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Does Exercise Reduce the Risk of Falling in Parkinson's Patients?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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Abstract

Objective: The objective of this selective EBM review is to determine whether or not exercise reduces the risk of falls in Parkinson's patients

Study Design: Review of three English language randomized control trials (RCTs) published in 2003, 2007 and 2010.

Data Sources: 3 randomized controlled trials published after 1999 were obtained using Pubmed.

Outcomes Measured: The Allen study used a Parkinson's disease fall risk scoring. The Ashburn study used patient dairies to record incidence of falls. The Hirsch study used Sensory Orientation testing assessing the trials resulting in falls.

Results: Allen et al and Ashburn et al found no significant reduce in the incidence in falls while Hirsch et al was able to show a significant reduction in the incidence of falls.

Conclusion: Evidence supporting the role of exercise in reducing the incidence of falls in Parkinson's patients in inconclusive and conflicting at this time. A more standard exercise program and method of collecting results is needed for studies that can last longer and represent a larger portion of the population of Parkinson's patients.

Parkinson's disease (PD) is a neurodegenerative brain disorder that occurs due to degeneration of dopaminergic neurons in the substantia nigra resulting in reduced striatal dopamine and intracytoplasmic proteinaceous inclusions known as Lewy bodies.[1] Clinical signs of Parkinson's result from the depletion of Dopamine and include bradykinesia, a resting tremor, rigidity and postural instability which results in a characteristic wide shuffling gait.[1 2] The cause of Parkinson's is mostly idiopathic (85-90%) and it affects men and women of all races with a mean onset of 60 years old but has manifested, mostly due to genetic factors, in patients in their twenties.[1]

Parkinson's, the second most common neurodegenerative disease in the United States, affects approximately one million people across the country and is the fourteenth leading cause of death according to the National Parkinson's Foundation.[3] According to a study by Kowal et al "the population with PD incurred approximately 1.9 million hospital inpatient days in 2010. Excess healthcare use attributed to PD in 2010 includes 1.26 million physician office visits, 57,000 outpatient visits, 31,000 emergency visits, 24,000 home health days, and 26,000 hospice days."[4] As Physician Assistants these statistics show we will often come across Parkinson's patients during our careers. With the population of Parkinson's patients expected to rise the healthcare costs are expected to rise with it. A study by Kowal et al states "The national economic burden of PD exceeded $14.4 billion in 2010 (approximately $22,800 per patient). The population with PD incurred medical expenses of approximately $14 billion in 2010. Indirect costs (e.g., reduced employment) are conservatively estimated at $6.3 billion (or close to $10,000 per person with PD)."[4] Although there is no exact data to show the amount of hospital visits that result from a Parkinson's patient falling, a study by Allen et al states "falls are a major problem amongst people with Parkinson's disease. Up to 68% of people with Parkinson's fall each year,

with around 50% falling repeatedly. Falls can cause injuries and fear of falling and contribute to inactivity and reduced quality of life."[5]

There is no cure for Parkinson's, however the following medicines seem to improve the symptoms of the disease: Levadopa, Dopamine Agonists: pramipexole, ropinirole, rotigotine and MOA-B Inhibitors: Selegiline and rasagiline. [1] However the medications used to slow the progression of PD have not had an effect on reducing the number of falls among PD patients.[5] With the population of PD patients expected to grow we can expect that PD related falls or going to have an increasingly larger impact on the health care system. [5]

There have been studies that suggest exercise consisting of resistance training, balance training or a combination of the two can help reduce the risk of falls and fear of falling in elderly patients.[6] This paper aims to evaluate three randomized controlled studies (RTCs) that have implemented an exercise program into the lives of PD patients to see if these programs have the ability to reduce the incidence of falls among the PD population.

Objective

The objective of this selective EBM review is to determine whether or not exercise reduces the risk of falls in Parkinson's patients.

Methods

The criteria used in the selection of the three RCTs for this review was test groups ages 30 and above that had been diagnosed with Idiopathic Parkinson's Disease by a neurologist. Although different specific methods were used in each study the intervention of interest was a prescribed exercise program including balance training. The comparison group of interest were those that had not received a prescribed exercise program. The outcomes searched for in each

article was a reduced incidence of falls in Parkinson's patients after a participating in a prescribed exercise program.

Key words searched for were "Parkinson's", "exercise" and "falls". All articles were published in English in peer reviewed journals. Articles were searched for by the author via Pubmed and selected based on their relevance to the clinical question, human subjects and outcomes that included patient orientated evidence that matters. Inclusion criteria included articles from 1999 to present, randomized controlled, double blind trials. Exclusion criteria included articles published prior to 1999 and patients without a confirmed diagnosis of Parkinson's disease. Statistics used within the studies are P-values, Confidence intervals (CI) and change from mean of baseline. Table 1 demonstrates the demographics of the participants in the study.

Outcomes Measured

The exercise group from the Ashburn et al study received a personalized home based exercise program that lasted 6 weeks comprised of "muscle strengthening exercises (knee and hip extensors, hip abductors), range of movement (ankle, pelvic tilt, trunk and head), balance training (static, dynamic and functional) and walking."[6] Participants were asked to perform exercises daily and to keep a standardized record of the exercises performed.[6] During the initial 6 week period weekly visits by a physiotherapist encouraged progression of exercises and proper instruction.[6] When the initial six week period was over each participant received a monthly phone call from a physiotherapist encouraging them to continue their exercises and ask questions regarding their progress.[6] The control group received their usual care from a Parkinson's disease nurses.[6] Outcomes for this study were measured by rates of falls at eight weeks and six months

Table 1 - Demographics & Characteristics of included studies

Study	Type	#pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
[2] Hirsch (2003)	RCT	15	75.7_1.8 70.8_2.8	Ambulatory volunteers diagnosed with IPD who had not participated in any balance or muscle strengthening activities before	acutely ill, suffering from unstable cardiovascular disease or other uncontrolled chronic conditions	0	Combined balance and resistance training
[5]Allen (2010)	RCT	48	30-80	-diagnosis of idiopathic PD walking independently -on the same medication for their PD at least 2 weeks -fallen in the last year, or at risk of falling	-had significant cognitive impairment -had another neurological/musculoskeletal/ cardiopulmonary /metabolic condition that would interfere	3	Exercise, 40 to 60min program of progressive lower limb strengthening and balance exercises 3 times per week for 6 months
[6]Ashburn (2007)	RCT	142	72.7(9.6)-71.6(8.8)	confirmed diagnosis of idiopathic PD, independently mobile, living at home in the community, experienced more than one fall in the previous 12 months and passed a screening test	unable to participate in assessments because of pain, and acute medical condition	12	home based exercise and strategy program

recorded in by patient in their patient diaries. Also examined was repeat falls, near falls and injurious falls. [6]

In the study by Allen et al the exercise group received a home based program comprising of a "40-60 minute program of progressive lower limb strengthening and balance exercises three times per week and balance exercises 3 times per week for 6 months."[5] Participants received one

to two home visits from a study therapist and were encouraged to attend a monthly exercise class led by two physiotherapists with experience in neurological rehabilitation. [5] The program sessions were based on a Parkinson's disease version of the Weight-bearing Exercises for Better Balance and included "standing up and sitting down, heel raises, half squats, and forward or lateral steps onto a box."[5] Resistance was added by the use of a weighted vest and progressively adjusted weight according to participant's performance and perceived exertion. The Borg Rating of perceived exertion was used with the goal of participants achieving a rating of 15 (hard or heavy).[5] Balance training consisted of "standing with a decreased base of support, forwards or sideways stepping or walking and graded reaching activities in standing."[5] The control group received their usual care from PD nurses. The outcomes measured was a Parkinson's disease fall risk score. The score consisted of contributions from results of three tests- 1) knee extensor strength, measured using a strain gauge, 2) balance, measured using a coordinated stability test and 3) freezing of gait 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". [5]

The exercise program used in the study by Hirsch et al included supervised progressive resistance training of the ankle plantarflexors and knee extensors and flexors due to their "presumed importance in balance in persons with Parkinson's disease." [2] The exercise sessions lasted 15 minutes per session and were held three times per week on nonconsecutive days with the program lasting ten weeks. Participants were trained and supervised by an exercise leader who was also in charge of recording exercises completed and resistance used.[2] The protocol for this study was based off of using an initial four repetition maximum. During the first two weeks participants performed one set of twelve repetitions per exercise with a two minute rest between exercises. The load was increased to 80% of the four repetition maximum at the end of the

second week. A four repetition maximum was measured every two weeks in order to adjust the stimulus so that load was kept at 80% of the new four repetition maximum.[2] Balance exercises based on an "adaptation of standard balance rehabilitation exercises that have been shown to improve balance in persons with Parkinson's disease"[2] were performed during thirty minute sessions, three days a week. Balance training included standing with feet shoulder width apart on a foam pad or standing without the foam pad. Participates were asked to "stand with feet shoulder width apart with eyes open, eyes closed, and neck in neutral or neck extended for 20 seconds repeated five times."[2] Participants would progress by adding a foam pad if not previously using one or placing more foam pads on top of ones already being used. The next set of balance exercise involved the participants being gently perturbed by a therapist while on the ground with eyes open or closed or on a foam pad with eyes open or closed. Lastly participants were asked to perform weight shifting exercises on the ground or on a foam pad. During these exercises participants would "sway to the limit of their stability, leaning as far as they could without falling and keeping the ankle, hip and shoulders in line."[2] Participants would sway forward, back, left and right holding each position for five seconds**.** Outcomes were measured using a Sensory Orientation Test measuring the "subject's response to reduced or altered visual and somatosensory orientation cues."[2] Tests resulting in falls were recorded pretreatment and post treatment.

Results

The study by Ashburn et al randomized participants into an exercise group (n=70) and a control group (n=72) each group assessed by a assessor that was blind to the allocation of participants at eight weeks and six months post intervention.[6] The two groups were originally compared according to disease severity, a motor assessment test, balance testing, timed get up

and go test and chair sit to stand test and found to have no significant differences between them.[6] All patients were assessed in the group to which they had been originally randomized into.[6] Adherence to the intervention was considered good as "64 participants in the control group completed all six of the weekly sessions, five had seven sessions and one had two sessions."[6] The conclusion of the study found lower fall rates in the exercise group at both eight weeks and six months but these reductions were not significant ($p = 0.423$ and 0.645 respectively).[6] A confidence interval was calculated showing no overlap thus one can say that the results between the groups are real. There were no injuries reported due to the intervention in this study. Table 2 displays the results for calculated p-value and Confidence Interval.

Table 2: single fall rates at 8 weeks and 6 months[6]

	Exercise Group (reported fall/n)	**Control Group (reported fall/n)**	**Unadjusted exercise-control difference (95% CI)**	**p-value**
Falls 8 weeks	37/65 (57%)	42/64 (66%)	-9% (-25%, 8%)	0.423
Falls 6 months	46/63 (73%)	49/63 (78%)	-5%(-20%,10%)	0.645

In the study by Allen et al, a randomized controlled trial with blinded assessment, forty eight participants with diagnosed Parkinson's were evaluated based on their risk of falling or if they had fallen in the past year.[5] "Participants were considered at risk to fall if they scored 25cm or less on a Functional Reach test or if they failed to reach criterion on one of the balance tests in the *QuickScreen*© Clinical Falls Risk Assesssment."[5] With no significant differences at baseline participants were then randomized into a control group (n=24) and an exercise group (n=24).[5] There were three drop outs from the exercise group and "worst case" analysis was not done. The

participants and their respective groups were kept blind from the physiotherapist who performed the post treatment assessment.[5] Of the possible six exercise classes offered, the exercise group attended a mean of 3.6 (SD 2.1) and completed 70% (SD 32%) of the total prescribed exercise sessions.[5] There were no adverse events reported by participants during this study.[5] While the exercise group was able to show a greater improvement on their falls risk score (mean difference between group = -7%, 95% CI -20 to 5) results were not significant (p= 0.26).[5] Results are shown in table 3.

Table 3 – Differences between Exercise and Control groups Pre and Post treatment. (Values as mean (SD) [5]

	Pre test		**Post test**			
	Exercise (n=24)	**Control (n=24)**	**Exercise (n=21)**	**Control (n=24)**	**Difference between groups** mean(95%CI)	**P value**
PD falls risk score	34(25)	39(34)	23(22)	38(31)	-7 (-20 to 5)	0.26

-a higher score reflects a poorer performance

The randomized control study by Hirsch et al participants were split into two groups, one received only balance exercise and one received a combination balance and resistance exercises.[2] Although for the purposes of this review the groups were combined when analyzing tests resulting in falls because balance training even alone is still considered exercise. Participants performed a pretreatment and post treatment balance test to measure the percentage of trials that resulted in falls.[2] Adherence to the prescribed program between the two groups was 90.6%. The data of two participants was eliminated from the study due to one being re-diagnosed as to not having Parkinson's and the other participant requiring a long hospitalization.[2] The study was

able to show significant decrease in the number of trials resulting in falls (p=0.018) from pretreatment to post treatment as shown in table 3. [2]

Table 4 – Percentage of trials resulting in falls (values in mean +/- standard errors of the mean) [2]

	Pretreatment (n=15)	**Post treatment (n=15)**	**P value**
% trials resulting in falls	32.86 +/- 8.04	12.77+/-4.07	0.018

Discussion

Of the three RCTs discussed in this systemic review that set out to evaluate the effectiveness of a prescribed exercise program in reducing the incidence of falls in PD patients only one study by Hirsch et al was able to show a significant reduction in falls post intervention. However there are several limitations to the studies. One being that the study by Hirsch et al did not have a control group to compare results against. The sample sizes studied 142, 48 and 15 do not accurately represent the population of 1 million PD patients in the United States. Another limiting factor is the lack of a standardized method to measure results which resulted in all three studies using a different method to measure whether or not the intervention had an effect. There was also a limiting factor due to the great variability in the exercises conducted and amount of supervised exercise time across all three studies.

Although the study by Hirsch et al was able to show a significant decrease in the amount of falls in PD patients post exercise intervention, it is unlikely that the specific type of training used for this study could provide a viable option for the majority of PD patients. Participants were provided access to a specialized training facility where they received one on one supervised training at each training session. These participants were able to receive personalized encouragement, guidance and support that the participant's in the other two studies were not

given. From a financial standpoint it is unknown if most participants could afford access (membership cost, location, transportation) to this type of facility and the added expense of one on one training. It is also unknown if insurance would be willing to pay for such expensive preventative measures. Unfortunately the cheaper options of group and self-monitored, home based training used in the other two studies did not prove to significantly decrease falls.

Lastly a limitation to the studies was the length of time of the studies. Parkinson's is a neurodegenerative disease that, regardless of how slow, is constantly exerting its degenerative effects on the diagnosed individual. Therefore exercise with a PD patient is not going to provide results as quickly as it may for a non-Parkinson's patient. Ashburn et al and Allen et al were both 6 months long and Hirsch ten weeks, even though only one was able to show significant improvement each study was able to show a trend towards a decrease in the number of falls after the intervention in both amounts of time. There is a possibility that longer studies would give the PD patients more time to adapt and show a greater reduction in falls over time.

There were two ethical limitations to these studies. One being that during the study participants were asked to refrain from additional training outside of the program. In the study by Ashburn et al "By six months 34% of the control group were participating in extra rehabilitation compared to 25% of the exercise group."[6] This may have affected the outcome of the study, however it is unethical to force participants to refrain from rehabilitation activity.[6] During the study by Allen et al "nine exercise and fourteen control participants had modifications to their medications."[5] For ethical reasons patients cannot be asked to refrain from altering their medications and although Parkinson's medications have not proven to reduce the incidence of falls it is possible that this had an effect on the results.[5]

Contraindications with this type of therapy are attempting exercise without first consulting your doctor, unsupervised exercising and performing exercises when the risks out weight the benefits.

Conclusion

The evidence that exercise can reduce the risk of falls in people diagnosed with Parkinson's disease is inconclusive and conflicting. A flaw in the studies is the reliance on the patients to honestly report whether or not they had performed their daily exercises or how many falls they experienced. This method of collecting information runs the risk of patients over or under reporting adherence to the prescribed program or how many falls they experienced.

Parkinson's management requires a multidisciplinary approach including pharmacologic and physical activity.[2] Although there is inconclusive and conflicting evidence that an exercise program can help decrease the incidence of falls among Parkinson patients, there is a trend showing it may help and can fill a role in management where medications have not yet been shown to help.[5] However more research must be done in order to create a standardized way of training patients and collecting results. More studies are needed over a longer period of time that properly represent the majority of the Parkinson's population and provide a feasible method of receiving this type of care.

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