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### A comparison of exercise intervention to standard care in decreasing fall risk for patients with Parkinson's disease

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## A comparison of exercise intervention to standard care in decreasing fall risk for patients with Parkinson's disease

### Disciplines

Physical Therapy

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**Title:** A comparison of exercise intervention to standard care in decreasing fall risk for patients with Parkinson's disease.

**Clinical scenario:** We are DPT students who will come into contact patients with idiopathic Parkinson's Disease (PD) in our future practices. This patient population is at increased risk for falls. We observed exercise interventions used to decrease fall risk in our clinical settings. We would like to know if exercise interventions can reduce fall risk specifically in patients with Parkinson's disease.

**Clinical question:** Do exercise programs focused on balance and strength training reduce fall risk in patients with Parkinson's disease?

**Clinical PICO:**

- P: People with idiopathic Parkinson's disease who are independent ambulators and are at increased fall risk.
- I: Exercise program focused on strength and balance training
- C: Usual care
- O: Number of reported falls in a six month period

**Overall Clinical Bottom Line:** Based on the studies done by Allen et al., Ashburn et al., and Goodwin et al. there are mixed results as to whether exercise programs including strength and balance training significantly reduce fall risk for individuals with PD. Allen et al. found no effect of exercise on fall risk using the PD risk assessment, but they did find a significant decrease in fall risk based on the 5 times sit-to-stand assessment. Ashburn et al. and Goodwin et al. both found participation in an exercise program did not significantly reduce number of fallers or number of falls respectively. Using a subgroup analysis based on disease severity, Ashburn et al. reported the exercise group had significantly fewer repeat fallers among participants in the less severe disease stage. Other than the fair internal validity and use of subjects from countries outside the United States the studies were generalizable to those in our patient population who are independent ambulators and who have no cognitive deficits. All subjects had idiopathic PD and treatments were feasible and cost effective. More research needs to be done to determine the effectiveness of exercise in reducing fall risk for patients with PD. Future research should include larger study populations for adequate power, assess exercise effectiveness in different disease stages, determine if there is a difference in effectiveness between individual, group therapy, or home exercise, and explore differences between different exercise protocols.

**Search terms:** Parkinson's disease, exercise, falls, balance

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**Rationale for chosen articles:** The articles chosen for our CAT were selected based on their similarities to our own PICO, our clinical question, and the quality of research based on PEDro scores. Our PICO included fall rates as the primary outcome measure. The Allen et al. article used a PD fall risk score and the 5 times sit-to-stand instead of actual fall rates as the outcome measure, but because all other factors of that study matched our requirements we chose to include it.

- ▣ Allen, N. E., Canning C. G., Sherrington C., Lord, S. R., Latt, M. D., Close, J. C. T., . . . Fung, V. S. C. (2010). The Effects of an Exercise Program on Fall Risk Factors in People with Parkinson's Disease: A Randomized Controlled Trial. *Movement Disorders*, 25(9), 1217-1225.

PEDro score: 8/10

- P: People with idiopathic Parkinson's disease who were at increased fall risk, and who were independent ambulators.
- I: 6 month exercise program including lower extremity strengthening and balance exercises done 3 times per week with a group exercise class once per month.
- C: Usual care and standardized fall prevention information booklet
- O: Parkinson's Disease fall risk score, Freezing of Gait Questionnaire, and timed sit-to-stand.

- ▣ Ashburn, A., Fazakarley, C. B., Pickering, R., McLellan, L. D., & Fitton, C. (2007). A randomised controlled trial of a home based exercise programme to reduce the risk of falling among people with Parkinson's disease. *Journal of Neurology, Neurosurgery, & Psychiatry*, 78, 678-684.

PEDro score: 8/10

- P: Patients with a confirmed diagnosis of idiopathic Parkinson's disease who were independently mobile, lived at home in the community, and had experienced more than one fall in the previous 12 months.
- I: Individualized six week home based exercise program that included weekly home visits from a physiotherapist to personalize and progress the exercises. Weekly visits were of one hour duration and patients were asked to perform the exercises daily on their own. Patients were also educated in strategies for fall prevention and movement initiation.
- C: Usual care which included contact with a local Parkinson's disease nurse.

O: Rates of falling at eight weeks and six months, Functional Reach, Berg Balance Test, timed up and go test, chair stand test, Self-assessment Parkinson's Disease Disability Scale, Euro Quol EQ-5D quality of life thermometer.

- ▣ Goodwin, V. A., Richards, S. H., Henley W., Ewings, P., Taylor, A. H., & Campbell, J. L. (2011). An exercise intervention to prevent falls in people with Parkinson's disease: a pragmatic randomised controlled trial. *Journal of Neurology, Neurosurgery, and Psychiatry*, 82, 1232-1238.

PEDro score: 7/10

P: People with Parkinson's Disease, with a history of 2 or more falls in the previous year, who were independent indoor ambulators.

I: 10 week group exercise program, focused on balance and strength, with supplementary home exercises

C: Usual care including medical management, ST, OT and PT

O: Number of falls recorded during the 10 week intervention period and a 10 week follow up period.

**Comparison of PEDro scores:**

	Allen et al.	Ashburn et al.	Goodwin et al.
Random Allocation	1	1	1
Concealed Allocation	1	1	1
Baseline Similarity	1	1	1
Subject Blinding	0	0	0
Therapist Blinding	0	0	0
Assessor Blinding	1	1	0
Outcomes from 85% of subjects	1	1	1
Intention to treat	1	1	1
Between-Group Comparison	1	1	1
Point Measure and Measure of Variability	1	1	1
Total Points	8/10	8/10	7/10

**Article 1:** Allen, N. E., Canning C. G., Sherrington C., Lord, S. R., Latt, M. D., Close, J. C. T., . . . Fung, V. S. C. (2010). The Effects of an Exercise Program on Fall Risk Factors in People with Parkinson's Disease: A Randomized Controlled Trial. *Movement Disorders*, 25(9), 1217-1225.

**Clinical Bottom Line:** Based on the results of this study, there is fair evidence to suggest that for patients with idiopathic Parkinson's disease (PD) who are independent ambulators, an intervention of a home-based exercise program targeting leg muscle strength, balance, and freezing of gait, which includes a monthly group exercise session may result in decreased fall risk compared to standard care. The exercise sessions for the intervention group consisted of 40 to 60 minutes of lower limb strengthening and balance exercises three times per week for six months, including education on strategies to reduce freezing of gait. The results showed no statistical difference between groups in the PD falls risk assessment. The exercise group did have a significant decrease ( $p = 0.03$ ) in the 5-times sit-to-stand times compared to the control group, indicating a decrease in fall risk. The exercise group improved by 2.73 seconds in the 5-times sit-to-stand with a medium effect size of 0.45 (our calculation). This is greater than the MCID (Meretta et al., 2006) of 2.3 seconds reported for patients with vestibular disorders. Threats to internal validity include small sample size, the inability to blind patients, unknown reliability of the PD falls risk assessment, lack of long-term follow up to determine actual falls and poor adherence to home exercise program. This would be a feasible treatment option if the exercise program was described in more detail and patients were compliant with the home exercise program and monthly group sessions. There were no differences between subjects in the study and our clinical patient population. To feel more confident applying this intervention to our patient population we would like to see further studies using the outcome measure of actual falls during the intervention period and in a six-month follow up period.

#### **Article PICO:**

**Population:** People with idiopathic Parkinson's disease who were independent ambulators and were determined to be at increased fall risk, between the ages of 30 to 80 years old.

**Intervention:** Six month home exercise program targeting lower extremity strengthening and balance, performed in sessions of 40 to 60 minutes duration, three times per week, including a group exercise class once per month and strategies to address freezing of gait.

**Comparison:** Usual care (not defined by authors)

**Outcomes:** PD falls risk score, knee extensor muscle strength, coordinated stability test (to measure balance in standing), Freezing of Gait Questionnaire, timed 5-times sit-to-stand, postural sway determined by a swaymeter, alternate step test component of Berg Balance Scale, Short Physical Performance Battery, walking velocity, Falls Efficacy Scale, Parkinson's Disease Questionnaire.

**Blinding:** The examiners were blinded in this study. It was not possible to blind subjects and therapists, as subjects either did or did not participate in exercise program, which served as the intervention. We did not consider this a serious threat to internal validity.

**Controls:** The control group received usual care, which was not further defined by the authors. Both groups received a booklet containing fall prevention advice. The intervention group participated in an exercise program, while the control group did not receive any additional intervention. Any differences between groups can be assumed to be due to the exercise program.

**Randomization:** Participant assignments to groups were randomized using randomly permuted block sizes. At baseline both groups were similar in age, sex, height, weight, BMI, disease duration, falls reported in the previous 12 months, amount of time spent exercising and performing ADLs. Both groups also had similar scores in the mini-mental state examination (MMSE) and the Unified Parkinson's Disease motor exam (UPDRS). However, pre-intervention fall risk scores were statistically significantly different, so randomization was not completely successful.

**Study:** The study was a randomized controlled trial with 24 subjects in the control group and 24 subjects in the treatment group. Inclusion criteria comprised of being diagnosed with idiopathic PD, being between 30-80 years of age, taking the same medication for at least two weeks, having fallen in the last year or being at risk for falling. Participants were considered at risk for falling if they obtained 25 cm or less on the functional reach test or failed to reach criterion on one of the balance tests in the QuickScreen Clinical Falls Risk Assessments. Exclusion criteria was either cognitive impairment defined by a score of less than 24 on the MMSE or any other medical condition that would make it unsafe for the participant to perform the intervention and assessments required by the study. Both groups received booklets containing fall prevention advice. The control group received usual care. The treatment group participated in 40 to 60 minute sessions of lower extremity (LE) strengthening and balance exercises three times per week for six months. This included one monthly group exercise class, while all other exercise required by the study was performed at home. Strategies to address freezing of gait were given to intervention participants who experienced this.

**Outcome measures:** Outcomes were measured immediately before and after the six month intervention period. The outcome measures most relevant to our clinical question were the PD fall risk score and the 5-times sit-to-stand score. We would prefer an outcome measure of number of falls experienced during and after the intervention at a one-year follow-up, as this would give a more accurate picture of whether the intervention actually had an impact on the number of falls, but only fall risk was assessed in this study, not actual number of falls.

The authors of this study state that they used an algorithm for their PD falls risk score based on a previous cohort study (Latt et al., 2009), yet they use only some of the identified measurements from that study and they do not elaborate on how they chose which ones to include in their assessment. There is no reported reliability or validity for this measurement. The PD falls risk score appears to have face validity in that each of the three measurements used (knee extensor muscle strength of the weaker leg, balance in standing, and freezing of gait) appear to impact fall risk. There is no reported MCID for the PD falls risk assessment.

The 5-times sit-to-stand has also been shown to be a valid measurement for predicting falls in patients with PD, with high intra-rater and test-retest reliability (Duncan et al., 2011). In this study the authors found that patients who scored greater than 16 seconds in the 5-times sit-to-

stand test were at greater risk for falling, with a sensitivity of 0.75 and a specificity of 0.68. In a search of the literature the only reported MCID for the 5-times sit-to-stand test was 2.3 seconds, but this was specifically for patients with vestibular disorders (Meretta et al., 2006).

**Study losses:** All 24 participants in the control group completed the study. There were three participant losses from the original 24 in the treatment group. It does not appear that study losses were primarily related to the intervention. Two losses were for unrelated health problems and one no longer wished to participate. An intention-to-treat analysis was performed to take into account the study losses.

**Summary of internal validity:** The internal validity of this study was fair, with one major threat and four minor threats. The major threat was the reliability of the PD falls risk assessment. One minor threat was the small number of subjects (48). The authors ran a power analysis that found that a sample size of 22 per group was needed in order to detect a 20% decrease in the PD falls risk assessment for the exercise group compared to the control group. Accounting for study losses the exercise group had only 21 subjects at the end of the study, but the authors performed an intention to treat analysis to account for these losses. Therefore the study may have inadequate power to detect a change in fall risk score. A minor threat was that subjects could not be blinded to whether or not they received the treatment, and similarly, clinicians could not be blinded to whether or not they were giving the treatment. This could possibly have interfered with performance if patients' knowledge of their group assignment affected their expectations. Another minor threat was that the follow-up period was not sufficiently long enough to determine long-term fall risk as a result of the intervention. Finally, the authors did not report on what type of exercises the control group was doing on their own, and whether they participated in the monthly exercise group that was available to them through the Parkinson's NSW support group that all participants were members of. Also there was poor adherence to the HEP. We could more clearly tell if exercise impacted the outcomes if the participants actually did all of the exercises.

**Evidence:** The evidence most applicable to our clinical question are the results from the PD falls risk score and the 5-times sit-to-stand score at baseline and after the six month intervention.

Table 1. Between (P=0.26) and within group comparison of PD fall risk assessment mean at baseline and at 6 months .

<b>Group</b>	<b>Baseline (SD)</b>	<b>6 months (SD)</b>	<b>Change from baseline to 6 months (95% confidence interval)</b>	<b>Effect Size</b>	<b>Between Group Difference (95% CI)</b>
Control	39 (34)	38 (31)	-1 (+18.92 to -20.92)	0.03	-7 (-20 to 5)
Exercise	34 (25)	23 (22)	-11(+3.96 to -25.96)	0.44 (medium)	

Table 1 shows the authors’ reported mean PD falls risk assessment scores at baseline and six months for the study participants in the control and exercise groups. The standard deviations for the mean scores were large for both groups. The authors calculated the between group difference using adjusted baseline scores based on ANCOVA. There was a difference of -7 between the control and exercise group. This difference was not statistically significant (P=0.26). The authors reported a large 95% CI of -20 to 5. The + 5 indicates that in some cases the control group might have a reduced fall risk as compared to the exercise group. We calculated the within group change, 95% CI, and the effect sizes. The PD falls risk assessment score for the control group only decreased by 1, with a large 95% CI of 18.92 to -20.92. For the exercise group the PD fall risk decreased by 11, with a large 95% CI of 3.96 to -25.96. The control group had an effect size of 0.03, which is to be expected with no intervention. The exercise group had a medium effect size of 0.44.

Table 2. Between (P=0.03) and within group comparison of 5-times sit-to-stand assessment at baseline and 6 months. Times reported in seconds.

<b>Group</b>	<b>Baseline (SD)</b>	<b>6 months (SD)</b>	<b>Change from baseline to 6 months (95% confidence interval)</b>	<b>Effect Size</b>	<b>Between Group Difference (95% CI)</b>
Control	12.75 (4.86)	12.54 (4.52)	-0.21 (+2.66 to -3.08)	0.04	-1.9 (-3.62 to -0.18)
Exercise	13.43 (6.11)	10.70 (3.14)	-2.73 (+0.40 to -5.86)	0.45 (medium)	

Table 2 shows the authors’ reported mean 5-times sit-to-stand scores at baseline and 6 months for the study participants in the control and exercise group. The authors calculated the between group difference using adjusted baseline scores based on ANCOVA. There was a statistically significant difference of 1.9 seconds between the control and exercise group (P=0.03). The authors reported a moderate 95% CI of -3.62 to -0.18. We calculated the within group change, 95% CI, and the effect sizes. The 5-times sit-to-stand score for the control group only decreased by 0.21 seconds, with a large 95% CI of 2.66 to -3.08, indicating that the sit-to-stand time could

have increased in this group. For the exercise group the 5-times sit-to-stand score decreased by 2.73 seconds, which exceeds the MCID of 2.3 seconds reported for patients with vestibular disorders. There was a large 95% CI of 0.40 to -5.86, indicating the possibility that the scores could have increased slightly. The 95% CI ranges overlap for the two groups, showing that in some cases there may be no difference between the two groups. The control group had an effect size of 0.04, which is to be expected with no intervention. The exercise group had a medium effect size of 0.45.

### **Applicability of study results:**

**Benefits vs. Costs:** The PD risk assessment showed no significant difference between groups indicating no benefit to the intervention. It is unclear if this is due to low validity of the assessment, ineffectiveness of the intervention, or other limitations of the study such as the small sample size. Using the 5-times sit-to-stand as a fall risk assessment, the exercise group made significant improvement over the control group. The exercise group decreased their time by 1.9 seconds more than the control group, indicating a small benefit to the intervention. Both groups' baseline scores were under 16 seconds, the reported cutoff time indicating high fall risk in patients with PD (Meretta et al., 2006). There was no follow-up measure of actual number of falls. This would be the best determinant of whether the intervention actually reduced fall risk. The intervention used would be a relatively low cost option for patients. The primary costs would be the patient's time which would be two to three hours per week, the therapist's time of one hour per month, and the financial cost of the group exercise sessions, which were held once per month. There were no adverse events due to the intervention.

**Feasibility of treatment:** The main limitation in the feasibility of this treatment was that the lower limb strengthening and balance exercises are not described. The article states that detailed information about the exercise program is available on a website, but does not provide information about how to access the website. The intervention was primarily a home exercise program with only six total group exercise sessions. This seems feasible but it is unclear if insurance would cover group exercise sessions. The home exercise program was feasible for patients as they completed a mean of 70% of all exercises. There was less compliance with the group exercise sessions. Participants attended a mean of 3.6 out of the six group sessions.

**Summary of external validity:** The fair internal validity somewhat compromises the ability to generalize the results of this study, primarily in that there was no follow-up to determine actual number of falls as a result of the intervention. Subjects were similar to those with PD who may be treated at a clinic, with a wide age range of 30 to 80 years old. The results cannot be extrapolated to individuals with PD who are not independent ambulators, nor to those who have cognitive impairments or other comorbidities that would make this program unsafe.

**Article 2:** Ashburn, A., Fazakarley, C. B., Pickering, R., McLellan, L. D., & Fitton, C. (2007). A randomised controlled trial of a home based exercise programme to reduce the risk of falling among people with Parkinson's disease. *Journal of Neurology, Neurosurgery, & Psychiatry*, 78, 678-684.

**Clinical Bottom Line:** Based on the results of this study, there is fair evidence to suggest that for patients with idiopathic Parkinson's disease (PD) who are independently mobile and who are in the early stages of the disease, an intervention of a home-based exercise program comprised of muscle strengthening, range of motion, balance training, and education in fall prevention strategies may prevent falling as compared to usual care. However, for the larger PD population, there is fair evidence to suggest that such an exercise program does not significantly reduce fall risk when compared to usual care. The exercise intervention consisted of 6 weekly home visits from a physiotherapist of one hour duration during which exercises were prescribed and progressed as needed, and instructions to participants to continue with daily exercises on their own. The results showed no statistically significant differences for falls between groups, with the exception of a subgroup analysis showing that in subjects who were rated a 2 or 3 on the Hoehn and Yahr Scale of PD severity, the exercise group had statistically significantly fewer repeat fallers at 6 months than the control group. We calculated the number needed to treat (NNT) for the H&Y 2-3 subgroup to be 4.83 (CI of 2.5 to 85.7). Threats to internal validity include a small sample size, lack of blinding of patients and therapists, failed blinding of the examiner, and an increase in the number of control subjects who sought out external rehabilitation during the 6 month follow-up period. The subjects in this study were similar to those in our patient population. To feel more confident applying this information to our patient population we would like to see future research that examines the interplay between disease severity and exercise interventions.

#### **Article PICO:**

**Population:** Patients with a confirmed diagnosis of idiopathic Parkinson's disease who were independently mobile, lived at home in the community, and had experienced more than one fall in the previous 12 months.

**Intervention:** Individualized six week home based exercise program that included weekly home visits from a physiotherapist to personalize and progress the exercises. Weekly visits were of one hour duration and patients were asked to perform the exercises daily on their own. Patients were also educated in strategies for fall prevention and movement initiation.

**Comparison:** Usual care which included contact with a local Parkinson's disease nurse.

**Outcomes:** Rates of falling at eight weeks and six months, Functional Reach, Berg Balance Test, timed up and go test, chair stand test, Self-assessment Parkinson's Disease Disability Scale, Euro Quol EQ-5D quality of life thermometer.

**Blinding:** Participants were not blinded, nor was the treating physiotherapist. The examiner was blinded in the beginning, but at the eight week assessment the examiner reported being aware of the allocation of some of the participants in both groups, and at six months the

examiner was aware of a greater number of the allocations, so the attempted blinding was unsuccessful.

**Controls:** The control group received usual care, which was defined by the authors only in that the majority of these participants had contact with a Parkinson's disease nurse. The researchers monitored participation in rehabilitation outside of the confines of the trial by both groups.

**Randomization:** Randomization of participants into group assignments was stratified using blocks of four. At baseline both groups were similar in age, sex, time since diagnosis, living arrangements, severity of their PD based on the Hoehn and Yahr Scale, and the number of participants in each group receiving rehabilitation external to the trial. While there was a wide range in the number of falls subjects had had in the previous year (2 to 1820 in the exercise group and 2 to 900 in the control group), both the mean and the median for both groups was similar. Members in the control group were more likely to be taking dopamine agonists. Overall, randomization was successful at producing similar groups at baseline.

**Study:** This study was a randomized controlled trial with 70 subjects in the treatment group and 72 subjects in the control group. Inclusion criteria comprised of having a confirmed diagnosis of idiopathic Parkinson's disease, being independently mobile, living at home in the community, experiencing more than one fall in the previous 12 months, and having intact gross cognitive function. The authors used the following definition of a fall: "an event that resulted in a person coming to rest unintentionally on the ground or other lower level, not as a result of a major intrinsic event or overwhelming hazard." Exclusion criteria included the inability to undergo assessments due to pain and having an acute medical condition for which the patient was undergoing or soon to undergo treatment. Subjects in the treatment group participated in an individualized six week home based exercise program that included weekly home visits from a physiotherapist to personalize and progress the exercises. Weekly visits were of one hour duration and patients were asked to perform the exercises daily on their own. Patients were also educated in strategies for fall prevention and movement initiation. The authors do not report on adherence to the home exercise program. After the six week intervention period, subjects in the treatment group were telephoned each month by the treating physiotherapist to encourage them to keep up with their exercises and to discuss any problems they were having. This telephone contact continued through to the six month follow up. The subjects in the control group received usual care. Both groups were monitored for participation in rehabilitation outside of the trial during the trial period.

**Outcome Measures:** Baseline measurements were taken prior to randomization, and outcomes were measured at eight weeks and at six months after randomization. The primary outcome, and the one most relevant to our clinical question, was self-reported falling or not at eight weeks and six months from a falls diary kept by the participants. The falls diaries were kept prospectively, which likely gave more accurate reporting than a retrospective measure would have (Mackenzie et al., 2006). We chose not to focus on reports of near falls, as that was a more subjective measurement.

**Study losses:** Of the 142 subjects who were randomized into groups, 15 were lost at the six month follow up (9 of these were lost by the eight week follow up). Of the 15 total losses, 2

disliked the exercises, 2 went to the hospital (1 with a fracture, 1 with a fall), 4 were unwell, 1 had a partner who was unwell, 1 moved away, 1 gave no reason for withdrawing, 1 withdrew with falls, and 3 died. Of the 15 total losses, 9 of these were from the control group. Of all of the study losses, it is notable that only 2 withdrew for reasons related to the intervention, that being the 2 who disliked the exercises. An intention to treat analysis was performed, with subjects being included in their assigned groups regardless of the number of home visits they received or the extent to which they completed their exercises. The authors do not report on any discrepancies as a result of the intention to treat analysis, so we assume that study losses did not significantly affect the results.

**Summary of internal validity:** We judged the internal validity of this study to be fair. We determined there to be five threats (one major, four minor). The major threat to internal validity was the fact that by the six month follow up period, 34% of the participants in the control group were participating in rehabilitation external to the trial, compared to only 25% of participants in the exercise group. At baseline there was a similar percentage of participants from both groups receiving rehabilitation external to the trial (24% of the exercise group and 22% of the control group), but during the six month trial period several more subjects in the control group sought out external rehabilitation, while the percentage in the exercise group remained closer to the baseline numbers. The authors tried to control for this possibility in their study design by encouraging participants not to alter their management and promising to offer advice about exercises to the control group once they reached the end of the six month follow-up period, but they suppose that participation in the trial may have raised interest in fall prevention and those in the control group may have been motivated to seek it on their own. The authors felt that it would have been unethical to have dictated no involvement in external rehabilitation for six months, but it is possible that the study results were affected and so we consider this is a major threat.

One minor threat to internal validity was that subjects and treating therapists were not blinded, which introduces the possibility of Hawthorne and Rosenthal effects, where patients act differently when they know they are being studied, or have an unusual reaction due to a “white coat effect”. In our judgment this is a minor threat with regards to the primary outcome measure of self-reported falls, especially for the Rosenthal effect, as these were kept track of by the subjects in diaries they kept at home. It is possible that in an effort to “please” the researchers or physiotherapists they could have under-reported falls (Hawthorne effect), however, the number of falls in a finite period is an objective measure, and thus less subject to the Hawthorne effect than a more subjective measure.

A second minor threat was the unsuccessful blinding of the assessing examiner. The authors designed this as a single blind study with the assessing examiner being blinded to group allocation at the start of the trial. This attempted blinding was unsuccessful, however, because at the eight week assessment the examiner admitted to being aware of the allocation for 29 subjects, and by the 6 month assessment the examiner was aware of the allocation for an additional 10 subjects. Because this blinding was unsuccessful, rater bias was a threat in this study, however, since the outcome measure we were interested in was self-reported falls reported by participants in a journal they kept at home, this remains a minor threat for our purposes.

A third minor threat was the selection process. Potential subjects were selected from the clinical registers of three Parkinson’s disease specialists in the UK. Patients on these registers were screened based on inclusion and exclusion criteria, and those deemed eligible were sent letters inviting them to participate in the study. Therefore, those who responded were self-selected and perhaps not representative of a wider PD patient population.

The fourth minor threat was the sample size. The authors ran a power analysis and found that a sample size of 100 in each group was needed to have an 80% power to detect a reduction from 70% to 50% in fall rates, yet this study had only 70 in the intervention group and 72 in the control group after the initial randomization. At the six month assessment study losses brought these numbers down to 65 in each group. The authors state that they ran an intention to treat analysis in that subjects were analyzed in their allocated groups regardless of the extent to which they participated in the home exercises or the final number of home visits they actually received, but because the number of subjects at baseline was below 100 for both groups, it is possible that this study had an inadequate power to detect a significant change between groups.

**Evidence:** The evidence most applicable to our clinical question is falls reported at 8 weeks and 6 months. The authors separated the results into the categories of falling (participants fell at least one time in the assessment period) and repeat falling (participants fell 2 or more time in the assessment period).

Table 1. Falling and Repeat Falling at 8 weeks and 6 months

	Exercise Group	Control Group	Between Group Difference (95% CI)	p Value
Falling				
• 8 weeks	37/65 (57%)	42/64 (66%)	-9% (25%, 8%)	0.423
• 6 months	46/63 (73%)	49/63 (78%)	-5% (-20%, 10%)	0.645
Repeat Falling				
• 8 weeks	21/65 (32%)	28/64 (44%)	-11% (-27%, 5%)	0.245
• 6 months	35/63 (56%)	42/63 (68%)	-11% (27%, 6%)	0.266

Table 1 shows the results for the categorical data of falling. The category of falling includes all participants who fell at least once during the assessment period, while the category of repeat falling includes participants who fell 2 or more times during the assessment period. There were no significant differences between the exercise and the control group in either category of falling. For the category of falling, the difference between the exercise group and the control group was -9% (CI of 25% to 8%) at 8 weeks, and -5% (CI of -20% to 10%) at 6 months. In the category of repeat falling, the difference between the exercise group and the control group was -11% (CI of -27% to 5%) at 8 weeks, and -11% (CI of 27% to 6%) at 6 months. Overall there was a trend toward lower falling rates in the exercise group at both 8 weeks and 6 months. We calculated the NNT at 8 weeks to be 11.49 (CI of 3.9 to -12.4), and at 6 months to be 21 (CI of 5.1 to -9.8). The confidence intervals of each of these NNTs range into the negative, which means that in some instances if the study were repeated there would actually be a number needed

to harm. For instance, at 8 weeks, the NNT of 11.49 means that we would need to treat 12 patients to see a decrease in falling that was significant, but the wide confidence interval that ranges from 3.9 to -12.4 means that we could see this difference when treating as few as 4 patients, but also that when treating 12 patients we could see an increase in falling. These conflicting numbers are not surprising, given that the trends toward seeing lower fall rates in the exercise group were not significant. We calculated the Odds Ratio as well, which gave similarly unhelpful information, due again to the lack of statistically significant results. At 8 weeks the Odds ratio was 0.69 (CI of 0.34 to 1.41), and at 6 months the odds ratio was 0.77 (CI of 0.34 to 1.74).

After analyzing the results and seeing no statistically significant differences in the primary outcome of reported falls, the researchers ran a subgroup analysis to see if disease severity made a difference in the results.

Table 2. Subgroup analysis of repeat falling at 6 months (Disease Severity)

	Exercise Group	Control Group	Between Group Difference (95% CI)	p Value	NNT
All Cases	35/63 (56%)	42/63 (68%)	-11% (-27%, 6%)	0.266	
<b>Hoehn and Yahr 2-3</b>	<b>20/47 (43%)</b>	<b>31/49 (63%)</b>	<b>-21% (-39%, -1%)</b>	<b>0.046</b>	<b>4.83 (2.5 to 85.7)</b>
Hoehn and Yahr 4	15/16 (94%)	11/14 (79%)	16% (-12%, 44%)	0.041*	

Hoehn and Yahr Scale: 2 = bilateral/midline involvement, no balance impairment; 3 = impaired righting reactions, mild or moderate disability, capable of leading independent lives; 4 = severe disability, can walk but marked disability on activities of daily living.

Table 2 shows a subgroup analysis based on severity of disease stage, which was assessed using the Hoehn and Yahr Scale (H&Y) for rating PD disease severity. When the group of participants from both groups who rated a 4 (severe disability) on the H&Y were separated out and analyzed separately, the authors found a statistically significant difference in the subgroup of participants with less disease severity (Hoehn and Yahr 2-3) between the exercise group and the control group when looking at repeat falling at six months. The difference between groups in this case was -21%, with a CI of -39% to -1%, and a p-value of 0.046. We calculated the number needed to treat (NNT) for the H&Y 2-3 subgroup to be 4.83 (CI of 2.5 to 85.7). This tells us that in this subgroup of participants in earlier stages of PD we would need to treat 5 patients to see 1 positive result, but the large CI tells us we might have to treat as many as 86 patients to see this result. We also calculated the Odds Ratio to be 0.43 (CI 0.19 to 0.98), indicating that the treatment group's risk for falling was 43% of the control group's risk. The large CI tells us that this range could be 19% to 98%.

The fact that the authors chose to track falls by categorizing participants into the categories of falling and repeat falling may offer an explanation for the lack of significant results, and may be a possible weakness of the study design. By categorizing this data the researchers lost numbers that could have given more sensitive information about decrease in fall risk. The numbers of falls reported in the previous year by participants at baseline ranged widely, with some

participants having fallen over 1800 times. For some of these participants to show improvement in this study, they would have had to have gone from falling an average of 5x per day to falling only once during the 8 week or 6 month period. It is possible that some of these patients improved and fell less often, but this data is lost by analyzing it categorically.

### **Applicability of study results:**

**Benefits vs. Costs:** The overall results show no significant difference between groups for fall rates, indicating no benefit to the intervention. However, the subgroup analysis that separated participants based on disease severity did show a statistically significant difference, with the exercise group having significantly fewer repeat fallers than the control group at 6 months. These results suggest that for patients in the early stages of Parkinson's disease participation in a home-based exercise program overseen by a physiotherapist could reduce falls. The primary costs of this intervention would be patient and therapist time, and cost of therapy sessions, a relatively low cost option for patients.

**Feasibility of treatment:** The exercise protocol in this study design was modeled to be similar to that encountered in routine physiotherapy practice. The weekly sessions with the physiotherapist in this study were in participants' homes. This would only be feasible for patients being seen in home health. It would be more typical for patients in early stages of PD to be seen in an outpatient clinic. The authors don't report adherence rates to the home exercise program, but participating in all six home visits was feasible for the majority of patients.

**Summary of external validity:** The fair internal validity somewhat compromises the ability to generalize the results of this study. Subjects were similar to those with PD who may be treated at a clinic, ranging in age from 44 to 91 years old. The results cannot be extrapolated to patients with PD who are not independently mobile.

**Article 3:** Goodwin, V. A., Richards, S. H., Henley W., Ewings, P., Taylor, A. H., & Campbell, J. L. (2011). An exercise intervention to prevent falls in people with Parkinson's disease: a pragmatic randomised controlled trial. *Journal of Neurology, Neurosurgery, and Psychiatry*, 82, 1232-1238.

**Clinical Bottom Line:** Based on the results of this study, there is fair evidence to suggest that for patients with idiopathic Parkinson's disease (PD) who are independent ambulators, an intervention of weekly group and home-based exercise program does not decrease fall risk compared to standard care. The exercise sessions for the intervention group consisted of a 60 minutes group class consisting of strengthening and balance exercises once per week for 10 weeks and a home exercise program done twice per week. The results showed no statistical difference between groups for fall risk using the odds ratio for self-reported falls. Threats to internal validity include small sample size, the inability to blind patients, lack of long-term follow up to determine actual falls and poor adherence to the exercise program. If the treatment had been successful, this would be a feasible treatment option as the exercise program was based

on a manual of exercises which are typical exercises used in physical therapy practice. There were no differences between subjects in the study and our clinical patient population. To feel more confident applying this intervention to our patient population we would like to see studies showing a statistically and clinically significant difference in number of falls between groups and reduction of falls in a one-year follow up period.

### **Article PICO:**

**Population:** People with idiopathic Parkinson's disease who were independent indoor ambulators with a history of two or more falls in the previous year

**Intervention:** 10 weeks of an hour-long group exercise class once per week and home exercise program (HEP) twice per week including strengthening and balance training.

**Comparison:** Usual care which could include medical and medication management, physical therapy, occupational therapy or speech therapy.

**Outcomes:** Number of falls reported during intervention and 10 week follow-up period, Falls Efficacy Scale International, EuroQOL-5D, Phone-FITT, Berg balance scale, and Timed up and go

**Blinding:** The assessors were not blinded in this study. The outcome we are primarily concerned with is self-reported falls, and assessors had no role in measuring this outcome measure. It was not possible to blind subjects and therapists, as subjects either did or did not participate in the exercise program, which served as the intervention. We did not consider this a serious threat to internal validity.

**Controls:** Both the control group and the exercise group received usual care including medical and medication management, occupational therapy, speech therapy or physical therapy which could include exercise, advice, providing walking aides or gait training. The intervention group participated in an exercise program, while the control group did not receive any additional intervention. Although some participants were receiving physical therapy outside of the study protocol, it was a small enough number that we do consider it a serious threat to the study design. Only seven percent of the intervention group and 2 percent of the control group were receiving physical therapy outside of the intervention protocol. Both groups received a booklet containing fall prevention advice. Differences between groups can be assumed to be due to the exercise program.

**Randomization:** Participant group assignments were randomized using computer generated random number tables. At baseline both groups were similar in age, sex, years since diagnosis, living arrangements, comorbidities and type of medicine taken with the exception of dopamine agonists. 61 percent of the intervention group was taking a dopamine agonist while only 41 percent of the control group was taking a dopamine agonist. Groups were also similar in stages of the Hoehn and Yahr stages of Parkinson's disease, which is a scale rating the severity of Parkinson's disease. Overall randomization was successful at producing similar groups at baseline.

**Study:** The study was a randomized controlled trial with 66 subjects in the control group and 64 subjects in the treatment group. Inclusion criteria comprised of being diagnosed with idiopathic PD using the UK Brain Bank criteria, self-reported history of 2 or more falls in the previous year, independent indoor ambulation with or without an assistive device and being a resident of Devon, a county in England. Exclusion criteria were comorbidity or symptoms affecting safety or ability to exercise and being unable to follow written or verbal instructions in English. Both the exercise and control groups continued usual care described above. The treatment group participated in a 10 week intervention including a 60 minute group exercise session once per week and a home exercise program twice per week for 10 weeks. There were 3 to 7 participants in each exercise group. The group sessions consisted of a 10 minute warm-up, 40 minutes of strength and balance exercises and a 10 minute cool down. The exercises were chosen from an effective falls prevention program for older adults. They were individually tailored and progressed for each patient by the physical therapist leading the session. The HEP also consisted of individually tailored exercises.

**Outcome measures:** The primary outcome measure was self-reported falls during the 10 week intervention and during a 10 week follow-up period. The authors also collected data on self-reported falls during a 10 week baseline period, before intervention. The authors used total falls per group, as well as median falls for each group as an outcome measure. The measure of actual number of falls during the intervention and follow-up periods matched our clinical PICO. The falls were recorded prospectively in weekly diaries kept by participants, which decreased the chance of under-reporting of falls, according to Mackenzie et al. (Mackenzie et al., 2006).

**Study losses:** There were a total of seven study losses. The three losses from the intervention group all occurred before the end of the intervention, including one due to death, one due to illness and another because of advice from general practitioner to withdraw. The control group lost three subjects during the 10 week intervention period, two due to hospital admission and one due to unknown reasons. In addition the control group had one study loss due to death between the end of the intervention period and the follow-up assessment. When less than five weekly fall diaries were missing in a 10 week period the authors used mean of previous diaries to replace the missing data, and performed an intention to treat analysis.

**Summary of internal validity:** The internal validity to the study was fair, with one major threat and 3 minor threats. One major threat was not having enough subjects to meet the requirement of the power analysis. The authors ran a power analysis that found that a sample size of 92 per group was needed in order to detect a 30% fall reduction. The actual study only had 64 participants in the intervention group and 66 in the control group. Therefore the study may have inadequate power to detect a fall reduction. A minor threat was that subjects could not be blinded to whether or not they received the treatment, and similarly, clinicians could not be blinded to whether or not they were giving the treatment. This could possibly have interfered with performance if patients' knowledge of their group assignment affected their expectations. An additional minor threat was that the 10 week follow-up period was not sufficiently long enough to determine long-term fall risk as a result of the intervention. There was also inconsistent compliance with attendance to group exercise and adherence to the HEP. We could

more clearly tell if exercise impacted the outcomes if the participants actually did all of the exercises. Another potential threat was lack of assessor blinding for secondary outcome measures. This did not impact the data we analyzed, because we were only concerned with the primary outcome measure of self-reported falls.

**Evidence:** The evidence most applicable to our clinical question is self-reported falls.

Table 1. Median and totals of self-reported falls at baseline, intervention, follow-up, and within group change and odds ratio (p = 0.44).

Group	Baseline Median (range)	Intervention Median (range)	Follow-up Median (range)	Change from baseline to follow-up	Odds Ratio (95% CI)
Control	6.5 (0, 577)	6 (0,677)	4(0, 678)	-2.5	0.70 (0.28 – 1.74)
Exercise	6.5 (0, 531)	3 (0, 398)	2.5 (0, 49)	-4	

Table 1 shows the median and ranges for self-reported falls during the 10 week period before, during, and after the exercise intervention. We calculated the within group change between baseline and follow-up. The median fall decrease was 2.5 for the control group and 4 for the exercise group. Therefore, after 10 weeks of exercise intervention and 10 weeks of follow up, the median falls of the exercise group decreased 1.5 more than median falls for the control group. Due to the authors’ lack of reporting means and standard deviations we were unable to determine if there was a significant between group difference for number of falls. Table 1 also includes odds risk reported by the authors, showing the between group difference of risk for falling. This was not statistically significant (p=0.44). The odds ratio was 0.70 indicating the treatment group’s risk for falling was 70 percent of the control group’s risk. The large 95% confidence interval of 0.28 to 1.74 indicates either the control or the treatment group could have a greater risk of falling.

**Applicability of study results:**

**Benefits vs. Costs:**

There was no significant difference in fall risk found between groups using the odds ratio, indicating no benefit to the intervention. It is unclear if this is due to ineffectiveness of the intervention or other limitations of the study such as the small sample size or skewed data due to large range of fall rates. The treatment is a relatively low cost option for patients. The primary costs would be the patient’s time which would be one hour per week for group exercise class plus additional travel time and time of HEP, the therapist’s time of one hour per week, and the financial cost of the group exercise sessions. There were no adverse events due to the intervention.

**Feasibility of treatment:**

This study utilizes a feasible treatment protocol. The physical therapists were provided with an exercise manual and one training session in which they received feedback on content, safety, effectiveness and personal performance. The exercises included in the treatment are common in physical therapy practice so no additional specialty training was needed. As in standard physical therapy practice the therapists were able to individualize programs to each specific patient's level of performance. The intervention was a combination of a home exercise program with a total of ten weekly group sessions. This seems feasible if insurance would cover group exercise sessions. Attending all 10 group exercise sessions appeared unfeasible for the participants. Patients attended a mean of 6 (3.6) of the 10 group sessions. Nine participants did not attend any of the group sessions. Though the mean home exercise sessions per week was 2, the number intended for the study, the authors report overall adherence to group sessions and HEP was similar to the 70% adherence rate reported in the study done by Allen et al.

**Summary of external validity:**

The fair internal validity somewhat compromises the ability to generalize the results of this study, primarily in that there was no long term follow-up and not enough subjects to rule out a type II error. Subjects were similar to those with PD who may be treated at a clinic, with a wide age range of 50 to 89 years old. The results cannot be extrapolated to individuals with PD who are not independent indoor ambulators, nor to those with comorbidities that would make this program unsafe. A significant limitation to the external validity of the study was the homogeneity of the population. All subjects lived in Devon, an area of southwest England. All were white and all but two were British.

**Synthesis and Discussion:** The purpose of this paper was to determine if exercise including balance and strength training decreases fall risk in patients with Parkinson's disease. All studies included were randomized control trials with a PEDRO score of 7 or 8. All studies included subjects who were ambulatory and diagnosed with idiopathic Parkinson's disease. All studies used an exercise intervention involving strengthening and balance training. They all included a home exercise program, while the Allen et al. and Goodwin et al. studies also incorporated a group exercise program. Duration of interventions was 6 months, 6 weeks, and 10 weeks.

Treatments were feasible and of reasonable cost, but for several reasons we were unable to definitively answer whether or not exercise intervention would decrease fall risk for our chosen patient population. The articles reported mixed results. There was no significant difference in fall risk using outcome measures of the PD fall risk assessment, number of people having a fall, and number of falls per person. There was a significantly decreased fall risk in the exercise group in the Allen et al. study using the outcome measure of 5 times sit to stand. The Ashburn et al. study also showed a significantly decreased fall risk in the exercise group, specifically for those participants in the Hoehn and Yahr stage 2 or 3 of disease severity, using the outcome measure of repeated falls.

Analyzing the effect of exercise on fall risk for patients with Parkinson's disease may be more meaningful if all participants are in the same Hoehn and Yahr stage of disease severity. Parkinson's disease is a progressive disorder, so patients will present with different impairments at different stages of the disease and potentially benefit from different interventions based on

their clinical presentation. Also, fall risk increases as disease severity increases, therefore using subjects in different Hoehn and Yahr stages could convolute the data. Ashburn et al. was the only study analyzing fall risk based on disease severity. Their results are potentially the most useful in demonstrating an effective exercise intervention to prevent falls in people with a specific level of disease severity according to the Hoehn and Yahr scale. More research needs to be done to identify the best intervention for decreasing fall risk in each stage of Parkinson's disease.

In our literature search the three articles we chose were the only three randomized controlled trials we found which compared the effects of exercise interventions to usual care in decreasing fall risk for PD patients. In recent years, alternative therapy methods have been proposed for PD patients, but there is limited research on these therapies. The "BIG" therapy model as formulated by Lee Silverman Voice Treatment (LSVT®) strives to improve movement and voice amplitude in PD patients, who typically experience hypokinesia and bradykinesia. A study by Farley et al. looked at the effects of "BIG" training on movement speed. Their results showed significant increases in speed for gait and reaching in response to four weeks of BIG therapy. Another alternative treatment getting recent attention for PD therapy is instruction in tango dancing. In our search we found a preliminary study by Hackney et al. on the effects of tango dancing on functional mobility in PD patients, in which the tango group showed significant improvements on the Berg Balance scale over the exercise group. We found no studies in the literature examining "BIG" therapy or tango therapy with regards to effects on fall risk for PD patients. We would like to see further research that compares "BIG" movement therapy and tango therapy to standard physical therapy exercises with regards to fall prevention.

In conclusion we can cautiously apply balance and exercise interventions to decrease fall risk in our patients with PD. In the three studies we compared, the generalizability to our patient population is compromised by fair internal validity, not having enough subjects for adequate power, and all subjects being either from the UK or Australia. More research is needed to determine whether or not exercise can decrease falls in patients with Parkinson's disease, the extent to which disease stage interferes with the effects of an exercise program, the optimal exercise protocol, and the effectiveness of alternative therapies.

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