Movement Disorders
Vol. 25, No. 9, 2010, pp. 1217–1225
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CME

The Effects of an Exercise Program on Fall Risk Factors in People with Parkinson's Disease: A Randomized Controlled Trial

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Abstract: This randomized controlled trial with blinded assessment aimed to determine the effect of a 6-month minimally supervised exercise program on fall risk factors in people with Parkinson's disease (PD). Forty-eight participants with PD who had fallen or were at risk of falling were randomized into exercise or control groups. The exercise group attended a monthly exercise class and exercised at home three times weekly. The intervention targeted leg muscle strength, balance, and freezing. The primary outcome measure was a PD falls risk score. The exercise group had no major adverse events and showed a greater improvement than the control group in the falls risk score, which was not statistically significant (between group mean difference = −7%, 95% CI −20 to 5, $P = 0.26$). There were statistically significant improvements in the exercise group compared with the control group for two secondary outcomes: Freezing of Gait Questionnaire ($P = 0.03$) and timed sit-to-stand ($P = 0.03$). There were statistically nonsignificant trends toward greater improvements in the exercise group for measures of muscle strength, walking, and fear of falling, but not for the measures of standing balance. Further investigation of the impact of exercise on falls in people with PD is warranted. © 2010 Movement Disorder Society

Key words: Parkinson's disease; accidental falls; exercise

Falls are a major problem amongst people with Parkinson's disease (PD). Up to 68% of people with PD fall each year, with around 50% falling repeatedly.[1] Falls can cause injuries[2,3] and fear of falling[4,5] and contribute to inactivity and reduced quality of life,[5,6] which in turn increases carer stress.[7,8] Between 4.1 and 4.6 million people across the world's 10 most populous nations had PD in 2005, with this number expected to double by 2030.[9] Despite advances in medical care, medications used to treat PD do not appear to reduce falls.[10,11] Therefore, the incidence of PD-related falls can be expected to have an even bigger impact on the health care system in the coming decades.

Little work has investigated the effects of exercise on falls in people with PD.[12,13] Ashburn et al. (2007) conducted the largest randomized controlled trial to target PD fallers and showed promising results, with a trend toward a reduction in fall events and a significant reduction in near-falls.[12] This was despite a relatively short (6 weeks) duration of the exercise program. In the general older population, the greatest effects of exercise on falls rates have been found in studies

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This study is registered with the Australian New Zealand Clinical Trials Registry (ACTRNO12607000193471).

Potential conflict of interest: None reported.

Received 17 September 2009; Revised 3 December 2009; Accepted 11 February 2010

Published online 13 April 2010 in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/mds.23082

involving a higher total dose of exercise (>50 hours total)[14] and several successful programs involve many months of exercise.[15] It is likely that people with PD would also receive greater benefits from higher-dose programs.

Ideally, studies of falls prevention interventions use fall rates as the primary outcome measure. As studies with falls outcomes require large sample sizes, several studies have used a fall risk score as the primary outcome measure to give an indication of the likely effects on falls themselves.[16,17] Assessment of the effect of exercise on fall risk factors offers an important interim step in addressing the pressing problem of falls in PD.

A recent prospective study of fall risk factors in PD identified that leg muscle weakness, poor balance, and freezing of gait are independent risk factors for falls.[18] There is evidence that these risk factors can all be improved in people with PD with targeted exercise.[12,19–23] Therefore, these three potentially remediable risk factors are logical targets for an exercise program aimed at reducing fall risk in people with PD.

Consequently, the research questions in this study of people with PD who had fallen or who were at risk of falling were as follows:

1 Does a 6-month exercise program which targets leg muscle strength, standing balance, and freezing of gait improve performance in measures of fall risk?
2 Does this exercise program improve physical abilities, fear of falling, and quality of life?

METHODS

Design

A randomized controlled trial of a 6-month exercise intervention for people with PD who had fallen or who were at risk of falling was conducted in 2007/8. Participants were recruited from five Parkinson's NSW support groups in the greater Sydney region, Australia. After baseline assessment, participants were allocated to exercise or control groups using a randomization schedule with randomly permuted block sizes. The randomization schedule was developed and held at a central location by an investigator not involved in subject recruitment or assessment (CS). Participants were assessed in their home ~1 hour after taking their usual PD medication, and the order of measurements was standardized. Postintervention assessments were performed on completion of the trial by a physiotherapist who was blind to the participant's group allocation.

Participants

The study was approved by the relevant Human Ethics Committee and all participants gave written informed consent. Volunteers were included if they: had a diagnosis of idiopathic PD and were able to walk independently (with or without an aid); were aged between 30 and 80 years; had been on the same medication for their PD for at least 2 weeks; and had fallen in the last year, or were deemed to be at risk of falling. Participants were deemed to be at risk of falling if they scored 25 cm or less on the Functional Reach test[24] or if they failed to reach criterion on one of the balance tests in the *QuickScreen*© Clinical Falls Risk Assessments.[25]

Volunteers were excluded if they: had significant cognitive impairment (Mini-mental state examination <24)[26] or had another neurological/musculoskeletal/cardiopulmonary/metabolic condition that would interfere with the safe conduct of the training or testing protocol. Before randomization, each participant was required to provide written medical clearance to certify him/her as safe to participate in the exercise program. Background information including medical history, prescribed medications, age, height, weight, Unified Parkinson's Disease Rating Scale (UPDRS)[27] motor exam score, falls history, and physical activity levels was recorded for all participants.

Intervention

Participants randomized to the exercise group were asked to undertake a 40 to 60 min program of progressive lower limb strengthening and balance exercises three times per week for 6 months. Participants attended a monthly exercise class conducted by one or two therapists in association with their Parkinson's NSW support group and performed the remaining exercise sessions at home, such that exercise was performed three times a week in total. Participants who experienced freezing of gait were also instructed in cueing strategies to reduce freezing as part of their exercise program.[28] More detailed information about the exercise program is available as Supporting Information on the website.

Four physiotherapists were involved in providing the exercise intervention (including authors NA and SM). All therapists had experience in neurological rehabilitation and all received training in the PD-WEBB before providing trial intervention.

The control group received usual care. Both groups received standardized falls prevention advice in the form of a booklet.[29]

Outcome Measures

The primary outcome measure was a PD falls risk score, which was determined using an algorithm developed in a recent prospective cohort study.[18] The algorithm consists of weighted contributions from knee extensor muscle strength of the weaker leg, balance in standing, and freezing of gait. Knee extensor muscle strength was measured in kg using a strain gauge.[30] Balance in standing was measured with the coordinated stability test.[31] Freezing of gait was measured by asking participants if they had experienced "a feeling that their feet were glued to the ground or that their walking was halted any time in the last month."[18]

Secondary outcome measures included measures of the three targeted falls risk factors. The three components of the PD falls risk score were used as discrete measures. Additional measures of standing balance and freezing of gait were also taken. A swaymeter,[32] which records displacement at the waist, was used to measure postural sway while standing on the floor and on a 15-cm thick rubber foam mat with eyes open,[30] as well as maximal standing balance range in an antero–posterior direction.[31] The alternate step test component of the Berg Balance Scale[33] (time taken to place each foot alternately on a step, four times each leg) was conducted using an 18-cm step and timed. Freezing of gait was measured using the Freezing of Gait Questionnaire (FOG Questionnaire).[34]

Other secondary outcomes were measures of physical ability, fear of falling, and quality of life. Physical ability was measured with The Short Physical Performance Battery (SPPB), which incorporates tests of balanced standing, sit-to-stand time (five repetitions), and walking velocity (over 2.5 m).[35] Performance of each item was timed to allow the SPPB to be scored as a continuous outcome measure.[36] Sit-to-stand time and walking velocity were also used as separate outcome measures. Fear of falling was measured with the Falls Efficacy Scale-International questionnaire (FES-I).[37] Quality of life was measured with the Parkinson's Disease Questionnaire (PDQ-39).[38] Falls were recorded during the intervention period (via monthly falls diaries) to monitor adverse outcomes while performing the exercises. The study was not powered to determine whether the intervention could reduce fall frequency.

Data Analysis

Power calculations found that a sample size of 22 participants per group was required to detect a 20% (SD 31%)[18] reduction in the PD falls risk score in the exercise group compared with the control group (power = 0.8, alpha = 0.05, correlation with covariate = 0.7), allowing for a 10% drop-out rate.

Linear regression analysis adjusted for baseline scores (ANCOVA) was used to determine if there were differences in outcome measures between the exercise and control groups at the end of the 6-month intervention period. Categorical data were dichotomized and between-group differences were compared using logistic regression models. An intention-to-treat approach was used for all analyses. Data were analyzed using SPSS v. 14 statistical software (Chicago, IL).

RESULTS

Flow of Participants Through the Trial

Forty-eight participants were randomized to exercise or control groups. Figure 1 shows the study design and flow of participants through the study.

The demographic characteristics of the participants are presented in Table 1. At the beginning of the study, 23 exercise group participants were taking levodopa (L-dopa). Twelve were taking it as a single medication and 11 were taking it in combination with other PD medications. One exercise participant was not taking any PD medications at all, but did have a deep brain stimulator in situ. Twenty-two control group participants were taking L-dopa, 7 were taking it as a single medication, and 13 were taking it in combination with other PD medications. Of the 2 control participants who were not taking L-dopa, one was taking other PD medications (MAO type B inhibitor and dopamine agonist), and the other was not taking any PD medications.

During the study period, 9 exercise and 14 control participants had modifications to their PD medication. Of these, 2 exercise and 7 control group participants had their L-dopa dose increased, and 3 exercise and 2 control group participants had their L-dopa dose decreased.

Exercise Compliance, Intensity, and Adverse Events

Examination of exercise recording sheets revealed that the exercise participants attended a mean of 3.6 (SD 2.1) exercise classes and had a mean of 2.2 (SD 0.9) home visits. They completed a mean of 70% (SD 32%) of total prescribed exercise sessions (three times per week in total including one monthly class and remainder home exercise). Thirteen of the 24 participants (54%) completed at least 75% of sessions. Of

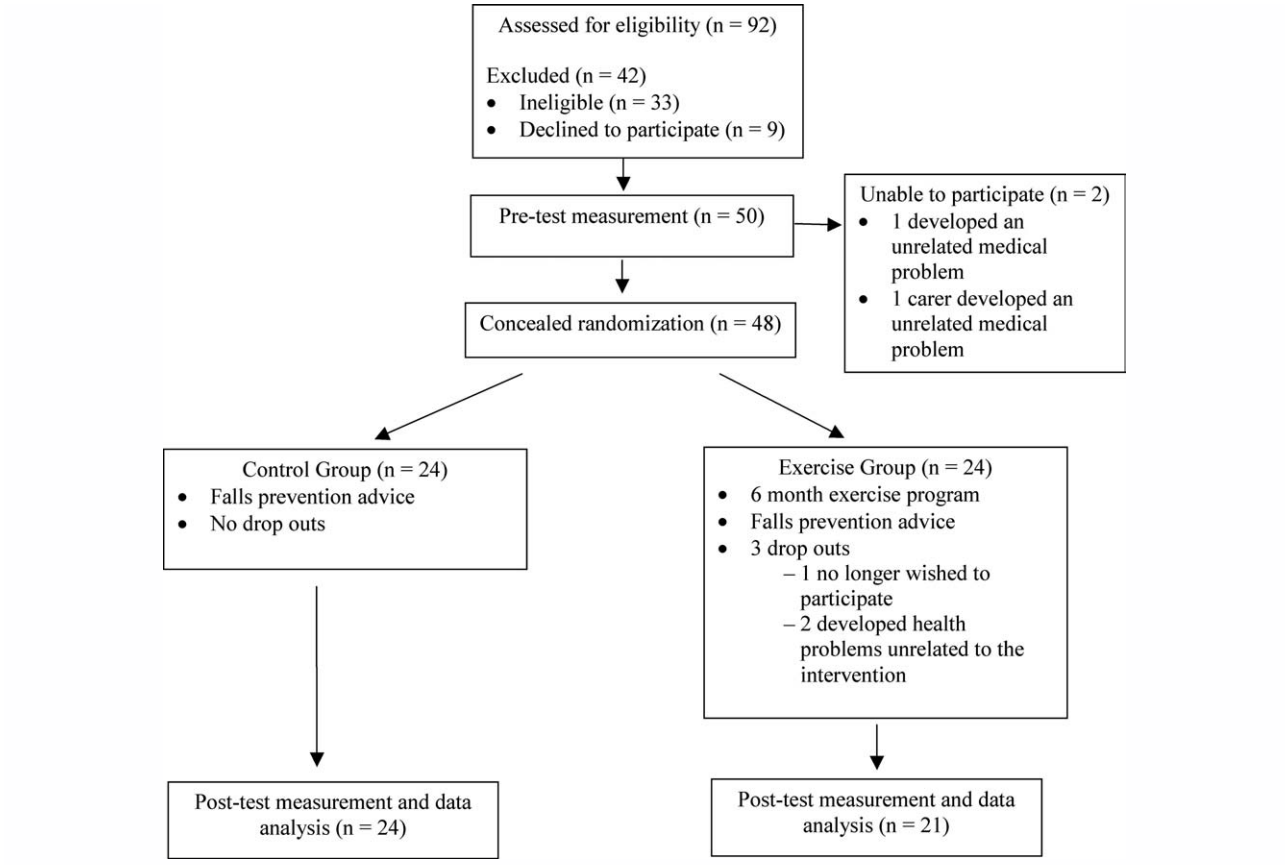

FIG. 1. Study design and flow of participants.

these, 6 (25%) completed all the prescribed exercise. Six participants (25%) completed less than half of the prescribed exercise, including the 3 participants who dropped out of the study.

Exercise participants increased the weight in their vest by a mean of 2.9% (SD 2.1) of their body weight. Four participants (16%) did not increase the weight in their vest, including two of the drop-outs.

None of the exercise group participants reported falling while carrying out the exercise program. Three participants developed joint pain (shoulder, back, and hip) which could not be directly attributed to the exercise program. Where required, prescribed exercise for these participants was modified to ensure their pain was not aggravated.

Effect of Intervention

Group data for the PD falls risk score and for measures of the three targeted risk factors for falls are presented in Table 2. The exercise group showed a 7% greater reduction in risk of falling compared with the control group but this was not statistically significant ($P = 0.26$). There were also no statistically significant between-group differences for any of the components of the PD falls risk score. However, in one of the components of the falls risk score—knee extensor strength—the exercise group showed a trend toward significant improvement compared with the control

TABLE 1. *Participant characteristics*

Variable	Exercise group (n = 24)	Control group (n = 24)
Age (yr)	66 ± 10	68 ± 7
Sex (men)	13 (54%)	13 (54%)
Height (m)	1.7± 0.1	1.7 ± 0.1
Weight (kg)	79 ± 17	78 ± 16
Body mass index (kg/m^2)	27 ± 5	28 ± 4
MMSE (range, 0 to 30)	29 ± 1	29 ± 1
Disease duration (yr)	7 ± 5	9 ± 6
UPDRS motor exam (range, 0 to 108)	29 ± 10	30 ± 15
Participants reporting ≥1 fall in past 12 months	14 (58%)	17 (71%)
Exercise (hr/wk)	2.6 ± 3.2	2.6 ± 1.8
ADL (hr/day)	2.1 ± 1.3	2.5 ± 1.3

The values are either mean ± SD or number and percentage.
MMSE, mini-mental state examination; UPDRS, unified Parkinson's disease rating scale; ADL, activities of daily living.

TABLE 2. *Mean (SD) and mean (95% CI) differences between groups for the primary outcome measure and secondary outcome measures related to the falls risk score for the exercise and the control groups*

Outcome	Groups: Pretest Exercise (n = 24)	Groups: Pretest Control (n = 24)	Groups: Post-test (6 months) Exercise (n = 21)	Groups: Post-test (6 months) Control (n = 24)	Difference between groups Exercise minus Control*
PD falls risk score[a]	**34 (25)**	**39 (34)**	**23 (22)**	**38 (31)**	**−7 (−20 to 5) *P* = 0.26**
Knee extensor strength[b] (weaker leg) (kg)	29.5 (9.8)	29.1 (15.7)	32.9 (10.4)	28.8 (12.2)	2.8 (−1.5 to 7.1) *P* = 0.20
Knee extensor strength (stronger leg) (kg)	32.0 (10.7)	34.5 (16.7)	36.1 (12.9)	31.9 (11.3)	4.6 (−0.2 to 9.5) *P* = 0.06
Knee extensor strength (average) (kg)	30.8 (10.2)	31.8 (16.1)	34.5 (11.3)	30.3 (11.4)	3.7 (−0.5 to 8.0) *P* = 0.08
Coordinated Stability[a,b] (errors)	14.5 (10.9)	15.1 (12.1)	12.9 (12.4)	14.8 (10.9)	−0.4 (−5.6 to 4.8) *P* = 0.87
Sway on floor (mm)[a]	106.9 (86.7)	119.1 (93.2)	121.7 (93.4)	127.5 (51.0)	6.8 (−36.1 to 49.7) *P* = 0.75
Sway on foam (mm)[a]	175.1 (109.3)	187.3 (110.7)	202.1 (166.3)	239.7 (123.8)	−22.0 (−100.7 to 56.7) *P* = 0.58
Maximum balance range in standing (mm)	164.9 (58.0)	180.7 (48.2)	162.8 (41.2)	174.3 (51.4)	−6.4 (−29.7 to 16.8) *P* = 0.58
Alternate step test (s)[a]	9.5 (2.8)	10.6 (3.9)	8.5 (2.0)	10.3 (3.9)	−0.05 (−1.8 to 1.3) *P* = 0.7
FOG (Yes/No)[b]	Y = 13	Y = 14	Y = 7	Y = 12	Odds ratio = 0.5 (0.1 to 2.2) *P* = 0.33
FOG Questionnaire[a] (0 to 24)	6.8 (5.1)	8.3 (5.8)	5.5 (5.9)	9.4 (6.2)	−2.8 (−5.4 to –0.3) *P* = 0.03

Values in bold indicate primary outcome measure.
*Values are change scores (post-test minus pre-test) and are adjusted for baseline (pre-test) score based on ANCOVA.
[a]High score reflects poor performance.
[b]Components of the PD falls risk score.
FOG, freezing of gait.

group (weaker leg $P = 0.20$, stronger leg $P = 0.06$; average of both legs $P = 0.08$). The exercise group showed a significant improvement in the FOG Questionnaire compared with the control group. There were no between-group differences for any of the standing balance measures.

Group data for measures of physical ability, fear of falling, and quality of life are presented in Table 3.

TABLE 3. *Mean (SD) and mean (95% CI) differences between groups for the secondary outcome measures related to physical abilities, fear of falling, and quality of life for the exercise and the control groups*

Outcome	Groups: Pretest Exercise (n = 24)	Groups: Pretest Control (n = 24)	Groups: Post-test (6 months) Exercise (n = 21)	Groups: Post-test (6 months) Control (n = 24)	Difference between groups Exercise minus Control*
Sit to stand time[a] (5 reps) (s)	13.43 (6.11)	12.75 (4.86)	10.70 (3.14)	12.54 (4.52)	−1.9 (−3.62 to −0.18) *P* = 0.03
Fast walking speed (m/s)	1.47 (0.38)	1.54 (0.35)	1.61 (0.35)	1.48 (0.43)	0.13 (−0.08 to 0.34) *P* = 0.21
Comfortable walking speed (m/s)	1.07 (0.27)	1.04 (0.25)	1.09 (0.26)	1.06 (0.32)	−0.01 (−0.16 to 0.14) *P* = 0.88
SPPB (continuous score)	2.10 (0.34)	2.09 (0.43)	2.23 (0.27)	2.13 (0.35)	0.001 (−0.17 to 0.18) *P* = 0.99
FES-I[a] (16 to 64)	28.1 (12.1)	29.1 (10.3)	25.8 (7.9)	30.4 (10.8)	−3.1 (−6.8 to 0.6) *P* = 0.10
PDQ-39[a] (%)	19.9 (14.7)	32.8 (15.9)	18.9 (13.9)	37.7 (30.8)	−4.4 (−17.4 to 8.7) *P* = 0.51

*Values are change scores (post-test minus pretest) and are adjusted for baseline (pretest) score based on ANCOVA.
[a]High score reflects poor performance.
SPPB, short physical performance battery; FES-I, falls efficacy scale—international; PDQ-39, the Parkinson's disease questionnaire.

Compared with the control group, the exercise group showed a statistically significant improvement in time taken for five repetitions of sit-to-stand and a trend toward a statistically significant improvement in fast walking speed and fear of falling (FES-I). There were no between-group differences for the SPPB summary score or quality of life.

DISCUSSION

This study shows that people with PD who have fallen or who are at risk of falling are able to exercise at home using a pragmatic, minimally supervised exercise program. Findings from this study show that performance of the exercise program results in improvements in freezing of gait and sit-to-stand time, as well as a trend toward improvement in overall falls risk, knee extensor muscle strength, fast walking speed, and fear of falling. These outcomes were achieved safely, with no exercise participants falling while carrying out the exercise program.

Exercise did not produce a statistically significant improvement in the primary outcome measure, a PD falls risk score. This may be because only one component of the score (knee extensor strength) showed evidence of improvement in the way it was measured for the score. While the FOG Questionnaire (a 24 point scale) did show significant improvements in the exercise group compared with the control group, the freezing of gait component of the falls risk score (a yes/no question about freezing) was not sensitive enough to reflect these improvements. Furthermore, this study was powered to detect a 20% between-group difference in falls risk, whereas results suggest the between-group difference was in the vicinity of 7%. This study has informed the development of a larger trial with the same intervention protocol[39] to assess whether this relatively small reduction in falls risk score translates into actual falls prevented.

Overall results from this study suggest that participants in the exercise group had some improvement in most measures. Given the degenerative nature of PD and the length of the program (i.e., 6 months), this is an important and encouraging finding. However, greater supervision may improve results by encouraging participants to exercise more often and at a higher intensity. In particular, the lack of improvement in balance outcomes may indicate that the need for participants to exercise safely in their homes without therapist supervision resulted in balance training that was not challenging enough to affect improvement. In spite of this, it is unlikely that most health care systems could fund highly supervised exercise on a long-term basis. Furthermore, our results showed 70% of all prescribed exercise sessions (including independent sessions) were completed and most participants were able to substantially increase the weight in their vest,[40] indicating a good level of adherence to this pragmatic program. Future monitoring of the level of perceived challenge when performing balance exercises at home may help to further clarify the intensity of independent exercise.

Despite the lack of improvement in balance outcomes in this study, several of the balance measures used have detected significant improvements with exercise in older people recently discharged from hospitals.[17] However, these measures may be unable to detect improvements in people with PD. Interestingly, in this study, the exercise group did show an improvement in sit-to-stand speed and a trend toward improvement in fast walking speed, both of which pose a substantial challenge to balance, and arguably may be used as indirect measures of balance.

Progressive resistance training has been shown to improve the muscle strength of people with PD.[19,20,41] This study also gives support for an improvement in knee extensor muscle strength with strength training. However, past studies have utilized specialized strength training equipment, requiring participants to attend and be supervised, at a gym facility or clinic to use them.[19,20,41] This study has shown that weighted vests can be successfully used by people with PD in their home as a safe and effective alternative form of resistance training.

Exercise has been found to improve health related quality of life in people with PD.[42] This study, however, did not find any effect of the exercise program on quality of life as measured by the PDQ39. However, the exercise group's improvement in the FOG Questionnaire and trend toward improvement in the FES-I suggests that the program may have had some benefits on participant's perceptions of their mobility.

We did not attempt to prevent participants from changing their medications during the study period for ethical reasons. It is interesting to note, however, that more control than exercise participants increased their dose of L-dopa during the intervention period. It is possible that this has influenced the results by improving the control group's performance at post-test. However, it may also be possible that the exercise program influenced the medication requirements of the exercise group. Larger scale studies are required to explore this issue.

In conclusion, a minimally supervised exercise program for mobile people with PD who have fallen or

who are at risk of falling may reduce overall risk of falling and can improve freezing of gait, sit-to-stand, and muscle strength. A larger randomized controlled trial to clarify the effect of exercise on frequency of falling in people with PD is underway.[39]

Acknowledgments: The authors wish to thank Parkinson's NSW for their practical assistance with this project, Renee Fortunato and Mary Leavesly for their assistance with exercise training, and Jutta Jablonski and Lauren Wade for their assistance with assessments. They are enormously grateful to the people who participated in this project. Funding for this project was provided by Parkinson's NSW and the Physiotherapy Research Foundation. Natalie E. Allen received financial assistance from The University of Sydney Faculty of Health Sciences Postgraduate Research Scholarship, the George Burniston-Cumberland Foundation Fellowship, and the Parkinson's NSW Research Student Award.

Financial Disclosures: This research was supported by a Parkinson's NSW Research Grant (to CG Canning, C Sherrington, SR Lord, and VSC Fung) and a Physiotherapy Research Foundation National Neurology Group Tagged Grant (to NE Allen, CG Canning, and C Sherrington). NE Allen received financial assistance from The University of Sydney Faculty of Health Sciences Postgraduate Research Scholarship, the George Burniston-Cumberland Foundation Fellowship and the Parkinson's NSW Research Student Award. C Sherrington and SR Lord receive salary funding from the National Health and Medical Research Council. SR Lord is a company director of Balance Systems Inc, which makes equipment items for the PPA (POWMRI FallScreen), which is commercially available through the Prince of Wales Medical Research Institute. All other authors have no financial disclosures to make.

Natalie E. Allen—Grants: Allen NE, Canning C, Sherrington C. Can support group-based exercise reduce risk factors for falling people with Parkinson's disease? Physiotherapy Research Foundation grant (tagged Neurology), 2008 $8,922; Other: The University of Sydney Faculty of Health Sciences Postgraduate Research Scholarship, The George Burniston-Cumberland Foundation Fellowship, The Parkinson's NSW Research Student Award. Colleen G. Canning—Employment: The University of Sydney, full-time Senior Lecturer; Grants: Canning CG, Sherrington C, Lord SR, Fung V, Close JC, Latt M. Exercise therapy for prevention of falls in people with Parkinson's disease: a randomized controlled trial. NHMRC Project Grant 2008–2010, $574,000. (ID 512326). Allen N, Canning CG, Sherrington C. Can support group-based exercise reduce risk factors for falling people with Parkinson's disease? Physiotherapy Research Foundation grant (tagged Neurology), 2008 $8,922. Catherine Sherrington—Consultancies: NSW Health Department; Employment: The George Institute for International Health; Royalties: Cambridge University Press (book called Falls in Older People); Grants: Sherrington C. Physical ability and falls: addressing gaps in the evidence base NHMRC Australian Research Training Fellowship (part-time, July 2004–June 2008) (ID 307710). Cameron ID, Crotty M, Grey L, Kurrle S, Luscz M, Scuffham P, Whitehead C, Lord S, Giles L, Halbert J, Sherrington C, Bartlett H, Rungie M, Hudd S. Transition care: innovation and evidence. NHMRC Health Services Research Grant, 2006–2010, $2,900,000. (ID 402791). Sherrington C, Cumming R, Lord S, Close J, Dean C, Vogler C. Minimising disability and falls in older people through a post-hospital individualised exercise program. NHMRC Project Grant, 2007–2009, $516,875 (ID: 457464). Canning C, Sherrington C, Lord SR, Fung V, Close JC, Latt M. Exercise therapy for prevention of falls in people with Parkinson's disease: a randomized controlled trial. NHMRC Project Grant 2008–2010, $574,000. (ID 512326). Lord SR, Sturnieks D, Fitzpatrick R, Rogers M, Sherrington C. Impaired stepping as a risk factor for falls in older people. NHMRC Project Grant 2008–2010, $541,650. (ID: 510110). Sherrington C, Clemson L, Lord SR, Howard K, Moseley AM, Vogler CM. NHMRC Project Grant. Exercise self-management to improve long-term functioning and prevent falls after hip fracture. 2009–2012, $809,875 (2009 $190,750; 2010 $255,500; 2011 $270,250; 2012 $93,375). (ID 570886). Lord SR, Smith ST, Sherrington C. NHMRC Project Grant. A novel, home-based volitional step training program for fall prevention. 2009–2011, $286,450 (2009 $114,250; 2010 $84,500; 2011 $87,700) (ID 568724). Allen N, Canning C, Sherrington C. Can support group-based exercise reduce risk factors for falling people with Parkinson's disease? Physiotherapy Research Foundation grant (tagged Neurology), 2008 $8,922. Herbert RD, Moseley AM, Maher CG, Sherrington C, Elkins MR. PEDro Supporting decisions about physiotherapy with high quality evidence. Motor Accidents Authority of New South Wales. 2008 $68,248, 2009 $68,248, 2009 $68,248. Maher C, McKeough Z, Latimer J, Sherrington C, Herbert R, Refshauge K, Crosbie J, Kilbreath S, Alison J. NHMRC equipment grant. A novel system for measuring physical activity in a free-living environment. 2008, $74 756. Schurr K, Dorsch S, Sherrington C, McCluskey A, Togher L. Optimising Rehabilitation Outcomes. Ingham Health Research Institute, 2008–2009. $152,500. Fairhall N, Sherrington C, Cameron I. Can a goal-focused exercise program increase participation in frail, community-dwelling older persons? Physiotherapy Research Foundation. National Gerontology Group Tagged Research Grant, 2009. $6 495. Stephen R. Lord—Consultancies: NSW Health Department; Employment: University of New South Wales; Honoraria: Australian Commission on Safety and Quality in Health Care; Royalties: Cambridge University Press (book called Falls in Older People); Grants: Finch CF, Stevenson MR, Norton RN, Zye AB, Lord SR, Williamson AM, Cameron DI. Population health approaches to injury prevention and control. NHMRC Capacity Building Grant in Population Health. 2005–2009 $2,351,750. Cameron ID, Crotty M, Grey L, Kurrle S, Luscz M, Scuffham P, Whitehead C, Lord S, Giles L, Halbert J, Sherrington C, Bartlett H, Rungie M, Hudd S. Transition care: innovation and evidence. NHMRC Health Services Research Grant 402791, 2006–2010, $2,900,000. Lord SR, Close JC. NSW Health Falls Prevention Network Co-ordinator. NSW Health 2007–2009, $170,826. Lord SR, Close JC, Sherrington C, Tiedemann A. Developing falls screens for ambulance officers and emergency departments and fall risk assessment tools for rehabilitation hospitals and residential care facilities. NSW Health 2007–2009, $228,835. Sherrington C, Cumming R, Lord SR, Close JC, Dean C, Vogler C. Minimising disability and falls in older people through a post-hospital individualized exercise program NHMRC

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Author Roles: Allen—conception, organization, and execution of research project; design and execution of statistical analysis; writing of the first draft and review and critique of manuscript. Canning—conception, organization, and execution of research project; review and critique of statistical analysis; review and critique of manuscript. Sherrington—conception, organization, and execution of research project; design and execution of statistical analysis; review and critique of manuscript. Lord—conception of research project; execution of statistical analysis; review and critique of manuscript. Latt—conception of research project; execution of statistical analysis; review and critique of manuscript. Close—conception of research project; execution of statistical analysis; review and critique of manuscript. O'Rourke—organization and execution of research project; execution and review and critique of statistical analysis; review and critique of manuscript. Murray—organization and execution of research project; review and critique of statistical analysis; review and critique of manuscript. Fung—conception of research project; review and critique of statistical analysis; review and critique of manuscript.

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