

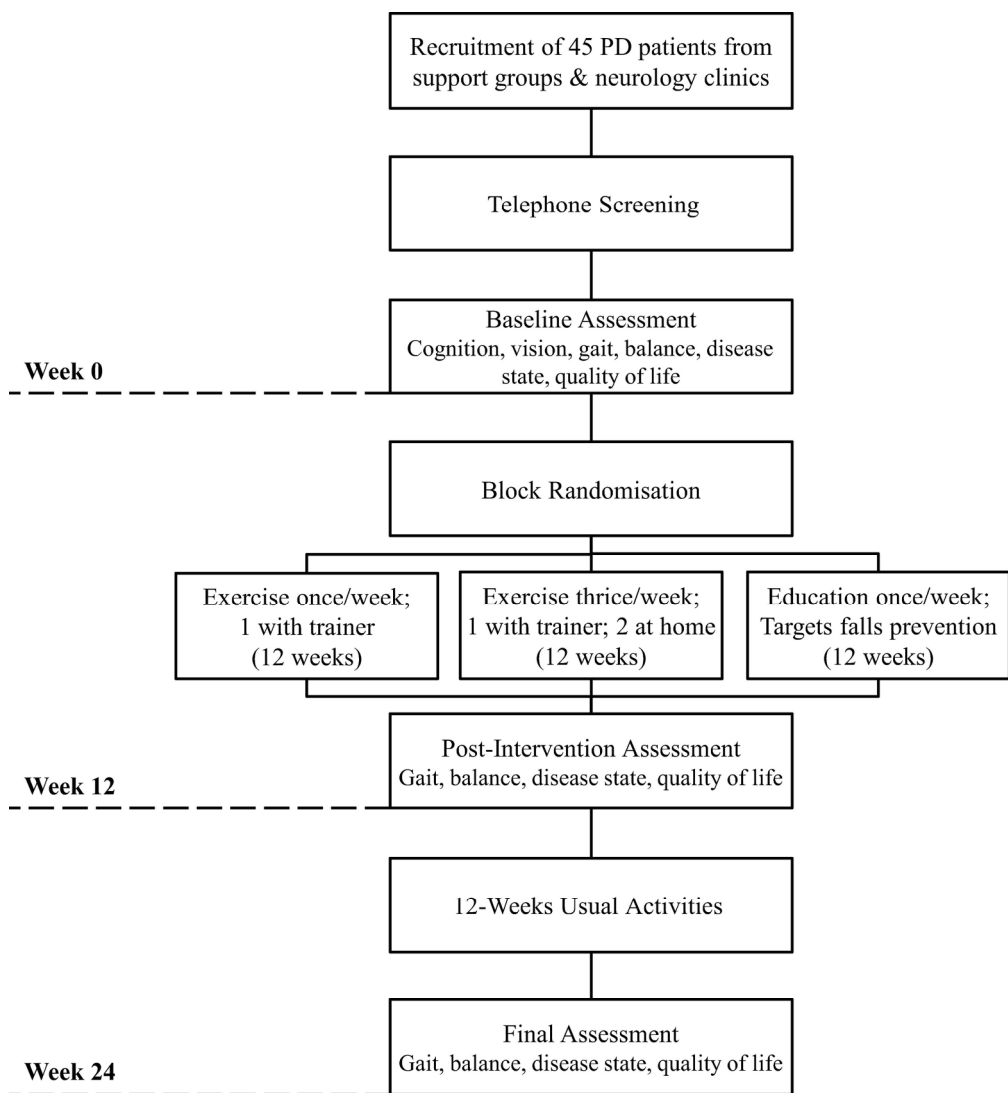
# BMJ Open

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

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

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>	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
<b>Introduction</b>	2a	Scientific background and explanation of rationale	4-7
<b>Background and objectives</b>	2b	Specific objectives or hypotheses	7
<b>Methods</b>	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7-8
<b>Trial design</b>	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
<b>Participants</b>	4a	Eligibility criteria for participants	7-8
	4b	Settings and locations where the data were collected	9
<b>Interventions</b>	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	14-16
<b>Outcomes</b>	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-12
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
<b>Sample size</b>	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
<b>Randomisation:</b>	8a	Method used to generate the random allocation sequence	14
<b>Sequence generation</b>	8b	Type of randomisation; details of any restriction (such as blocking and block size)	14
<b>Allocation concealment mechanism</b>	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
<b>Implementation</b>	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	14
<b>Blinding</b>	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	14



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	assessing outcomes) and how	
11b	If relevant, description of the similarity of interventions	NA
12a	Statistical methods used to compare groups for primary and secondary outcomes	16-17
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
<b>Results</b>		
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	NA
13b	For each group, losses and exclusions after randomisation, together with reasons	NA
14a	Dates defining the periods of recruitment and follow-up	NA
14b	Why the trial ended or was stopped	NA
15	A table showing baseline demographic and clinical characteristics for each group	NA
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	NA
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
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
<b>Discussion</b>		
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	NA
21	Generalisability (external validity, applicability) of the trial findings	NA
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	NA
<b>Other information</b>		
23	Registration number and name of trial registry	3
24	Where the full trial protocol can be accessed, if available	NA
25	Sources of funding and other support (such as supply of drugs), role of funders	200

\* 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](http://www.consort-statement.org).

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3 1 Title: Trunk muscle exercises as a means of improving postural stability in people  
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5 2 with Parkinson's disease: a protocol for a randomised-controlled trial  
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7 3  
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9 4 Authors: Ryan P. Hubble<sup>1\*</sup>, Geraldine A. Naughton<sup>2</sup>, Peter A. Silburn<sup>3</sup>, Michael H. Cole<sup>1\*</sup>  
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30 Submission Type: Study Protocol  
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56 25 Word Count: 4403 words (Introduction to Discussion, excluding tables)  
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2  
3 26 **ABSTRACT**  
4

5 27 **Introduction:** During walking, the trunk is important for dynamic postural stability as it  
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7 28 attenuates forces ascending from the feet to ensure the visual and vestibular systems are  
8  
9 29 unperturbed. People with Parkinson's disease (PD) who fall demonstrate less regular head and  
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11 30 trunk movements during walking, suggesting that this compensatory strategy may be  
12  
13 31 different in these individuals. Evidence shows that exercise can improve clinical measures of  
14  
15 32 strength, balance and mobility, and in some cases, can improve symptoms of tremor and  
16  
17 33 rigidity in individuals with PD. Despite this, it remains unclear whether improvements in  
18  
19 34 trunk control can correct postural stability deficits in this population. The proposed  
20  
21 35 randomised controlled trial will evaluate the effects of a 12-week intervention aimed at  
22  
23 36 improving trunk mobility and endurance on postural stability in people with PD.  
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29 38 **Methods and Analysis:** Forty-five individuals diagnosed with idiopathic PD with a history  
30  
31 39 of falls or multiple near misses will be recruited. At baseline, participants will complete tests  
32  
33 40 of cognition, vision, disease severity, fear of falling, mobility and quality of life. Postural  
34  
35 41 stability under static conditions will also be assessed while standing on a force platform and  
36  
37 42 three-dimensional accelerometers on the head and trunk will assess dynamic stability during  
38  
39 43 walking. Following baseline testing, participants will be randomly-assigned to one of three  
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41 44 intervention groups; i) exercise once per week; ii) exercise thrice per week; iii) education.  
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43 45 Participants will repeat the tests conducted at baseline after the 12-week intervention and  
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45 46 following a 12-week sustainability period.  
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52 48 **Ethics and Dissemination:** This study has received ethics approval from the Australian  
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54 49 Catholic University Human Research Ethics Committee (Approval #2013 223Q). The  
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3 50 findings of this study will be disseminated via peer-reviewed articles published in clinical and  
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5 51 movement science journals and conference presentations.  
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10 53 **Trial registration:** The protocol for this study is registered with the Australian New Zealand  
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12 54 Clinical Trials Registry (ACTRN12613001175763).  
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14 55 Study Strengths and Limitations:

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17 56 • This study has been designed as a randomised controlled trial, which is currently  
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19 57 considered the best methodological approach for evaluating the efficacy of a specific  
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21 58 intervention.  
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23 59 • This proposed study will be the first to assess whether dynamic postural stability  
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25 60 during walking can be improved or maintained in people with Parkinson's disease  
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27 61 who regularly perform specific exercises to improve trunk mobility and endurance.  
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29 62 • This study seeks to assess changes in dynamic balance using continuous measures  
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31 63 rather than graded clinical tests that are based on Likert scales, as these may be more  
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33 64 sensitive for detecting improvements in postural stability for this patient group.  
34  
35 65 • While it would be important to examine whether improvements in postural stability  
36  
37 66 are associated with a reduction in falls, the large sample size required to achieve this  
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39 67 goal (approximately 120 participants per group) is prohibitive.  
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41 68 • Due to the nature of the chosen intervention, the findings may only be applicable to  
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43 69 patients who experience mild to moderate symptoms that are healthy enough to  
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45 70 perform the exercises. As such, alternate interventions may be necessary for  
46  
47 71 individuals who present with more advanced symptoms.  
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52 72 **Keywords:** Postural stability, trunk, exercise, accelerometry, randomised-controlled trial  
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## 75 INTRODUCTION

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

86 Falls can be quite common for healthy older individuals, with 33% of people aged 65  
87 years and over reportedly falling at least once within a 12-month period.<sup>[5 6]</sup> However, the  
88 incidence of falls is much greater for people with PD, with prospective studies indicating that  
89 up to 68% of people with PD will fall at least once each year and up to 50% of these  
90 individuals will experience recurrent falls.<sup>[7 8]</sup> The increased falls risk in this population is  
91 compounded by an increased risk of injury, as differences in the postural responses of people  
92 with PD place them at a greater risk of sustaining a significant fall-related injury than age-  
93 matched controls.<sup>[9]</sup> Falls and fall-related injuries often lead to a fear of falling, reduced  
94 mobility, poorer muscle strength and loss of independence, all of which ultimately influence  
95 an individual's mortality, morbidity and quality of life.<sup>[10]</sup>

96 It is important for individuals to be able to effectively control their body's segments to  
97 maintain postural stability and limit the risk of falling during both static and dynamic  
98 activities of daily living. Older adults demonstrate poorer postural stability during tasks  
99 requiring dynamic postural control (e.g. walking and turning), which can place them at an



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3 100 increased risk of falling.<sup>[11]</sup> Age-related declines in dynamic postural control may be further  
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5 101 exacerbated with the presence of PD, which would exacerbate the decreased balance and  
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7 102 higher falls rate evident in this population.<sup>[7 12 13]</sup>  
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10 103         Given that the head and trunk comprise 60% of the overall mass of the body,<sup>[14]</sup> it  
11  
12 104 seems reasonable to suggest that one's ability to precisely coordinate trunk movements would  
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14 105 contribute significantly to maintaining postural stability during these activities. An  
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16 106 examination of segmental stability for different regions of the upper body in a healthy  
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18 107 population showed that trunk movements were smaller than those of the head and neck  
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20 108 during walking.<sup>[15]</sup> However, separate research suggests that the trunk has a more irregular  
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22 109 movement pattern than the head during gait.<sup>[16]</sup> The authors argued that the trunk may serve  
23  
24 110 to attenuate forces during dynamic tasks to stabilize the head, and preserve the quality of the  
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26 111 visual and vestibular feedback required for postural control. If an individual was unable to  
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28 112 adequately control the trunk segment during dynamic tasks, then the exaggerated movements  
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30 113 of the trunk may have a direct impact on head stability and overall balance.  
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34 114         People with PD who fall are known to have increased medial-lateral (ML) and  
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36 115 anterior-posterior (AP) movements of the trunk during sitting<sup>[17]</sup>, less regular pelvic  
37  
38 116 movements<sup>[18]</sup> and increased ML head movement during gait.<sup>[7 19]</sup> Collectively, these studies  
39  
40 117 suggest that some of the falls experienced by people with PD may be related to a reduced  
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42 118 capacity for these individuals to adequately coordinate the body's segments during dynamic  
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44 119 tasks. As such, there is a clear need to evaluate the efficacy of different non-invasive  
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46 120 interventions aimed at maintaining and/or improving trunk mobility and control to improve  
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48 121 postural stability in this population. To date, few studies have investigated the efficacy of  
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50 122 different non-invasive methods for improving balance and reducing falls risk in this high-risk  
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52 123 population.<sup>[20-24]</sup>  
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3 124 It is widely recognised that exercise is an effective means of maintaining or  
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5 125 improving cardiovascular and musculoskeletal health, both of which are critical for  
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7 126 preserving physiological functioning and independence. Furthermore, exercise has been  
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9 127 shown to be effective in improving standing balance<sup>[25]</sup>, symptoms of anxiety and  
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11 128 depression<sup>[26]</sup> and reducing falls rates<sup>[25 27]</sup> in otherwise healthy individuals. A number of  
12  
13 129 previous studies have also provided evidence to support the short-term benefits of exercise  
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15 130 for improving clinical measures of mobility<sup>[18 20 28 29]</sup>, postural stability<sup>[18 20 28 29]</sup> and  
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17 131 symptoms of severity in people with PD.<sup>[29]</sup> Current evidence suggests that when programs  
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19 132 include more challenging balance exercises, they may offer greater benefits for balance and  
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21 133 mobility.<sup>[20]</sup> For example, tai chi is a specific form of exercise known to challenge the  
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23 134 balance system. Previous research has shown tai chi can improve measures of static postural  
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25 135 stability in people with PD.<sup>[30]</sup> However, it is important to note that the results of a recent  
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27 136 systematic review suggest that other forms of exercise may also provide similar benefits to  
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29 137 balance in this population.<sup>[29]</sup>

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34 138 While this systematic evidence supports that exercise improves clinical measures of  
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36 139 balance, mobility and disease severity, many of the improvements did not achieve a level that  
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38 140 would be considered a minimally clinically important change.<sup>[29]</sup> Furthermore, most of the  
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40 141 balance and mobility assessments used in previous studies have relied on Likert scales to  
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42 142 assess function, which may limit their ability to discriminate between people with PD who  
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44 143 fall and those who do not. As such, it is possible that the incorporation of continuous  
45  
46 144 biomechanical measures of dynamic postural stability may improve our capacity to  
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48 145 accurately detect improvements or declines in balance for this population, which would  
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50 146 facilitate better identification of patients who are at a higher risk of falling. However, the  
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52 147 investigators are unaware of any previous research that has investigated whether exercise can  
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54 148 improve quantitative and continuous measures of dynamic postural stability in people with  
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3 149 PD. A possible explanation for this may be that such a study would require the use of  
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5 150 complex measuring equipment that is typically only available in a laboratory setting, making  
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7 151 it a higher order of investigation and difficult to assess in a clinical environment.  
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10 152 As such, the proposed randomised-controlled trial aims to establish whether a 12-  
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12 153 week exercise program aimed at improving trunk mobility and endurance in people with PD;  
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14 154 i) is more effective than education at improving dynamic postural stability; ii) is more  
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16 155 effective at improving dynamic postural stability when training frequency is increased; and  
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18 156 iii) provides greater long-term benefits to dynamic postural stability than education over a 12-  
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20 157 week period. It is hypothesized that the exercise program will produce greater benefits to  
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22 158 dynamic postural stability than education, and increased training frequency will yield better  
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24 159 improvements for the people with PD.  
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## 29 161 **METHODS**

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32 162 The proposed randomised-controlled trial will be conducted in 2014/2015 and seeks  
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34 163 to improve the mobility and endurance of the trunk and its supporting musculature. This  
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36 164 study protocol was developed in accordance with the Consolidated Standards of Reporting  
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38 165 Trials (CONSORT) guidelines.<sup>[31]</sup>  
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### 43 167 **Participants**

44  
45 168 Forty-five participants diagnosed with idiopathic PD, based on the UK Brain Bank  
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47 169 Criteria<sup>[32]</sup> and who have a history of two or more near-misses and/or one fall or more in the  
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49 170 previous 12 months will be recruited from: i) neurology clinics, ii) community support  
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51 171 groups, iii) and a pre-existing database of people with PD who have expressed an interest to  
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53 172 participate in research. Participants will be excluded if they: i) are unable to stand and walk  
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55 173 independently without the use of a walking aid, ii) have any significant visual (Bailey-Lovie  
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3 174 high contrast visual acuity > 0.30 logMAR) or cognitive impairment (Addenbrooke's  
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5 175 cognition examination score <82), iii) have uncontrolled hypertension, iv) are taking  
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7 176 psychotropic medications, v) have any significant limitations due to osteoporosis, vi) have  
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10 177 had any orthopaedic surgery within the previous year, vii) have any serious neck, shoulder or  
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12 178 back injuries; including spinal fusions, or viii) have received deep brain stimulation surgery  
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14 179 to manage their symptoms. For the purposes of this study, a fall will be defined as "any  
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16 180 coming to the ground or lower level not as the result of a major intrinsic event or  
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18 181 overwhelming hazard" and a near miss will be defined as "an event on which an individual  
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21 182 felt that they were going to fall but did not actually do so".<sup>[21]</sup>

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23 183 Prospective participants will be sent an information letter outlining the details of the  
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25 184 study and inviting them to contact a member of the research team if they are interested in  
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27 185 participating in the research. All volunteers will be asked to provide written informed  
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29 186 consent in accordance with the Declaration of Helsinki prior to participation in the study.  
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31 187 The primary measure for this study is the calculation of a harmonic ratio. The sample size  
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33 188 was calculated using mediolateral head accelerations from a previous study that assessed  
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35 189 differences in dynamic postural stability between people with PD and healthy controls using  
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37 190 a continuous measure known as the harmonic ratio.<sup>[33]</sup> On the basis of this calculation, it was  
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39 191 concluded that a minimum of 11 participants per group is needed to confidently report any  
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41 192 significant changes in dynamic postural stability (diff = 0.05, SD = 0.04, Cohen's d = 1.25,  
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43 193 Power = 80%, p = 0.05). Given the longitudinal nature of the research, 15 individuals will be  
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45 194 recruited per intervention group to accommodate a 25% rate of attrition. The experimental  
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47 195 procedures for this study have been approved by the Australian Catholic University Human  
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49 196 Research Ethics Committee.

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## 199 **Clinical Measures**

200 Individuals who provide consent to participate in this study will be asked to attend an  
201 initial session at the Australian Catholic University (Brisbane) during which a series of  
202 baseline assessments to be performed. This battery of tests will include clinical assessments  
203 of: i) cognitive function (Addenbrooke's Cognitive Examination (ACE)<sup>[34]</sup>), ii) visual acuity  
204 (Bailey-Lovie high contrast visual acuity<sup>[35]</sup>), iii) disease severity (Unified Parkinson's  
205 Disease Rating Scale (UPDRS), the modified Hoehn & Yahr (H&Y) scale<sup>[36]</sup>, the Schwab &  
206 England Activities of Daily Living Scale<sup>[37]</sup> and the PD Gait and Falls Questionnaire (PD-  
207 GFQ)<sup>[38]</sup>), iv) fear of falling (Activity-specific Balance Confidence Scale<sup>[39]</sup>), v) mobility  
208 (Timed Up and Go<sup>[40]</sup>) and vi) quality of life (Parkinson's disease questionnaire 39 (PDQ-  
209 39)).<sup>[41]</sup> The PD-GFQ is a 16-item tool that assesses falls and the extent of any gait  
210 difficulties experienced by people with PD and incorporates 6 questions that are summed to  
211 give the freezing of gait (FOG) score.<sup>[37]</sup> The ACE was selected to assess cognitive function,  
212 as it incorporates the Mini Mental State Examination and has been shown to have high  
213 sensitivity and specificity for detecting dementia (cut-off <82 gives 82% sensitivity and  
214 100% specificity). The other assessments were selected as they have been shown to be both  
215 reliable and valid,<sup>[34 42-45]</sup> and have been used previously to assess individuals with PD.<sup>[18 46]</sup>

## 217 **Postural Stability Measures**

218 To evaluate dynamic postural stability, participants will be asked to walk along a 10  
219 m walkway at a comfortable self-selected pace for four trials and will be offered a rest break  
220 between trials to minimise the risk of fatigue. While completing this task, movement patterns  
221 of the head and trunk will be measured using two microelectromechanical system (MEMS)  
222 three-dimensional accelerometers (Noraxon Inc., Scottsdale, AZ) sampling at a rate of 500  
223 Hz. Prior to testing, the accelerometers will be statically calibrated using the methods

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2  
3 224 described previously.<sup>[47]</sup> Calibration involves aligning each sensing axis of the accelerometer  
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5 225 perpendicular to a horizontal surface to determine a conversion factor that describes  
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7 226 gravitational acceleration (1 gravitational unit or 1g). Following static calibration, an  
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10 227 accelerometer will be firmly attached over the occipital protuberance of the skull via a sport  
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12 228 headband and another will be attached directly to the skin using double-sided tape over the  
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14 229 spinous process of the 10<sup>th</sup> thoracic vertebra (T10). To detect gait events, such as heel strike  
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16 230 and toe off during the gait cycle, two pressure-sensitive footswitches (Noraxon Inc.,  
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18 231 Scottsdale, AZ) will be placed bilaterally under the calcaneus, the distal end of the first  
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21 232 phalange and the distal end of the first and fifth metatarsals of the foot.

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23 233 Static postural stability will be assessed while participants are standing quietly on a  
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25 234 portable force plate that is sampling data at an effective rate of 200 Hz (Advanced  
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27 235 Mechanical Technology Inc., USA). Participants will complete two 30 second trials that will  
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29 236 involve standing as still as possible for each of the following conditions: i) on a firm surface  
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31 237 with eyes open, ii) on a firm surface with eyes closed, iii) on a foam surface with eyes open  
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33 238 and iv) on a foam surface with eyes closed. Before commencement of each trial, participants  
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35 239 will be asked to look straight ahead at a cross that will be placed on the wall at eye level with  
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37 240 their arms resting at their sides and their feet 10 cm apart. Measurements derived from the  
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39 241 force plate data will include: peak RMS displacement of the centre of pressure (COP) and  
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41 242 postural sway velocity in the AP and ML directions.

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45 243 In addition to the acceleration profiles that will be collected for the head and trunk,  
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47 244 muscle activation patterns for the thoracic and lumbar erector spinae will be measured at  
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49 245 1500 Hz using a wireless Noraxon surface electromyography (EMG) system (Noraxon, Inc.,  
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51 246 Scottsdale, AZ). In healthy individuals, the erector spinae muscles show a phasic increase in  
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53 247 activation just after heel-contact to counter forward trunk flexion during walking.<sup>[48]</sup> The  
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55 248 erector spinae muscles were chosen for evaluation because individuals with PD are known to  
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3 249 have decreased trunk muscle performance than age-matched controls,<sup>[49]</sup> which may  
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5 250 influence their capacity to control trunk motion during walking. Prior to applying the surface  
6  
7 251 electrodes over the muscles of interest, the skin will be prepared with an abrasive gel  
8  
9  
10 252 (Nuprep; Weaver & Company, Aurora, CO), and then cleaned thoroughly with an isopropyl  
11  
12 253 alcohol wipe to minimise impedance at the electrode-skin interface and improve clarity of the  
13  
14 254 myoelectric signal.<sup>[50]</sup> For individuals with excessive hair over the muscles of interest, the  
15  
16 255 area will be shaved in order to maximise the fidelity of the myoelectric signal and ensure the  
17  
18 256 best possible adherence to the skin. After skin preparation, four pairs of Ag/AgCl pre-gelled  
19  
20 257 surface electrodes (AMBU Blue Sensor, Ballerup, DK; 34 mm diameter, 10 mm<sup>2</sup> sensing  
21  
22 258 area) will be placed with a centre-to-centre inter-electrode distance of 34 mm. Specifically,  
23  
24 259 these electrode pairs will be placed bilaterally 5 cm lateral to the spinous process of the T10  
25  
26  
27 260 vertebral body and 2 cm lateral to the spinous process of the 3<sup>rd</sup> lumbar (L3) vertebral  
28  
29  
30 261 body.<sup>[51]</sup>

31  
32 To facilitate comparisons between the different testing dates and the different  
33  
34 263 participant groups, the EMG data will be normalised to the muscle activity levels recorded  
35  
36 264 for the participants during a maximal voluntary contraction (MVC) of the erector spinae. To  
37  
38 265 perform the MVC, the participants will lie prone/prostrate on a padded table with their hips  
39  
40 266 flexed and their feet on the floor. The participant will then be asked to complete three  
41  
42 267 practice trials to learn the movement before performing three maximal efforts that involve  
43  
44 268 simultaneously extending both hips to raise the legs to a horizontal position to activate the  
45  
46 269 erector spinae muscle group. A restraining force will be applied to the legs of the participants  
47  
48 270 to make sure that their legs remain horizontal (180°) while performing the test to produce the  
49  
50 271 MVC. This method was chosen in preference to the traditional Biering-Sorensen test, due to  
51  
52 272 the potential difficulties that older participants may have with this movement.<sup>[51]</sup>  
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273 **Table 1:** The primary, secondary and tertiary outcomes measures and the time points at which they  
 274 will be assessed during the study

	Outcome Measures	Baseline (Week 0)	Post-Intervention (Week 12)	Final Assessment (Week 24)
<b>Primary Outcome Measure</b>				
<i>Dynamic Postural Stability</i>	Harmonic Ratio (AP, ML, VT)	X	X	X
<b>Secondary Outcome Measures</b>				
<i>Static Postural Stability</i>	Peak RMS Displacement (AP, ML)	X	X	X
	Sway Velocity (AP, ML)	X	X	X
<i>Bilateral Trunk Muscle Function</i>	Peak RMS activity (ES at T10 and L3 levels)	X	X	X
<b>Tertiary Outcome Measures</b>				
<i>Disease Severity</i>	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
<i>Other Variables</i>	Intervention Compliance	X	X	x
	Adverse Events	X	X	X
	Daily Levodopa Equivalents	X	X	X
<b>Screening Measures</b>				
<i>Cognitive Function</i>	Addenbrooke's Cognitive Exam	X		
<i>Visual Function</i>	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.

275

276 All data collection will be performed using the MyoResearch XP software to ensure  
 277 that the data from the different systems remain synchronised. Participants will be re-tested  
 278 using the assessments outlined above: i) after the 12-week intervention to establish the  
 279 immediate effects of the exercise program on postural stability and ii) 12-weeks after the  
 280 completion of the intervention to evaluate the retention of any benefits over the longer term  
 281 (i.e. 24-weeks following baseline). To ensure that participants are assessed under similar  
 282 conditions on each of the testing days, all procedures will be scheduled to start within 1 to 2  
 283 hours of the participants taking their medication to ensure they are optimally-medicated. The



1  
2  
3 284 battery of assessments and the time points at which they will be taken are summarised in  
4  
5 285 Table 1 and the flow of recruitment, data collection and follow-up procedures are outlined in  
6  
7 286 Figure 1.  
8  
9

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11 288

INSERT FIGURE 1 ABOUT HERE

12 289

### 13 290 **Data Analyses**

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17  
18 291 Data from the raw accelerations will be low-pass filtered using a bi-directional fourth  
19  
20  
21 292 order Butterworth filter with a cut-off frequency of 30 Hz.<sup>[52]</sup> Measurements derived from  
22  
23 293 the accelerometry data will include: i) peak acceleration (root mean square (RMS)) and ii)  
24  
25 294 harmonic ratio, both of which will be calculated for the AP, ML and vertical (VT) axes of the  
26  
27 295 head and trunk accelerometers separately. The harmonic ratio (HR) provides a measure of  
28  
29 296 the stability of gait-related accelerations by evaluating the stride-to-stride regularity of the  
30  
31 297 harmonics within the acceleration signals.<sup>[53]</sup> Walking patterns that produce higher HRs will  
32  
33 298 be characterised by more a more regular acceleration profile over successive gait cycles (i.e.  
34  
35 299 less stride-to-stride variability), hence, the gait pattern is deemed to be more stable.<sup>[54]</sup> The  
36  
37 300 HR has been used previously to evaluate dynamic postural instability in people with PD<sup>[18 33]</sup>  
38  
39 301 and will be used in this study to provide an indication of how well the movement patterns of  
40  
41 302 the head and trunk are controlled during normal gait.  
42  
43

44  
45 303 Raw EMG data will be high-pass filtered at 100 Hz to remove heart rate artefact from  
46  
47 304 the signal and then full-wave rectified and low-pass filtered (4<sup>th</sup> order Butterworth filter) at  
48  
49 305 20 Hz.<sup>[55]</sup> Following filtering of the data, peak RMS muscle activity throughout the gait  
50  
51 306 cycle will be calculated over a 50 ms<sup>[55]</sup> moving average window, with a 25 ms overlap.<sup>[51]</sup>  
52  
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54 307

55 308

**309 Randomisation and Blinding**

310 After completion of the baseline assessments, participants will be randomised using a  
311 computerised random number generator (block size=3) in a 1:1:1 ratio to one of the three  
312 intervention groups: i) exercise one day per week, ii) exercise three days per week or iii)  
313 education. To minimise the possibility of introducing issues related to inter-rater reliability  
314 and/or biasing the outcomes, the clinical assessments will be conducted by an individual who  
315 is trained to administer the tests, but who will not be involved with the recruitment and  
316 allocation of participants to intervention groups and will also be blinded to intervention  
317 status. Furthermore, another member of the research team responsible for processing and  
318 analysing the data related to the assessment of static and dynamic postural stability will  
319 recruit and assign participants to intervention groups, however will be blinded to the group  
320 allocation of the participants during data analysis.

321

**322 Intervention**

323 All participants assigned to these groups will receive a 10-15 minute one-off  
324 presentation outlining the evidence that supports exercise as an effective means of improving  
325 movement and postural stability in people with PD. Participants in the education group will  
326 be encouraged to continue their day-to-day lives, as usual, but will receive a weekly multi-  
327 disciplinary education package that will include a health tip that will explain how, for  
328 example, exercise, nutrition and/or sleep quality may influence their falls risk and quality of  
329 life. The education group represents what would normally be seen in everyday life, with the  
330 education brochures created from research and information provided freely to the community.

331 Participants assigned to the exercise groups will complete a low-level supervision, 12-  
332 week exercise program aimed at improving trunk mobility and endurance, which will involve  
333 one supervised session each week with a trained Exercise Scientist at the University. The

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2  
3 334 group exercising once per week will receive the intervention during the weekly supervised  
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5 335 session, while the group exercising three times per week will be asked to complete the  
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7 336 protocol at home on two other days of the week, for a total of three training days per week.  
8  
9  
10 337 The exercise program consists primarily of exercises previously used in two different  
11  
12 338 exercise-based intervention studies involving older adults<sup>[56]</sup> and people with PD.<sup>[57]</sup> It has  
13  
14 339 been designed to conform to the current recommendations for exercise-based interventions  
15  
16 340 for stability<sup>[27 30 58]</sup> and will progress in complexity to accommodate individuals with different  
17  
18 341 physical capabilities. The primary movements used for the program are outlined in Table 2.  
19  
20 342 Hold times for the endurance exercises begin at five seconds and repetitions begin at 10 or as  
21  
22 343 many as achievable by the participant. In addition, as the participant progresses in the  
23  
24 344 program, a round and flat air filled disc will be incorporated to create an unstable surface and  
25  
26 345 create a balance challenging environment during the exercises. For the walking portion of  
27  
28 346 the program, this will be completed on an outdoor walking path that specifically incorporates  
29  
30 347 varying degrees of incline and decline, stairs and multiple surface types to simulate walking  
31  
32 348 during activities of daily living. The various challenges offered by this walking course will  
33  
34 349 serve to improve the participants' capacity to safely and effectively ambulate in both  
35  
36 350 predictable and unstable real world environments.

37  
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39  
40 351 To facilitate monitoring of activity levels during the 12-week intervention and the 12-  
41  
42 352 week sustainability periods, all participants will be asked to record their weekly activity  
43  
44 353 levels using the International Physical Activity Questionnaire (IPAQ)<sup>[59]</sup> during these periods.  
45  
46 354 The IPAQ is a questionnaire that has been shown to be both a valid and reliable tool for  
47  
48 355 quantifying activity levels in different populations.<sup>[60 61]</sup> In addition, compliance to the  
49  
50 356 intervention protocol and any adverse events will also be monitored and reported by the  
51  
52 357 researchers.  
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359 **Table 2:** Summary of the specific tasks, repetitions and progressions for each of the exercises

Task	Movement	Repetitions/Progression
<b>Trunk Mobility Warm-up</b>	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
	<b>Trunk Endurance</b>	Abdominal Hollowing
Side Bridging		• Increased hold times
Front Bridging		• Movement complexity
Bird Dog		• Introduce unstable support surface
<b>Mobility</b>	Walking over surfaces of varying incline/decline, density and up and down stairs	8-10 minutes of walking on an outdoor walking path
	Walking	2 minutes (incline/decline)
<b>Active Cool down</b>	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

360

361 **Statistical Analysis**

362 Continuous data will first be checked for normal distribution and, where applicable,  
363 log transformation will be applied to the data. To assess for any significant differences  
364 between the groups with respect to the continuous demographic variables (e.g. age, height,  
365 weight,) a one way ANOVA will be used, while the Chi-square test will be used to identify  
366 any significant differences in the frequency of categorical data (e.g. gender, Hoehn & Yahr  
367 scale). If a significant difference is found from the ANOVA, the Tukey's honestly significant  
368 difference test will be used to perform post-hoc comparisons among the three groups. If the  
369 assumptions of normality (Shapiro-Wilks test) or homogeneity of variance (Levene's test) are  
370 still violated after log transformation, the non-parametric Kruskal-Wallis testing will replace  
371 the ANOVA. Analysis of the outcome measures for static and dynamic postural stability will



1  
2  
3 372 be based on intention to treat principles. To assess the acute (12 weeks) and long-term (24  
4  
5 373 weeks) effects of the intervention on measures of postural stability, a repeated measures  
6  
7 374 analysis of covariance (RM-ANCOVA) will be conducted, with the baseline value for each  
8  
9 375 outcome measure and disease severity entered as covariates. To determine covariates,  
10  
11 376 variables of age and disease severity will be graphed in relation to baseline measures of  
12  
13 377 postural stability to identify any linear relationships. All statistical analyses will be completed  
14  
15 378 in the Statistical Package for the Social Sciences (SPSS v21.0) and the level of significance  
16  
17 379 will be set at  $p < 0.05$ .  
18  
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## 22 381 **DISCUSSION**

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24  
25 382 For people with PD, the increased risk of falls and fall-related injuries has the  
26  
27 383 potential to significantly influence an individual's psychological, physiological and socio-  
28  
29 384 economic state; ultimately impacting their quality of life. Although oral medications are  
30  
31 385 known to improve many of the motor and non-motor symptoms associated with PD, late-  
32  
33 386 stage symptoms such as gait difficulties and postural instability are not always responsive to  
34  
35 387 this therapeutic intervention.<sup>[62]</sup> As postural instability and gait difficulties contribute  
36  
37 388 significantly to the high risk of falls in patients with PD, there is a strong need for further  
38  
39 389 research examining additional non-invasive interventions that target the improvement of  
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41 390 segmental control and postural alignment in this population.  
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45 391 To date, a number of studies have demonstrated that an exercise intervention can  
46  
47 392 improve strength<sup>[63 64]</sup>, measures of static postural stability<sup>[65]</sup> and motor symptoms<sup>[20 28 66]</sup> in  
48  
49 393 people with PD. In contrast, a separate study reported no significant improvements in self-  
50  
51 394 reported disability or clinical measures of balance, mobility or quality of life for people with  
52  
53 395 PD following a 6-week home-based exercise intervention.<sup>[21]</sup> Although these clinical tests  
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55 396 have been widely used to assess falls risk in people with PD, they may lack the sensitivity to  
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3 397 provide real insight into the falls risk of this population. Specifically, it has been shown that  
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5 398 the Tinetti Balance and Gait Assessment, Berg Balance Scale, Timed Up and Go, Functional  
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7 399 Reach and Physiological Profile Assessment (PPA) of falls risk achieve only moderate  
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9  
10 400 sensitivities (65-69%), specificities (62-69%) and accuracies (53-68%) when predicting  
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12 401 prospective falls for people with PD.<sup>[46]</sup> Continuous biomechanical measures, such as those  
13  
14 402 provided by force platforms and accelerometers may help to resolve this problem by  
15  
16 403 increasing the sensitivity of outcome measures to more accurately detect changes in motor  
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18 404 performance.

20  
21 405 From the perspective of maintaining balance, the trunk is believed to play an  
22  
23 406 important role in maintaining head stability during dynamic tasks. During walking, forces  
24  
25 407 are transmitted upwards from the feet following heel contact, which requires the legs, trunk  
26  
27 408 and neck to act as shock absorbers to attenuate the load and maintain smooth movement  
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29 409 patterns for the head.<sup>[16]</sup> However, individuals with PD are known to have deficits in trunk  
30  
31 410 control and trunk muscle function<sup>[49]</sup>, which may impair their capacity to perform this role  
32  
33 411 and increase their risk of falling. The findings of previous research tend to support this  
34  
35 412 notion, indicating that people with PD who fall have greater ML head movement while  
36  
37 413 walking on firm<sup>[7]</sup> and compliant<sup>[19]</sup> surfaces and poorer pelvic control<sup>[18]</sup> during  
38  
39 414 unconstrained gait. As such, interventions aimed at improving trunk muscle functioning may  
40  
41 415 help to improve postural stability and reduce falls for individuals with PD.

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43 416 The intervention for this study was specifically developed to achieve this goal and  
44  
45 417 will incorporate a series of safe and progressive exercises that were adapted from two  
46  
47 418 previous studies examining the effects of exercise on balance and trunk muscle performance.  
48  
49 419 The findings of these studies demonstrated that progressive exercises targeting improvements  
50  
51 420 in the function of the deeper trunk muscles were effective in improving clinical measures of  
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53 421 balance in older women who were at a high risk of falling.<sup>[56]</sup> Similar exercises, when  
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3 422 combined with aerobic exercises and stretching, were shown to significantly improve the  
4  
5 423 strength and mobility of the trunk muscles in individuals with PD, but the authors did not  
6  
7 424 report whether these improvements were associated with any changes in postural stability.<sup>[57]</sup>  
8

9  
10 425 Separate studies have provided evidence to suggest that regular exercise has the  
11  
12 426 potential to reduce the risk of falling in people with PD<sup>[20]</sup> and may even help to reduce the  
13  
14 427 number of falls experienced by some individuals.<sup>[21]</sup> This study will be the first to examine  
15  
16 428 whether a 12-week training program aimed at improving trunk mobility and endurance has  
17  
18 429 the potential to improve continuous measures of static and dynamic postural stability in this  
19  
20 430 population. If found to be effective, this training program will provide a safe and inexpensive  
21  
22 431 exercised-based therapy option that will help to maintain and/or improve postural stability  
23  
24 432 and ultimately contribute to improving quality of life for people with Parkinson's disease.  
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#### 29 434 **LIST OF ABBREVIATIONS USED**

30  
31 435 ANOVA = analysis of variance

32  
33 436 AP = anterior-posterior

34  
35 437 COP = centre of pressure

36  
37 438 EMG = electromyography

38  
39 439 H&Y = Hoehn & Yahr scale

40  
41 440 IPAQ = International Physical Activity Questionnaire

42  
43 441 MEMS = microelectromechanical system

44  
45 442 ML = medial-lateral

46  
47 443 MVC = maximal voluntary contract

48  
49 444 PD = Parkinson's disease

50  
51 445 RM-ANCOVA = repeated measures analysis of covariance

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53 446 RMS = root mean square  
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3 447 UPDRS = Unified Parkinson's Disease Rating Scale

4  
5 448 VT = vertical

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10 **450 COMPETING INTERESTS**

11 451 None

12  
13 452

14  
15  
16 **453 AUTHORS' CONTRIBUTIONS**

17  
18 454 RPH and MHC designed the study, obtained funding, and completed extensive preparation to

19  
20 455 develop the study protocol. MHC will oversee the execution of the study and will be

21  
22 456 responsible for administering the clinical tests and assisting with recruitment of participants.

23  
24 457 RPH will be responsible for the day-to-day management of the study, data collection, data

25  
26 458 analysis, and interpretation of the findings. GAN provided important assistance with the

27  
28 459 development of the study protocol and will be responsible for participant allocation. PAS

29  
30 460 will be involved in assisting with participant recruitment and with the interpretation of the

31  
32 461 clinical relevance of the study's outcomes. RPH and MHC developed the initial draft of this

33  
34 462 manuscript and all authors contributed to the refinement and finalisation of the submitted

35  
36 463 manuscript.

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42 **465 AUTHORS' INFORMATION**

43 466 None

44  
45 467

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49  
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51  
52 470 The funding body played no role in the study design, and will not contribute to data

53  
54 471 collection, analysis, decision to publish or preparation of any manuscripts.

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3 4724  
5 473 **ENDNOTES**6  
7 474 None8  
9 47510  
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3 659 **Figure Legend**

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5 660 Title: Study outline

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7 661 **Figure 1:** Flow chart depicting the order of recruitment and testing procedures for the

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10 662 outlined study.  
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# BMJ Open

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

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3 1 Title: Trunk muscle exercises as a means of improving postural stability in people  
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5 2 with Parkinson's disease: a protocol for a randomised-controlled trial  
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56 25 Word Count: 4850 words  
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3 26 **ABSTRACT**  
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5 27 **Background:** Exercise has been shown to improve clinical measures of strength, balance  
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7 28 and mobility, and in some cases, has improved symptoms of tremor and rigidity in people  
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9 29 with Parkinson's disease (PD). However, to date, no research has examined whether  
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11 30 improvements in trunk control can remedy deficits in dynamic postural stability in this  
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13 31 population. The proposed randomised-controlled trial aims to establish whether a 12-week  
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15 32 exercise program aimed at improving dynamic postural stability in people with PD; i) is more  
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17 33 effective than education; ii) is more effective when training frequency is increased; and iii)  
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19 34 provides greater long-term benefits than education.  
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25 36 **Methods/Design:** Forty-five community-dwelling individuals diagnosed with idiopathic PD  
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27 37 with a falls history will be recruited. Participants will complete baseline assessments  
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29 38 including tests of cognition, vision, disease severity, fear of falling, mobility and quality of  
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31 39 life. Additionally, participants will complete a series of standing balance tasks to evaluate  
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33 40 static postural stability, while dynamic postural control will be measured during walking  
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35 41 using head and trunk-mounted three-dimensional accelerometers. Following baseline testing,  
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37 42 participants will be randomly-assigned to one of three intervention groups, who will receive  
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39 43 either exercise once per week, exercise three days per week, or education. Participants will  
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41 44 repeat the same battery of tests conducted at baseline after the 12-week intervention and  
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43 45 again following a further 12-week sustainability period.  
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49 47 **Discussion:** This study has the potential to show that low-intensity and progressive trunk  
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51 48 exercises can provide a non-invasive and effective means for maintaining or improving  
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53 49 postural stability for people with Parkinson's disease. Importantly, if the program is noted to  
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3 50 be effective, it could be easily performed by patients within their home environment or under  
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5 51 the guidance of available allied health professionals.  
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10 53 **Trial registration:** The protocol for this study is registered with the Australian New Zealand  
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12 54 Clinical Trials Registry (ACTRN12613001175763).  
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17 56 Strengths and Limitations to this study:

- 18 57 • This study has been designed as a randomised controlled trial, which is currently  
19 58 considered the best methodological approach for evaluating the efficacy of a specific  
20 59 intervention.  
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22 61 • The proposed study will be the first to assess whether dynamic postural stability  
23 62 during walking can be improved or maintained in people with Parkinson's disease  
24 63 who regularly perform specific exercises to improve trunk mobility and endurance.  
25 64  
26 65 • This study seeks to assess changes in static and dynamic balance using continuous  
27 66 measures rather than graded clinical tests that are based on Likert scales, as these may  
28 67 be more sensitive for detecting improvements in postural stability for this patient  
29 68 group.  
30 69  
31 70 • While it would be important to examine whether improvements in postural stability  
32 71 are associated with a reduction in falls, the large sample size required to achieve this  
33 72 goal (approximately 120 participants per group) is prohibitive.  
34 73  
35 74 • Due to the nature of the chosen intervention, the findings may only be applicable to  
36 75 patients who experience mild to moderate symptoms and are healthy enough to  
37 76 perform the exercises. As such, alternate interventions may be necessary for  
38 77 individuals who present with more advanced symptoms.  
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56 83 **Keywords:** Parkinson, Posture, Exercise, Stability, Acceleration  
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## 84 INTRODUCTION

85 Prospective studies indicate that the incidence of falls are much greater for people with PD  
86 than for age-matched controls, with up to 68% of people with PD falling at least once each  
87 year and up to 50% of these individuals experiencing recurrent falls.<sup>[1, 2]</sup> The increased falls  
88 risk in this population is compounded by an increased risk of injury, as differences in the  
89 postural responses of people with PD place them at a greater risk of sustaining a significant  
90 fall-related injury than age-matched controls.<sup>[3]</sup> Falls and fall-related injuries often lead to a  
91 fear of falling, reduced mobility, poorer muscle strength and loss of independence, all of  
92 which ultimately influence an individual's mortality, morbidity and quality of life.<sup>[4]</sup>

93 Biomechanical research involving healthy younger adults<sup>[5]</sup> has shown that the trunk segment  
94 plays an important role in modulating gait-related oscillations and maintaining head stability;  
95 an important goal of the human postural control system. However, the increased axial rigidity  
96 that is evident in people with PD<sup>[6]</sup> significantly impairs the trunk's capacity to attenuate  
97 these movement-related forces, which inadvertently reduces head stability and impairs the  
98 clarity of the visual and vestibular information used in balance control. In the early stages of  
99 the disease, the symptoms of PD are typically managed using any number of anti-  
100 parkinsonian medications. However, these medications are unfortunately not always  
101 effective at improving symptoms of axial rigidity<sup>[6]</sup> and often lead to undesirable side effects  
102 including dopamine-induced dyskinesias or motor fluctuations that have the potential to  
103 increase the risk of falls in people with PD. As such, there is a clear need for alternative  
104 therapies that can be easily implemented, have low running costs and have the potential to  
105 improve postural control, segmental mobility and falls risk in this population.

106 It is important for individuals to be able to effectively control their body's segments to  
107 maintain postural stability and limit the risk of falling during both static and dynamic  
108 activities of daily living. Older adults demonstrate poorer postural stability during tasks

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3 109 requiring dynamic postural control (e.g. walking and turning), which can place them at an  
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5 110 increased risk of falling.<sup>[7]</sup> Age-related declines in dynamic postural control may be further  
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7 111 exacerbated with the presence of PD, which would exacerbate the decreased balance and  
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9 112 higher falls rate evident in this population.<sup>[1, 8, 9]</sup>

113         Given that the head and trunk comprise 60% of the overall mass of the body,<sup>[10]</sup> it  
114 seems reasonable to suggest that one's ability to precisely coordinate trunk movements would  
115 contribute significantly to attenuating movement-related oscillations and maintaining postural  
116 stability during these activities. An examination of segmental stability for different regions  
117 of the upper body in a healthy population showed that trunk movements were smaller than  
118 those of the head and neck during walking.<sup>[11]</sup> However, separate research suggests that the  
119 trunk has a more irregular movement pattern than the head during gait.<sup>[5]</sup> The authors argued  
120 that the trunk may serve to attenuate forces during dynamic tasks to stabilize the head, and  
121 preserve the quality of the visual and vestibular feedback required for postural control. If an  
122 individual has increased axial rigidity<sup>[6]</sup> and is unable to adequately control the trunk segment  
123 during dynamic tasks, then the exaggerated movements of the trunk may have a direct impact  
124 on head stability and overall balance.

125         A common method used to evaluate head and trunk stability during dynamic tasks is  
126 the harmonic ratio (HR), which provides a measure of the stability of gait-related  
127 accelerations by evaluating the stride-to-stride regularity of the harmonics within the  
128 acceleration signal.<sup>[12]</sup> Walking patterns that produce higher HRs will be characterised by a  
129 more regular acceleration profile over successive gait cycles (i.e. less stride-to-stride  
130 variability); hence, the gait pattern is deemed to be more stable.<sup>[13]</sup> People with PD who fall  
131 are known to have increased medial-lateral (ML) and anterior-posterior (AP) movements of  
132 the trunk during sitting<sup>[14]</sup>, less regular pelvic movements (lower HRs)<sup>[15]</sup> and increased ML  
133 head movement during gait.<sup>[1, 16]</sup> Collectively, these studies suggest that some of the falls



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3 134 experienced by people with PD may be related to a reduced capacity for these individuals to  
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5 135 adequately coordinate the body's segments during dynamic tasks. As such, there is a clear  
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7 136 need to evaluate the efficacy of different non-invasive interventions aimed at maintaining  
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10 137 and/or improving trunk mobility and control to improve postural stability in this population.  
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12 138 To date, few studies have investigated the efficacy of different non-invasive methods for  
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14 139 improving balance and reducing falls risk in this high-risk population.<sup>[17-21]</sup>

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17 140 It is widely recognised that exercise is an effective means of maintaining or  
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19 141 improving cardiovascular and musculoskeletal health, both of which are critical for  
20  
21 142 preserving physiological functioning and independence. Furthermore, some modes of  
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23 143 exercise have been shown to be effective at improving standing balance<sup>[22, 23]</sup>, symptoms of  
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25 144 anxiety and depression<sup>[24, 25]</sup> and reducing fall rates<sup>[26]</sup> and risk of falling<sup>[22, 27]</sup> in otherwise  
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27 145 healthy individuals. A number of previous studies have also provided evidence to support the  
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29 146 short-term benefits of exercise for improving clinical measures of mobility<sup>[15, 17, 28-30]</sup>,  
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31 147 postural stability<sup>[15, 17, 28-30]</sup>, quality of life<sup>[31]</sup>, cognitive function<sup>[31, 32]</sup> and symptom severity  
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33 148 in people with PD.<sup>[29, 30]</sup> Current evidence suggests that when programs include more  
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35 149 challenging balance exercises, they may offer greater benefits for balance and mobility.<sup>[17]</sup>  
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37 150 For example, tai chi is a specific form of exercise known to challenge the balance system.  
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39 151 Previous research has shown tai chi can improve measures of static postural stability in  
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41 152 people with PD.<sup>[33]</sup> However, it is important to note that the results of a recent systematic  
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43 153 review suggest that other forms of exercise may also provide similar benefits to balance in  
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45 154 this population<sup>[34]</sup>.

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49 155 While this systematic evidence supports that exercise improves clinical measures of  
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51 156 balance, mobility and disease severity, many of the improvements did not achieve a level that  
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53 157 would be considered a minimally clinically important change. Furthermore, most of the  
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55 158 balance and mobility assessments used in previous studies have relied on Likert scales to  
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3 159 assess function, which may limit their ability to discriminate between people with PD who  
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5 160 fall and those who do not. As such, it is possible that the incorporation of biomechanical  
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7 161 measures of dynamic postural stability may improve our capacity to accurately detect  
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10 162 improvements or declines in balance for this population, which would facilitate better  
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12 163 identification of patients who are at a higher risk of falling. However, the investigators are  
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14 164 unaware of any previous research that has investigated whether exercise can improve  
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16 165 quantitative measures of dynamic postural stability in people with PD. A possible explanation  
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18 166 for this may be that such a study would require the use of complex measuring equipment that  
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20 167 is typically only available in a laboratory setting, making it a higher order of investigation  
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22 168 and difficult to assess in a clinical environment.

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25 169 As such, the proposed randomised-controlled trial aims to establish whether a 12-  
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27 170 week exercise program aimed at improving dynamic postural stability in people with PD; i) is  
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29 171 more effective than education; ii) is more effective when training frequency is increased; and  
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31 172 iii) provides greater long-term benefits than education. It is hypothesized that the both  
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33 173 exercise programs will improve dynamic postural stability more than education, however  
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35 174 training at an increased frequency will yield better improvements for the people with PD.  
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## 176 **METHODS**

177 The proposed randomized-controlled trial will be conducted in 2014/2015 and seeks  
178 to improve the mobility and endurance of the trunk and its supporting musculature. This  
179 study protocol was developed in accordance with the Consolidated Standards of Reporting  
180 Trials (CONSORT) guidelines.<sup>[35]</sup>

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### 182 **Participants**

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3 183 Forty-five participants diagnosed with idiopathic PD, based on the UK Brain Bank  
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5 184 Criteria<sup>[36]</sup> and who have a history of two or more near-misses and/or one fall or more in the  
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7 185 previous 12 months will be recruited from: i) neurology clinics, ii) community support  
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10 186 groups, iii) and a pre-existing database of people with PD who have expressed an interest in  
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12 187 participating in research. Prospective participants will be sent an information letter outlining  
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14 188 the details of the study and inviting them to contact a member of the research team if they are  
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16 189 interested in participating in the research. Upon contacting a member of the research team,  
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18 190 prospective participants will be screened to ensure that they are meet the requirements of the  
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20 191 study and, if they are deemed eligible for inclusion, a time will be scheduled to conduct the  
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22 192 baseline assessments. Participants will be excluded if they: i) are unable to stand and walk  
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24 193 independently without the use of a walking aid, ii) have any significant visual (Bailey-Lovie  
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26 194 high contrast visual acuity > 0.30 logMAR) or cognitive impairment (Addenbrooke's  
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28 195 cognition examination score <82), iii) have uncontrolled hypertension, iv) are taking  
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30 196 psychotropic medications, v) have any significant limitations due to osteoporosis, vi) have  
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32 197 had any orthopaedic surgery within the previous year, vii) have any serious neck, shoulder or  
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34 198 back injuries; including spinal fusions, or viii) have received deep brain stimulation surgery  
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36 199 to manage their symptoms. For the purposes of this study, a fall will be defined as "any  
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38 200 coming to the ground or lower level not as the result of a major intrinsic event or  
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40 201 overwhelming hazard" and a near miss will be defined as "an event on which an individual  
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42 202 felt that they were going to fall but did not actually do so".<sup>[18]</sup> All volunteers will be asked to  
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44 203 provide written informed consent in accordance with the Declaration of Helsinki prior to  
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46 204 participation in the study.  
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52 205 To determine a suitable sample size, a power calculation was completed based on the  
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54 206 harmonic ratio, the primary measure of this study. The sample size was calculated using  
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56 207 medio-lateral head accelerations from a previous study that assessed differences in dynamic  
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208 postural stability in PD compared with healthy controls using the harmonic ratio.<sup>[37]</sup> On the  
209 basis of this calculation, it was concluded that a minimum of 11 participants per group is  
210 needed to confidently report any significant changes in dynamic postural stability (diff =  
211 0.05, SD = 0.04, Cohen's d = 1.25, Power = 80%, p = 0.05). Given the longitudinal nature of  
212 the research, 15 individuals will be recruited per intervention group to accommodate a 25%  
213 rate of attrition. The experimental procedures for this study have been approved by the  
214 Australian Catholic University Human Research Ethics Committee. To ensure participants  
215 are assessed under similar conditions during each testing session, all procedures will be  
216 scheduled to start within 1 to 2 hours of the participants taking their medication. This will  
217 ensure the participants are comfortable and safe during the assessments and that the results  
218 are representative of how the individuals might perform such tasks in the real world.

## 220 Clinical Measures

221 Individuals who provide consent to participate in this study will be asked to attend an  
222 initial session at the Australian Catholic University (Brisbane) during which a series of  
223 baseline assessments to be performed. This battery of tests will include clinical assessments  
224 of: i) cognitive function (Addenbrooke's Cognitive Examination (ACE)<sup>[38]</sup>), ii) visual acuity  
225 (Bailey-Lovie high contrast visual acuity<sup>[39]</sup>), iii) disease severity (Unified Parkinson's  
226 Disease Rating Scale (UPDRS), the modified Hoehn & Yahr (H&Y) scale<sup>[40]</sup>, the Schwab &  
227 England Activities of Daily Living Scale<sup>[41]</sup> and the PD Gait and Falls Questionnaire (PD-  
228 GFQ)<sup>[42]</sup>), iv) fear of falling (Activity-specific Balance Confidence Scale<sup>[43]</sup>), v) mobility  
229 (Timed Up and Go<sup>[44]</sup>) and vi) quality of life (Parkinson's disease questionnaire 39 (PDQ-  
230 39)).<sup>[45]</sup> The PD-GFQ is a 16-item tool that assesses the extent of any falls and gait  
231 difficulties experienced by people with PD and incorporates 6 questions that are summed to  
232 give the freezing of gait (FOG) score.<sup>[42]</sup> The ACE was selected to assess cognitive function,

233 as it incorporates the Mini Mental State Examination and has been shown to have high  
234 sensitivity and specificity for detecting dementia (cut-off <82 gives 82% sensitivity and  
235 100% specificity). The other assessments were selected as they have been shown to be both  
236 reliable and valid,<sup>[38, 46-49]</sup> and have been used previously to assess individuals with PD.<sup>[15, 50]</sup>

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### 238 **Postural Stability Measures**

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

254 Static postural stability will be assessed while participants are standing quietly on a  
255 portable force plate that is sampling data at an effective rate of 200 Hz (Advanced  
256 Mechanical Technology Inc., USA). Participants will complete two 30 second trials that will  
257 involve standing as still as possible for each of the following conditions: i) on a firm surface



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2  
3 258 with eyes open, ii) on a firm surface with eyes closed, iii) on a foam surface with eyes open  
4  
5 259 and iv) on a foam surface with eyes closed. Before commencement of each trial, participants  
6  
7 260 will be asked to look straight ahead at a cross that will be placed on the wall at eye level with  
8  
9 261 their arms resting at their sides and their feet 10 cm apart. Measurements derived from the  
10  
11 262 force plate data will include: peak RMS displacement of the centre of pressure (COP) and  
12  
13 263 postural sway velocity in the AP and ML directions.

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15  
16 264 In addition to the acceleration profiles that will be collected for the head and trunk,  
17  
18 265 muscle activation patterns for the thoracic and lumbar erector spinae will be measured at  
19  
20 266 1500 Hz using a wireless Noraxon surface electromyography (EMG) system (Noraxon, Inc.,  
21  
22 267 Scottsdale, AZ). In healthy individuals, the erector spinae muscles show a phasic increase in  
23  
24 268 activation just after heel-contact to counter forward trunk flexion during walking.<sup>[52]</sup> The  
25  
26 269 erector spinae muscles were chosen for evaluation because individuals with PD are known to  
27  
28 270 have decreased trunk muscle performance than age-matched controls,<sup>[53]</sup> which may  
29  
30 271 influence their capacity to control trunk motion during walking. Prior to applying the surface  
31  
32 272 electrodes over the muscles of interest, the skin will be prepared with an abrasive gel  
33  
34 273 (Nuprep; Weaver & Company, Aurora, CO), and then cleaned thoroughly with an isopropyl  
35  
36 274 alcohol wipe to minimise impedance at the electrode-skin interface and improve clarity of the  
37  
38 275 myoelectric signal.<sup>[54]</sup> For individuals with excessive hair over the muscles of interest, the  
39  
40 276 area will be shaved in order to maximise the fidelity of the myoelectric signal and ensure the  
41  
42 277 best possible adherence to the skin. After skin preparation, four pairs of Ag/AgCl pre-gelled  
43  
44 278 surface electrodes (AMBU Blue Sensor, Ballerup, DK; 34 mm diameter, 10 mm<sup>2</sup> sensing  
45  
46 279 area) will be placed with a centre-to-centre inter-electrode distance of 34 mm. Specifically,  
47  
48 280 these electrode pairs will be placed bilaterally 5 cm lateral to the spinous process of the T10  
49  
50 281 vertebral body and 2 cm lateral to the spinous process of the 3<sup>rd</sup> lumbar (L3) vertebral  
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52 282 body.<sup>[55]</sup>  
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283 To facilitate comparisons between the different testing dates and the different  
 284 participant groups, the EMG data will be normalised to the muscle activity levels recorded  
 285 for the participants during a maximal voluntary contraction (MVC) of the erector spinae. To  
 286 perform the MVC, the participants will lie prone/prostrate on a padded table with their hips  
 287 flexed and their feet on the floor. The participant will then be asked to complete three  
 288 practice trials to learn the movement before performing three maximal efforts that involve  
 289 simultaneously extending both hips to raise the legs to a horizontal position to activate the  
 290 erector spinae muscle group. A restraining force will be applied to the legs of the participants  
 291 to make sure that their legs remain horizontal (180°) while performing the test to produce the  
 292 MVC. This method was chosen in preference to the traditional Biering-Sorensen test, due to  
 293 the potential difficulties that older participants may have with this movement.<sup>[55]</sup>  
 294 **Table 1:** The primary, secondary and tertiary outcomes measures and the time points at which they  
 295 will be assessed during the study

	Outcome Measures	Baseline (Week 0)	Post-Intervention (Week 12)	Final Assessment (Week 24)
<b>Primary Outcome Measure</b>				
<i>Dynamic Postural Stability</i>	Harmonic Ratio (AP, ML, VT)	X	X	X
<b>Secondary Outcome Measures</b>				
<i>Static Postural Stability</i>	Peak RMS Displacement (AP, ML)	X	X	X
	Sway Velocity (AP, ML)	X	X	X
<i>Bilateral Trunk Muscle Function</i>	Peak RMS activity (ES at T10 and L3 levels)	X	X	X
<b>Tertiary Outcome Measures</b>				
<i>Disease Severity</i>	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
<i>Other Variables</i>	Intervention Compliance	X	X	x
	Adverse Events	X	X	X
	Daily Levodopa Equivalents	X	X	X
	International Physical Activity Questionnaire		X	X

**Screening Measures**

<i>Cognitive Function</i>	Addenbrooke's Cognitive Exam	X
<i>Visual Function</i>	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.

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**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.<sup>[56]</sup> 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<sup>[15, 37]</sup> 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.

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3 317 Raw EMG data will be high-pass filtered at 100 Hz to remove heart rate artefact from  
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5 318 the signal and then full-wave rectified and low-pass filtered (4<sup>th</sup> order Butterworth filter) at  
6  
7 319 20 Hz.<sup>[57]</sup> Following filtering of the data, the RMS of the muscle activity throughout the  
8  
9 320 walking trials will be calculated over a 50 ms<sup>[57]</sup> moving average window, with a 25 ms  
10  
11 321 overlap.<sup>[55]</sup> To facilitate comparisons between participants and across testing days, the  
12  
13 322 activation levels of the trunk muscles will be normalised to the peak RMS amplitude of the  
14  
15 323 muscle activity recorded during the MVC trials. The peak normalised RMS muscle activities  
16  
17 324 derived from three complete gait cycles for each leg from each of the four trials (n = 12 gait  
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19 325 cycles per leg) will then be averaged and these data will be used for all subsequent analyses.  
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### 327 **Randomisation and Blinding**

27 328 After completion of the baseline assessments, participants will be randomised using a  
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29 329 computerised random number generator (block size=3) in a 1:1:1 ratio to one of the three  
30  
31 330 intervention groups: i) exercise one day per week, ii) exercise three days per week or iii)  
32  
33 331 education. To minimise the possibility of introducing issues related to inter-rater reliability  
34  
35 332 and/or biasing the outcomes, the clinical assessments will be conducted by an individual who  
36  
37 333 is trained to administer the tests, but who will not be involved with the recruitment and  
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39 334 allocation of participants to intervention groups and will also be blinded to intervention  
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41 335 status. Furthermore, another member of the research team responsible for processing and  
42  
43 336 analysing the data related to the assessment of static and dynamic postural stability will  
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45 337 recruit and assign participants to intervention groups, however will be blinded to the group  
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47 338 allocation of the participants during data analysis.  
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### 340 **Intervention**

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3 341 At baseline, all participants will receive a 10-15 minute one-off presentation outlining  
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5 342 the evidence that supports exercise as an effective means of improving movement and  
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7 343 postural stability in people with PD. Participants in the education group will be encouraged  
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9  
10 344 to continue their day-to-day lives, as usual, but will receive a weekly multi-disciplinary  
11  
12 345 education package that will include a health tip that will explain how, for example, exercise,  
13  
14 346 nutrition and/or sleep quality may influence their falls risk and quality of life. The education  
15  
16 347 group represents what would normally be seen in everyday life, with the education brochures  
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18 348 created using scientific evidence drawn from pre-existing research and freely-available  
19  
20 349 information sheets produced by government and not-for-profit organisations.  
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23 350 Participants assigned to the exercise groups will complete a low-level supervision, 12-  
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25 351 week exercise program aimed at improving trunk mobility and endurance, which will involve  
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27 352 one supervised session each week with a trained Exercise Scientist at the University. The  
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29 353 group exercising once per week will receive the intervention during the weekly supervised  
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31 354 session, while the group exercising three times per week will be asked to complete the  
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33 355 protocol at home on two other days of the week, for a total of three training days per week.  
34  
35 356 The exercise program consists primarily of exercises that have previously been used in two  
36  
37 357 different exercise-based interventions involving older adults<sup>[58]</sup> and people with PD,<sup>[59]</sup> that  
38  
39 358 focused on improving trunk muscle strength and endurance. Importantly, the program was  
40  
41 359 designed to conform to the current recommendations for best clinical practice with respect to  
42  
43 360 the implementation of exercise-based interventions for improving postural stability.<sup>[27, 33, 60]</sup>  
44  
45 361 Specifically, the program includes movements focussing on improving trunk mobility,  
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47 362 exercises that target muscular strength and endurance, tasks that aim to develop balance  
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49 363 under challenging situations (i.e. on an unstable surface) and ambulating over different  
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51 364 terrains in a real-world environment. The program will progress in complexity to  
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53 365 accommodate individuals with different physical capabilities. The primary movements used  
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366 for the program are outlined in Table 2. Hold times for the endurance exercises begin at five  
 367 seconds and repetitions begin at 10 or as many as achievable by the participant. In addition,  
 368 as the participant progresses in the program, a round and flat air filled disc will be  
 369 incorporated to create an unstable surface and create a balance challenging environment  
 370 during the exercises. For the walking portion of the program, this will be completed on an  
 371 outdoor walking path that specifically incorporates varying degrees of incline and decline,  
 372 stairs and multiple surface types to simulate walking during activities of daily living. The  
 373 various challenges offered by this walking course will serve to improve the participants'  
 374 capacity to safely and effectively ambulate in both predictable and unstable real world  
 375 environments.

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

383  
 384 **Table 2:** Summary of the specific tasks, repetitions and progressions for each of the exercises

Task	Movement	Repetitions/Progression
<b>Trunk Mobility Warm-up</b>	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



<b>Trunk Endurance</b>	Abdominal Hollowing Side Bridging Front Bridging Bird Dog	Increase difficulty of exercise by: <ul style="list-style-type: none"> <li>• Increased hold times</li> <li>• Movement complexity</li> <li>• Introduce unstable support surface</li> </ul>
<b>Mobility</b>	Walking over surfaces of varying incline/decline, density and up and down stairs	8-10 minutes of walking on an outdoor walking path
<b>Active Cool down</b>	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

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386 **Statistical Analysis**

387 Continuous data will first be checked for normal distribution and, where applicable,  
388 log transformation will be applied to the data. To assess for any significant differences  
389 between the groups with respect to the continuous demographic variables (e.g. age, height,  
390 weight,) a one way ANOVA will be used, while the Chi-square test will be used to identify  
391 any significant differences in the frequency of categorical data (e.g. gender, Hoehn & Yahr  
392 scale). If a significant difference is found from the ANOVA, the Tukey's honestly significant  
393 difference test will be used to perform post-hoc comparisons among the three groups. If the  
394 assumptions of normality (Shapiro-Wilks test) or homogeneity of variance (Levene's test) are  
395 still violated after log transformation, the non-parametric Kruskal-Wallis testing will replace  
396 the ANOVA. Analysis of the outcome measures for static and dynamic postural stability will  
397 be based on intention to treat principles. To assess the acute (12 weeks) and long-term (24  
398 weeks) effects of the intervention on measures of postural stability, a repeated measures  
399 analysis of covariance (RM-ANCOVA) will be conducted, with the baseline value for each  
400 outcome measure and disease severity entered as covariates. To determine covariates,  
401 variables of age and disease severity will be graphed in relation to baseline measures of  
402 postural stability to identify any linear relationships. All statistical analyses will be completed

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3 403 in the Statistical Package for the Social Sciences (SPSS v21.0) and the level of significance  
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5 404 will be set at  $p < 0.05$ .

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## 8 9 406 **DISCUSSION**

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11 407 For people with PD, the increased risk of falls and fall-related injuries has the  
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13 408 potential to significantly influence an individual's psychological, physiological and socio-  
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15 409 economic state; ultimately impacting their quality of life. Although oral medications are  
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17 410 known to improve many of the motor and non-motor symptoms associated with PD, late-  
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19 411 stage symptoms such as gait difficulties and postural instability are not always responsive to  
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21 412 this therapeutic intervention.<sup>[64]</sup> As postural instability and gait difficulties contribute  
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23 413 significantly to the high risk of falls in patients with PD, there is a strong need for further  
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25 414 research examining additional non-invasive interventions that target the improvement of  
26  
27 415 segmental control and postural alignment in this population.

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29 416 To date, a number of studies have demonstrated that an exercise intervention can  
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31 417 improve strength<sup>[65, 66]</sup>, measures of static postural stability<sup>[67]</sup> and motor symptoms<sup>[17, 28, 68]</sup> in  
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33 418 people with PD. In contrast, a separate study reported no significant improvements in self-  
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35 419 reported disability or clinical measures of balance, mobility or quality of life for people with  
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37 420 PD following a 6-week home-based exercise intervention.<sup>[18]</sup> Although these clinical tests  
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39 421 have been widely used to assess falls risk in people with PD, they may lack the sensitivity to  
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41 422 provide real insight into the falls risk of this population. Specifically, it has been shown that  
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43 423 the Tinetti Balance and Gait Assessment, Berg Balance Scale, Timed Up and Go, Functional  
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45 424 Reach and Physiological Profile Assessment (PPA) of falls risk achieve only moderate  
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47 425 sensitivities (65-69%), specificities (62-69%) and accuracies (53-68%) when predicting  
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49 426 prospective falls for people with PD.<sup>[50]</sup> Continuous biomechanical measures, such as those  
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51 427 provided by force platforms and accelerometers may help to resolve this problem by  
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3 428 increasing the sensitivity of outcome measures to more accurately detect changes in motor  
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5 429 performance.  
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7 430 From the perspective of maintaining balance, the trunk is believed to play an  
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9 431 important role in maintaining head stability during dynamic tasks. During walking, forces  
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11 432 are transmitted upwards from the feet following heel contact, which requires the legs, trunk  
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13 433 and neck to act as shock absorbers to attenuate the load and maintain smooth movement  
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15 434 patterns for the head.<sup>[5]</sup> However, individuals with PD are known to have deficits in trunk  
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17 435 control and trunk muscle function<sup>[53]</sup>, which may impair their capacity to perform this role  
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19 436 and increase their risk of falling. The findings of previous research tend to support this  
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21 437 notion, indicating that people with PD who fall have greater ML head movement while  
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23 438 walking on firm<sup>[1]</sup> and compliant<sup>[16]</sup> surfaces and poorer pelvic control<sup>[15]</sup> during  
24  
25 439 unconstrained gait. As such, interventions aimed at improving trunk muscle functioning may  
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27 440 help to improve postural stability and reduce falls for individuals with PD.  
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32 441 The intervention for this study was specifically developed to achieve this goal and  
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34 442 will incorporate a series of safe and progressive exercises that were adapted from two  
35  
36 443 previous studies examining the effects of exercise on balance and trunk muscle performance.  
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38 444 The findings of these studies demonstrated that progressive exercises targeting improvements  
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40 445 in the function of the deeper trunk muscles were effective in improving clinical measures of  
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42 446 balance in older women who were at a high risk of falling.<sup>[58]</sup> Similar exercises, when  
43  
44 447 combined with aerobic exercises and stretching, were shown to significantly improve the  
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46 448 strength and mobility of the trunk muscles in individuals with PD, but the authors did not  
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48 449 report whether these improvements were associated with any changes in postural stability.<sup>[59]</sup>  
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51 450 As with any study of this nature, there are a number of limitations that have the  
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53 451 potential to influence the outcomes of the proposed exercise-based intervention. First, to  
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55 452 ensure the comfort and safety of the participants throughout the data collection and exercise  
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3 453 (if applicable) sessions, participants will complete the baseline, follow-up and training  
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5 454 sessions while on-medication. As such, it is possible that dopamine-induced side-effects of  
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7 455 the medication may influence their performances on some of the laboratory and/or clinical  
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10 456 assessments. However, details regarding medications will be collected and participants will  
11  
12 457 be asked to report any changes in medications during the study period. If differences are  
13  
14 458 identified between the groups with respect to disease duration, disease severity or  
15  
16 459 medications, these variables will be entered as covariates in the statistical model. Second, the  
17  
18 460 sample size for this study may seem small compared with other studies that have used  
19  
20 461 exercise-based interventions to reduce falls in older adults<sup>[69]</sup> or people with PD<sup>[18]</sup>.  
21  
22 462 However, as supported by the presented power calculation, the target sample size of 15  
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24 463 participants per group is adequate to detect differences in our chosen primary outcome  
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26 464 measure and will accommodate an attrition rate of 25%.

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29 465 **In conclusion, there is a growing body of evidence to suggest that regular exercise has**  
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31 466 **the potential to reduce the risk of falling in people with PD<sup>[17]</sup> and may even help to reduce**  
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33 467 **the number of falls experienced by some individuals.<sup>[18]</sup> This study will be the first to**  
34  
35 468 **examine whether a 12-week training program aimed at improving trunk mobility and**  
36  
37 469 **endurance has the potential to improve measures of postural stability in this population. If**  
38  
39 470 **found to be effective, this training program will provide a safe and inexpensive exercised-**  
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41 471 **based therapy option that will help to maintain and/or improve postural stability and**  
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43 472 **ultimately contribute to improving quality of life for people with Parkinson's disease.**

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#### 48 49 474 **LIST OF ABBREVIATIONS USED**

50  
51 475 ANOVA = analysis of variance

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53 476 AP = anterior-posterior

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55 477 COP = centre of pressure

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2  
3 478 EMG = electromyography  
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5 479 H&Y = Hoehn & Yahr scale  
6  
7 480 IPAQ = International Physical Activity Questionnaire  
8  
9 481 MEMS = microelectromechanical system  
10  
11 482 ML = medial-lateral  
12  
13 483 MVC = maximal voluntary contract  
14  
15 484 PD = Parkinson's disease  
16  
17 485 RM-ANCOVA = repeated measures analysis of covariance  
18  
19 486 RMS = root mean square  
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21 487 UPDRS = Unified Parkinson's Disease Rating Scale  
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23 488 VT = vertical  
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#### 29 490 **COMPETING INTERESTS**

31 491 None  
32  
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#### 36 493 **AUTHORS' CONTRIBUTIONS**

37 494 RPH and MHC designed the study, obtained funding, and completed extensive preparation to  
38  
39 495 develop the study protocol. MHC will oversee the execution of the study and will be  
40  
41 496 responsible for administering the clinical tests and assisting with recruitment of participants.  
42  
43 497 RPH will be responsible for the day-to-day management of the study, data collection, data  
44  
45 498 analysis, and interpretation of the findings. GAN provided important assistance with the  
46  
47 499 development of the study protocol and will be responsible for participant allocation. PAS  
48  
49 500 will be involved in assisting with participant recruitment and with the interpretation of the  
50  
51 501 clinical relevance of the study's outcomes. RPH and MHC developed the initial draft of this  
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2  
3 502 manuscript and all authors contributed to the refinement and finalisation of the submitted  
4  
5 503 manuscript.  
6

7 504

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10 505 **AUTHORS' INFORMATION**

11 506 None

12  
13 507

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15  
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17  
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19  
20 510 The funding body played no role in the study design, and will not contribute to data

21  
22 511 collection, analysis, decision to publish or preparation of any manuscripts.  
23  
24  
25 512

26  
27 513 **ENDNOTES**

28  
29 514 None  
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14 694 **Figure Legend**

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16 695 Title: Study outline

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20 697 **Figure 1:** Flow chart depicting the order of recruitment and testing procedures for the  
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22 outlined study.  
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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
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction	2a	Scientific background and explanation of rationale	4-7
	2b	Specific objectives or hypotheses	6-7
Methods	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
	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	15-16
	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-13
Outcomes	6b	Any changes to trial outcomes after the trial commenced, with reasons	NO / N/A
	7a	How sample size was determined	8-9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NO / N/A
Randomisation:	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
	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
	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	14

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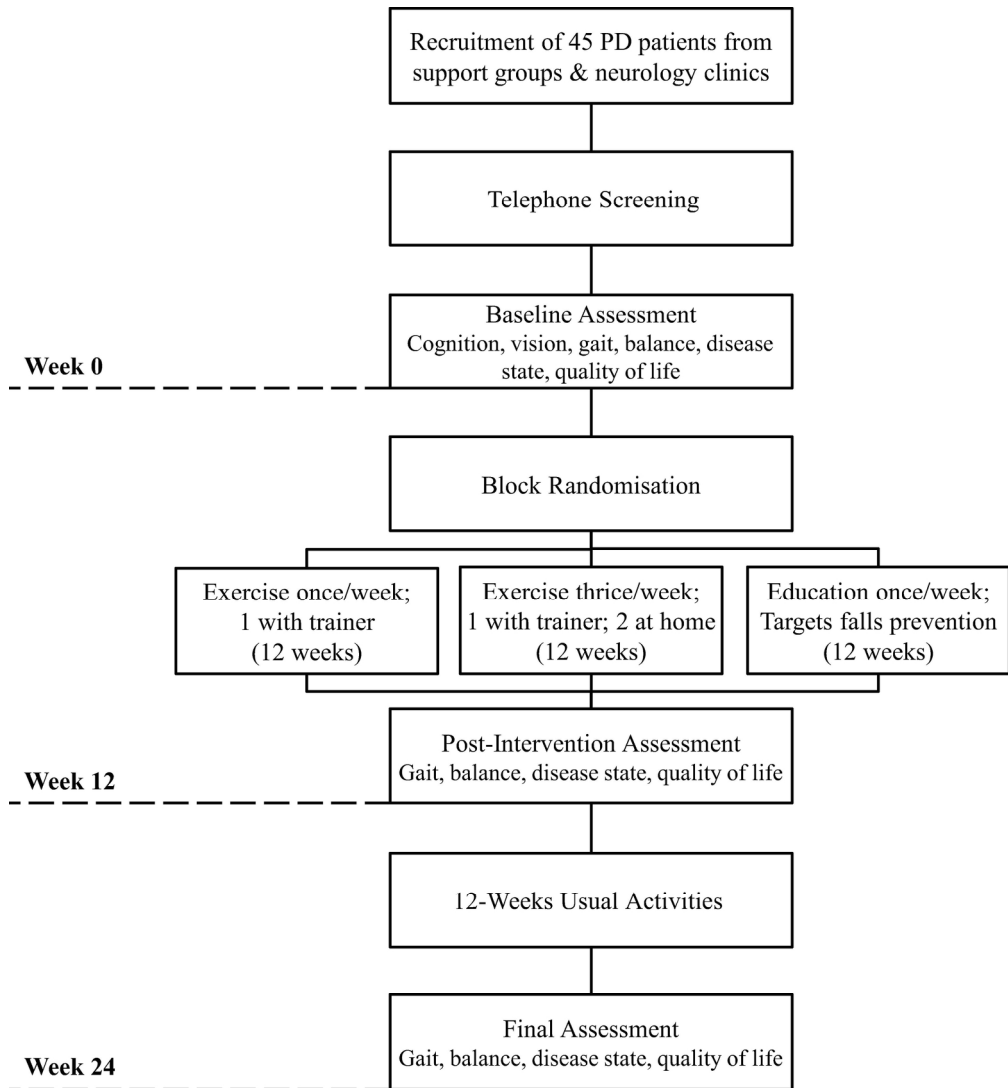
		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	17-18
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
<b>Results</b>			
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
<b>Discussion</b>			
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
<b>Other information</b>			
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	3

\*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](http://www.consort-statement.org).

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