 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 (i.e. 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 medial-lateral (ML) and anterior-posterior (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 rates[26] 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 programs 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 program aimed at improving dynamic postural stability in people with PD; i) is more effective than education; ii) is more effective when training frequency is increased; and iii) provides greater long-term benefits than education. It is hypothesized that the both exercise programs 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 randomized-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 Criteria[36] 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: i) neurology clinics, ii) community support groups, iii) 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. Upon contacting a member of the research team, prospective participants will be screened to ensure that they are 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: i) are unable to stand and walk independently without the use of a walking aid, ii) have any significant visual (Bailey-Lovie high contrast visual acuity > 0.30 logMAR) or cognitive impairment (Addenbrooke's cognition examination score <82), iii) have uncontrolled hypertension, iv) are taking psychotropic medications, v) have any significant limitations due to osteoporosis, vi) have had any orthopaedic surgery within the previous year, vii) have any serious neck, shoulder or back injuries; including spinal fusions, or viii) 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 harmonic ratio, the primary measure of this study. The sample size was calculated using medio-lateral head accelerations from a previous study that assessed differences in dynamic

postural stability in PD compared with healthy controls using the harmonic ratio.[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 to 2 hours 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 to be performed. This battery of tests will include clinical assessments of: i) cognitive function (Addenbrooke's Cognitive Examination (ACE)[38]), ii) visual acuity (Bailey-Lovie high contrast visual acuity[39]), iii) disease severity (Unified Parkinson's Disease Rating Scale (UPDRS), the modified Hoehn & Yahr (H&Y) scale[40], the Schwab & England Activities of Daily Living Scale[41] and the PD Gait and Falls Questionnaire (PD-GFQ)[42]), iv) fear of falling (Activity-specific Balance Confidence Scale[43]), v) mobility (Timed Up and Go[44]) and vi) 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 6 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 (MEMS) three-dimensional accelerometers (Noraxon Inc., Scottsdale, AZ) 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 1g). 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., Scottsdale, AZ) 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 second trials that will involve standing as still as possible for 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. Before commencement 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 (COP) 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., Scottsdale, AZ). 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, CO), 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 pre-gelled surface electrodes (AMBU Blue Sensor, Ballerup, DK; 34 mm diameter, 10 mm^2 sensing area) will be placed with a centre-to-centre inter-electrode 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 3rd 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]

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)	Post-Intervention (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 Exam	X
Visual Function	Bailey-Lovie High-Contrast Visual Acuity	X

Abbreviations: **AP** = Anteroposterior, **ML** = Mediolateral, **VT** = Vertical, **ES** = Erector Spinae, **UPDRS III** = Motor Subscale of Unified Parkinson's Disease Rating Scale, **FOGQ** = Freezing of Gait Questionnaire, **ABC Scale** = Activities-Specific Balance Confidence Scale, **PDQ-39** = Parkinson's Disease Questionnaire 39.

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: i) after the 12-week intervention to establish the immediate effects of the exercise program on postural stability and ii) 12-weeks after the completion of the intervention to evaluate the retention of any benefits over the longer term (i.e. 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.

INSERT FIGURE 1 ABOUT HERE

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: i) peak acceleration (root mean square (RMS)) and ii) harmonic ratio, 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 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 ms[57] 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: i) exercise one day per week, ii) exercise three days per week or iii) 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 minute 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 multi-disciplinary 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 program aimed at improving trunk mobility and 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 program consists primarily of exercises that have previously been used in two different exercise-based interventions involving older adults[58] and people with PD,[59] that focused on improving trunk muscle strength and endurance. Importantly, the program 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 program includes movements focussing on improving trunk mobility, exercises that target muscular strength and endurance, tasks that aim to develop balance under challenging situations (i.e. on an unstable surface) and ambulating over different terrains in a real-world environment. The program will progress in complexity to accommodate individuals with different physical capabilities. The primary movements used

for the program are outlined in Table 2. Hold times for the endurance exercises begin at five seconds and repetitions begin at 10 or as many as achievable by the participant. In addition, as the participant progresses in the program, 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 program, 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 both 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.

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

Trunk Endurance	Abdominal Hollowing Side Bridging Front Bridging Bird Dog	Increase difficulty of exercise by: • Increased hold times • Movement complexity • Introduce unstable support surface
Mobility	Walking over surfaces of varying incline/decline, density and up and down stairs	8-10 minutes of walking on an outdoor walking path
Active Cool down	Hamstring stretch Quadriceps stretch Gastrocnemius/ soleus stretch Triceps stretch Pectoral stretch	2 sets of 20 second holds 2 sets of 20 second holds 2 sets of 20 second holds 2 sets of 20 second holds 2 sets of 20 second holds

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 (e.g. age, height, weight,) a one way ANOVA will be used, while the Chi-square test will be used to identify any significant differences in the frequency of categorical data (e.g. 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 v21.0) 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 socio-economic 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 stability[67] 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 firm[1] and compliant[16] surfaces and poorer pelvic control[15] 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 adults[69] 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 PD[17] 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 program 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 program will provide a safe and inexpensive exercised-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.

LIST OF ABBREVIATIONS USED

ANOVA = analysis of variance

AP = anterior-posterior

COP = centre of pressure

EMG = electromyography

H&Y = Hoehn & Yahr scale

IPAQ = International Physical Activity Questionnaire

MEMS = microelectromechanical system

ML = medial-lateral

MVC = maximal voluntary contract

PD = Parkinson's disease

RM-ANCOVA = repeated measures analysis of covariance

RMS = root mean square

UPDRS = Unified Parkinson's Disease Rating Scale

VT = vertical

COMPETING INTERESTS

None

AUTHORS' CONTRIBUTIONS

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.

AUTHORS' INFORMATION

None

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ENDNOTES

None

REFERENCES

1. Cole, M.H., et al., *Falls in Parkinson's disease: kinematic evidence for impaired head and trunk control.* Movement disorders, 2010. **25**(14): p. 2369-2378.
2. Wood, B., et al., *Incidence and prediction of falls in Parkinson's disease: a prospective multidisciplinary study.* Journal of Neurology, Neurosurgery & Psychiatry, 2002. **72**(6): p. 721-725.
3. Grimbergen, Y.A., M. Munneke, and B.R. Bloem, *Falls in Parkinson's disease.* Current opinion in neurology, 2004. **17**(4): p. 405-415.
4. Bloem, B.R., et al., *Falls and freezing of gait in Parkinson's disease: a review of two interconnected, episodic phenomena.* Movement Disorders, 2004. **19**(8): p. 871-884.
5. Kavanagh, J., R. Barrett, and S. Morrison, *The role of the neck and trunk in facilitating head stability during walking.* Experimental brain research, 2006. **172**(4): p. 454-463.
6. Wright, W., et al., *Axial hypertonicity in Parkinson's disease: direct measurements of trunk and hip torque.* Experimental neurology, 2007. **208**(1): p. 38-46.
7. Clark, S. and D.J. Rose, *Evaluation of dynamic balance among community-dwelling older adult fallers: a generalizability study of the limits of stability test.* Archives of physical medicine and rehabilitation, 2001. **82**(4): p. 468-474.
8. Goldberg, A., M.E. Hernandez, and N.B. Alexander, *Trunk repositioning errors are increased in balance-impaired older adults.* The Journals of Gerontology Series A: Biological Sciences and Medical Sciences, 2005. **60**(10): p. 1310-1314.

9. Grabiner, M.D., et al., *Trunk kinematics and fall risk of older adults: translating biomechanical results to the clinic.* Journal of Electromyography and Kinesiology, 2008. **18**(2): p. 197-204.
10. Winter, D.A., *Biomechanics and motor control of human movement*. 2009: John Wiley & Sons.
11. Cromwell, R., et al., *Sagittal plane analysis of head, neck, and trunk kinematics and electromyographic activity during locomotion.* The Journal of orthopaedic and sports physical therapy, 2001. **31**(5): p. 255.
12. Smidt, G.L., J.S. Arora, and R.C. Johnston, *Accelerographic analysis of several types of walking.* American Journal of Physical Medicine & Rehabilitation, 1971. **50**(6): p. 285-300.
13. Menz, H.B., S.R. Lord, and R.C. Fitzpatrick, *Acceleration patterns of the head and pelvis when walking on level and irregular surfaces.* Gait & posture, 2003. **18**(1): p. 35-46.
14. Van der Burg, J., et al., *Postural control of the trunk during unstable sitting in Parkinson's disease.* Parkinsonism & related disorders, 2006. **12**(8): p. 492-498.
15. Latt, M.D., et al., *Clinical and physiological assessments for elucidating falls risk in Parkinson's disease.* Movement disorders, 2009. **24**(9): p. 1280-1289.
16. Cole, M.H., et al., *Falls in Parkinson's disease: Evidence for altered stepping strategies on compliant surfaces.* Parkinsonism & related disorders, 2011. **17**(8): p. 610-616.
17. Allen, N.E., et al., *The effects of an exercise program on fall risk factors in people with Parkinson's disease: a randomized controlled trial.* Movement disorders, 2010. **25**(9): p. 1217-1225.
18. Ashburn, A., et al., *A randomised controlled trial of a home based exercise programme to reduce the risk of falling among people with Parkinson's disease.* Journal of Neurology, Neurosurgery & Psychiatry, 2007. **78**(7): p. 678-684.
19. Ebersbach, G., et al., *Whole body vibration versus conventional physiotherapy to improve balance and gait in Parkinson's disease.* Archives of physical medicine and rehabilitation, 2008. **89**(3): p. 399-403.
20. Morris, M., et al., *Falls and mobility in Parkinson's disease: protocol for a randomised controlled clinical trial.* BMC neurology, 2011. **11**(1): p. 93.
21. Morris, M.E., et al., *Protocol for a home-based integrated physical therapy program to reduce falls and improve mobility in people with Parkinson's disease.* BMC neurology, 2012. **12**(1): p. 54.
22. Barnett, A., et al., *Community-based group exercise improves balance and reduces falls in at-risk older people: a randomised controlled trial.* Age and Ageing, 2003. **32**(4): p. 407-414.
23. Rochester, L., et al. *Evidence for motor learning in Parkinson's disease: acquisition, automaticity and retention of cued gait performance after training with external rhythmical cues*. Brain research, 2010. **1319**, 103-11 DOI: 10.1016/j.brainres.2010.01.001.
24. Fox, K.R., *The influence of physical activity on mental well-being.* Public health nutrition, 1999. **2**(3a): p. 411-418.
25. Cooney, G.M., et al., *Exercise for depression.* Cochrane Database Syst Rev, 2013. **9**.
26. Gillespie, L.D., et al., *Interventions for preventing falls in older people living in the community.* Cochrane Database Syst Rev, 2012. **9**(11).
27. Sherrington, C., et al., *Effective exercise for the prevention of falls: a systematic review and meta-analysis.* Journal of the American Geriatrics Society, 2008. **56**(12): p. 2234-2243.

28. Lun, V., et al., *Comparison of the effects of a self-supervised home exercise program with a physiotherapist-supervised exercise program on the motor symptoms of Parkinson's disease.* Movement disorders, 2005. **20**(8): p. 971-975.
29. Tomlinson, C.L., et al., *Physiotherapy intervention in Parkinson's disease: systematic review and meta-analysis.* BMJ: British Medical Journal, 2012. **345**.
30. Tomlinson, C.L., et al., *Physiotherapy versus placebo or no intervention in Parkinson's disease.* Cochrane Database Syst Rev, 2012. **8**.
31. Oguh, O., et al., *Back to the basics: regular exercise matters in Parkinson's disease: Results from the National Parkinson Foundation registry study.* Parkinsonism & related disorders, 2014.
32. Murray, D.K., et al., *The effects of exercise on cognition in Parkinson's disease: a systematic review.* Translational neurodegeneration, 2014. **3**(1): p. 5.
33. Li, F., et al., *Tai chi and postural stability in patients with Parkinson's disease.* New England Journal of Medicine, 2012. **366**(6): p. 511-519.
34. Tomlinson, C.L., et al., *Physiotherapy for Parkinson's disease: a comparison of techniques.* The Cochrane Library, 2014.
35. Schulz, K.F., D.G. Altman, and D. Moher, *CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials.* BMC medicine, 2010. **8**(1): p. 18.
36. Hughes, A.J., et al., *Accuracy of clinical diagnosis of idiopathic Parkinson's disease: a clinico-pathological study of 100 cases.* Journal of Neurology, Neurosurgery & Psychiatry, 1992. **55**(3): p. 181-184.
37. Lowry, K.A., et al., *Walking stability using harmonic ratios in Parkinson's disease.* Movement disorders, 2009. **24**(2): p. 261-267.
38. Mathuranath, P., et al., *A brief cognitive test battery to differentiate Alzheimer's disease and frontotemporal dementia.* NEUROLOGY, 2000. **55**(11): p. 1613-1620.
39. Bailey, I.L. and J. Lovie, *New design principles for visual acuity letter charts.* American journal of optometry and physiological optics, 1976. **53**(11): p. 740.
40. Hoehn, M.M. and M.D. Yahr, *Parkinsonism: onset, progression, and mortality.* Neurology, 1998. **50**(2): p. 318-318.
41. Schwab, R.S. and A.C. England. *Projection technique for evaluating surgery in Parkinson's disease*. in *Third symposium on Parkinson's disease. Edinburgh: Livingstone*. 1969.
42. Giladi, N., et al., *Construction of freezing of gait questionnaire for patients with Parkinsonism.* Parkinsonism & related disorders, 2000. **6**(3): p. 165-170.
43. Powell, L.E. and A.M. Myers, *The activities-specific balance confidence (ABC) scale.* The Journals of Gerontology Series A: Biological Sciences and Medical Sciences, 1995. **50**(1): p. M28-M34.
44. Podsiadlo, D. and S. Richardson, *The timed" Up & Go": a test of basic functional mobility for frail elderly persons.* Journal of the American geriatrics Society, 1991. **39**(2): p. 142.
45. Peto, V., et al., *The development and validation of a short measure of functioning and well being for individuals with Parkinson's disease.* Quality of Life Research, 1995. **4**(3): p. 241-248.
46. Goetz, C.G., et al., *Movement Disorder Society Task Force report on the Hoehn and Yahr staging scale: Status and recommendations The Movement Disorder Society Task Force on rating scales for Parkinson's disease.* Movement disorders, 2004. **19**(9): p. 1020-1028.
47. Lovie-Kitchin, J.E., *Validity and reliability of viscual acuity measurements.* Ophthalmic and physiological optics, 1988. **8**(4): p. 363-370.

48. Martinez-Martin, P., et al., *Intermediate scale for assessment of Parkinson's disease. Characteristics and structure.* Parkinsonism & related disorders, 1995. **1**(2): p. 97-102.
49. Ramaker, C., et al., *Systematic evaluation of rating scales for impairment and disability in Parkinson's disease.* Movement disorders, 2002. **17**(5): p. 867-876.
50. Kerr, G., et al., *Predictors of future falls in Parkinson disease.* Neurology, 2010. **75**(2): p. 116-124.
51. Moe-Nilssen, R., *A new method for evaluating motor control in gait under real-life environmental conditions. Part 2: Gait analysis.* Clinical Biomechanics, 1998. **13**(4): p. 328-335.
52. Winter, D. and H. Yack, *EMG profiles during normal human walking: stride-to-stride and inter-subject variability.* Electroencephalography and clinical neurophysiology, 1987. **67**(5): p. 402-411.
53. Bridgewater, K.J. and M.H. Sharpe, *Trunk muscle performance in early Parkinson's disease.* Physical therapy, 1998. **78**(6): p. 566-576.
54. Hewson, D., et al., *Evolution in impedance at the electrode-skin interface of two types of surface EMG electrodes during long-term recordings.* Journal of Electromyography and Kinesiology, 2003. **13**(3): p. 273-279.
55. Vera-Garcia, F.J., J.M. Moreside, and S.M. McGill, *MVC techniques to normalize trunk muscle EMG in healthy women.* Journal of Electromyography and Kinesiology, 2010. **20**(1): p. 10-16.
56. Kavanagh, J., R. Barrett, and S. Morrison, *Upper body accelerations during walking in healthy young and elderly men.* Gait & posture, 2004. **20**(3): p. 291-298.
57. Robichaud, J.A., et al., *Effect of medication on EMG patterns in individuals with Parkinson's disease.* Movement Disorders, 2002. **17**(5): p. 950-960.
58. Hesari, A.F., et al., *Comparisons of berg balance scale following core stabilization training in women elderly.* Annals of Biological Research, 2012. **3**(3): p. 1499-1504.
59. Bridgewater, K.J. and M.H. Sharpe, *Trunk muscle training and early Parkinson's disease.* Physiotherapy Theory and Practice, 1997. **13**(2): p. 139-153.
60. Smania, N., et al., *Effect of balance training on postural instability in patients with idiopathic Parkinson's disease.* Neurorehabilitation and Neural Repair, 2010. **24**(9): p. 826-834.
61. Booth, M.L., et al., *International physical activity questionnaire: 12-country reliability and validity.* Medicine & Science in Sports & Exercise, 2003. **195**(9131/03): p. 3508-1381.
62. Hagstromer, M., P. Oja, and M. Sjostrom, *The International Physical Activity Questionnaire (IPAQ): a study of concurrent and construct validity.* Public health nutrition, 2006. **9**(6): p. 755-762.
63. Hallal, P.C. and C.G. Victora, *Reliability and validity of the international physical activity questionnaire (IPAQ).* Med Sci Sports Exerc, 2004. **36**(3): p. 556.
64. Ferraye, M.U., et al., *Effects of pedunculopontine nucleus area stimulation on gait disorders in Parkinson's disease.* Brain, 2010. **133**(1): p. 205-214.
65. Crizzle, A.M. and I.J. Newhouse, *Is physical exercise beneficial for persons with Parkinson's disease?* Clinical Journal of Sport Medicine, 2006. **16**(5): p. 422-425.
66. Goodwin, V.A., et al., *The effectiveness of exercise interventions for people with Parkinson's disease: A systematic review and meta-analysis.* Movement disorders, 2008. **23**(5): p. 631-640.
67. Hirsch, M.A., et al., *The effects of balance training and high-intensity resistance training on persons with idiopathic Parkinson's disease.* Archives of physical medicine and rehabilitation, 2003. **84**(8): p. 1109-1117.

68. Jöbges, E.M., et al., *Clinical relevance of rehabilitation programs for patients with idiopathic Parkinson syndrome. II: Symptom-specific therapeutic approaches.* Parkinsonism Relat Disord, 2007. **13**(4): p. 203-213.

69. Kyrdalen, I.L., et al., *The Otago Exercise Program performed as group training versus home training in fall-prone older people: a randomized controlled Trial.* Physiother Res Int, 2014. **19**(2): p. 108-16.

Figure Legend

Title: Study outline

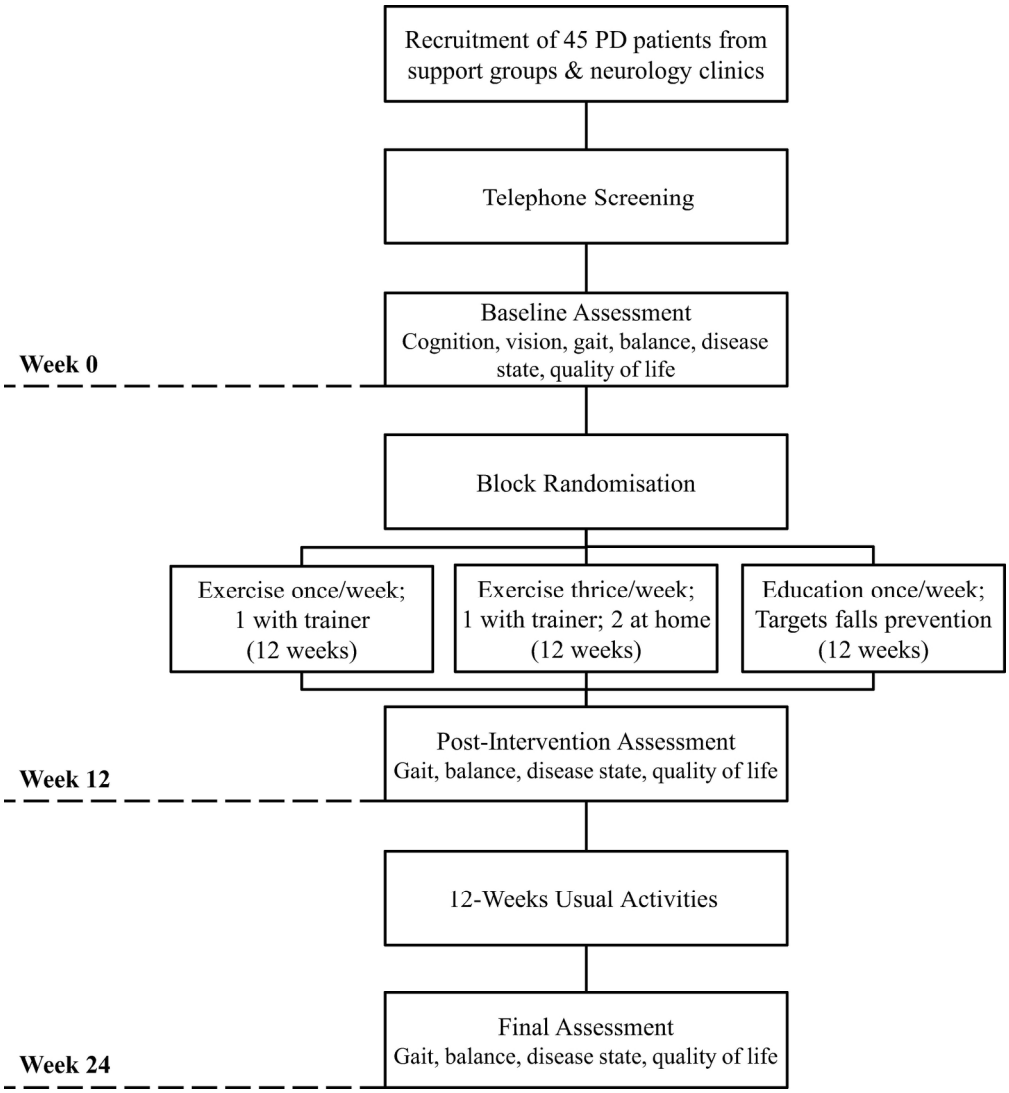
Figure 1: Flow chart depicting the order of recruitment and testing procedures for the outlined study.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-7
	2b	Specific objectives or hypotheses	6-7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7, 14
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	No / N/A
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	15-16
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	No / NA
Sample size	7a	How sample size was determined	8-9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	No / NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	14
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	14
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	14
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	14
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	14

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	17-18
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	N/A
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	N/A
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	N/A
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	N/A
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	N/A
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	N/A
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	N/A
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	N/A
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.



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