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Attentional Focus During Balance Training in Idiopathic Parkinson's Disease (PD): A Randomized Clinical Trial

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ATTENTIONAL FOCUS DURING BALANCE TRAINING IN IDIOPATHIC PARKINSON'S DISEASE (PD): A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

The purpose of this study was to compare the effects of various attentional focus strategies on balance in people with PD. Forty-nine adults with idiopathic PD were randomized into one of four groups (internal focus, external focus, no focus, and control). The three intervention groups participated in a month-long balance program. The outcomes measured were the Sensory Organization Test, Berg Balance Scale, self-selected gait velocity, Dynamic Gait Index, Activities-specific Balance Confidence Scale and obstacle course completion time. These outcomes were measured at baseline, post intervention, 2-weeks post intervention, and 8-weeks post intervention. Statistical analyses yielded no significant differences among the groups. This study demonstrated that attentional focus instructions may not have a long-term effect on balance in individuals with PD. It also suggests that a standardized balance program including treadmill training, an obstacle course, and standing balance activities may not be sufficient to improve gait and balance in people with PD.

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INTRODUCTION

PD is a highly prevalent and financially burdensome disease, partly due to the increased risk of falls and subsequent injury. Over a five-year period, it was found that people with parkinsonism were 1.3 times more likely to sustain an injury compared to healthy, age-matched individuals (Pressley et al., 2003). Furthermore, it has been found that people with parkinsonism are 3.2 times more likely to experience a hip fracture compared to equal counterparts without parkinsonism (Johnell et al., 1992). The increased fall rate associated with the disease contributes to the financial burden that people with PD must face. The total per capita cost of PD has been found to be between $19,178 and $21,626 in 2009, including both direct and indirect costs of the disease (Chen, 2010). Decreasing the fall risk of people with PD by improving balance is therefore a main focus of treatment for the disease.

One effective mode of treatment for preventing and treating balance impairment is physical therapy. Physical therapy treatment for people with PD can include but is not limited to the use of strengthening, stretching, balance training, gait training and functional training. Such physical activity and exercise has been shown to have a positive impact on balance in people with PD (Allen et al., 2011; Dibble et al., 2009a; Dibble et al., 2009b). Current research indicates that the risk of falling in older people can be reduced through physical activity programs that include balance, strength or cardiovascular training, as well as a combination of these three (Allen et al., 2011; Gillespie et al., 2009; Hill et al., 2004). Similarly, a literature review (Pereira et al., 2008) reported that programs including strength, agility, stretching, and multi-modal treatments decreased fear of falling, number of falls, and injuries from falls in the elderly population. In subjects with PD, short-term improvements in muscle strength and balance were found after a treatment combining high-intensity resistance training with balance training (Hirsch et al., 2003).

Research has also shown that people with PD can decrease their overall fall risk as well as sit to stand time and freezing of gait by participating in practical, minimally supervised exercise programs (Allen et al., 2010). Unfortunately, several studies have shown that dopaminergic therapy alone does not prevent postural instability in subjects with PD (Jankovic, 2008; Maurer et al., 2003) and may actually decrease stability (Bronte-Stewart et al.,2002). Since domaminergic therapy has not been shown to decrease postural instability, studies on non-pharmacologic approaches are warranted.

One theorized strategy to improve balance in PD is to give individuals attentional focus instructions while performing balance activities (Landers et al., 2005; Wulf et al., 2009). This method either directs the person's attention toward the effect of the action (external focus) or the body movements (internal focus). For example, while a person balances on a movable platform, instructions could be given to either focus on the support surface (external focus) or to focus on the feet (internal focus) (Landers et al., 2005). External focus instructions, compared with internal focus instructions and no instructions, have shown to decrease sway during balance activities in people with PD who have a fall history (Landers et al., 2005). To verify these findings, Wulf et al. (Wulf et al., 2009) conducted a similar study using a more challenging balance activity. They found similar results supporting the benefits of external focus over internal focus and no instruction (Wulf et al., 2009). While attentional focus in general has been a component of balance training programs historically, current research suggests that external focus is more beneficial than internal focus.

The objective of this study was to test the generalizability of previous research findings (Landers et al., 2005; Wulf et al., 2009) to the learning of various balance tasks in individuals with PD. Specifically, the previous studies by Landers et al. and Wulf et al. demonstrated acute decreases in postural sway when an external focus was adopted; however, no long-term effects were investigated and only postural sway was measured. Therefore, we hypothesized that the positive effects of external attentional focus instructions during balance training would translate into real world or clinical benefit with long-term, meaningful changes in individuals with PD. In a secondary hypothesis we proposed that balance training, regardless of attentional focus, was better than no training. This study aims to investigate the effects of both internal and external attentional focus instructions on balance training in patients with PD.

METHODS

Subjects

Forty-nine community-dwelling individuals with idiopathic PD were recruited using advertisement through the local American Parkinson's Disease Association quarterly publication and through fliers (table 1). Participants were excluded from the study if they were non-ambulatory or if significant comorbidities were present (e.g., stroke, total hip/knee replacement). They were also excluded if they had a history of surgical intervention for PD (e.g., deep brain stimulation, thalamotomy or pallidotomy). Participants were instructed to maintain their routine medication schedule and participated in the testing and interventions during peak "ON" periods of the medication regimen if receiving dopaminergic therapy. Written informed consent, under Institutional Review Board approval at the University of Nevada, Las Vegas, was received from each subject prior to starting the experiment. Figure 1 illustrates the subject recruitment, allocation, and analysis.

Insert table 1

Insert figure 1 here

<u>Procedures</u>

Participants were asked to report to the Gait and Balance Laboratory at the University of Nevada, Las Vegas for screening, intervention sessions, and outcomes assessment. Following completion of an informed consent form, they were screened for eligibility and then randomly assigned using a random numbers table to one of four groups (A, B, C, or D). Baseline measurements were taken immediately prior to beginning a 4-week long treatment program.

The experimental design included four groups of participants with PD (3 treatment groups and 1 control group). The 3 treatment groups practiced various static and dynamic balance tasks for a period of 4 weeks, and the control group received no training during this period (table 2). One group received external focus instructions for each task (Group A), while another group was given internal focus instructions (Group B). A third group practiced the same balance tasks but was not given attentional focus instructions (Group C). The fourth group served as the control group and did not receive any training (Group D). While all participants in Groups A-C were given general instructions regarding how to perform the various tasks, participants in Groups A and B were given additional attentional focus instructions. Participants in Groups A-C performed practice sessions under their respective attentional focus group 3 times per week, about 45 minutes per day, for 4 weeks.

Each treatment session for groups A, B and C consisted of: 10 minutes of treadmill training, 10 minutes of obstacle course negotiation and 10 minutes of balance training on a compliant surface in a harness (tandem stance, narrow support stance, single leg stance, eyes closed and external perturbations). External perturbations consisted of 5 to 10 pounds of expected and unexpected nudging. The obstacle course consisted of stepping over 3 obstacles that were 5 inches tall, walking on a balance beam forward, backward, and side-stepping, weaving through 5 cones, and finishing by turning 180 degrees to start the course again. This course was repeated 3 times, which took approximately 5 minutes to complete; a 30 second rest period was given, and the 5 minute routine was repeated, for a total of 10 minutes spent on the obstacle course. For safety reasons, all participants performed each of these training tasks in an overhead, non-deweighting harness. Group D, the control group, received no supervised training.

Insert table 2 here

The tasks were performed at each practice session, and performance was monitored by recording the time necessary to complete each task. In general, each of the tasks performed could be manipulated for the varying balance capabilities of the participants. Therefore, the balance treatment could be tailored to each individual participant, but only to a certain extent; the program components were universal for each subject. Immediately following the 4-week long intervention phase (post intervention), all outcome measurements were taken. After a 2-week retention interval (2-week post intervention), a retention and transfer test without attentional focus instructions were conducted. For the retention test, the participant was timed on an obstacle course that was different than the one they had practiced on during the training; however, no attentional focus instructions were given. All of the other outcome measures were also assessed at this time and then again 6 weeks later (8-week post intervention).

A single-blinded technique was used in which the investigators were informed of the group assignment but the subjects were not. The participants were not informed of the hypotheses of the study or educated on which group they were assigned to. The treatment sessions were one on one with a research assistant. All groups were on the same outcome measurement schedule (before treatment, immediately after treatment, 2 weeks after treatment, and 2 months after treatment). The treatment groups underwent similar treatment protocol with the exception of varying verbal direction during activities; the control group did not attend treatment sessions, but followed the same outcome measurement schedule as the other 3 groups.

Outcome measures

Outcomes were measured at baseline, immediately post intervention, 2 weeks post intervention and 2 months post intervention. At each measurement session, the following were evaluated (table 3): Sensory Organization Test (SOT), Berg Balance Scale (BBS), self-selected gait velocity (SSGV), Dynamic Gait Index (DGI), and Activities-specific Balance Confidence Scale (ABC). SOT was measured using the NeuroCom Smart® Balance Master system (Balance Master).[*]

Insert table 3 here

[*] NeuroCom®, a division of Natus®, 9570 SE Lawnfield Road, Clackamas, OR 97015, USA

Statistics

In the primary analysis, the data were analyzed using a 4 (group: A, B, C, and D) X 4 (time: baseline, post intervention, 2-week post intervention, 8-week post intervention) analysis of variance (ANOVA). A one-way ANOVA was used to analyze the 2 week retention trial of the alternate obstacle course. A secondary analysis was used to compare all three treatment groups to the control group over time. In this secondary analysis, as three of the groups had an intervention component, groups A, B, and C were combined into one group (Intervention) and compared to the group D (Control). This analysis was a 2 (group: intervention and control) X 4 (time: baseline, post intervention, 2-week post intervention, 8-week post intervention) ANOVA. All analyses were conducted using an intent-to-treat (ITT) approach with the last observation carried forward method. In addition to the ITT analyses, the data were analyzed using a per protocol method (PP) wherein only the data from the subjects who completed the trial, as they were originally randomized, were used.

RESULTS

An interim futility analysis was conducted on all of the data at the predetermined midway point of this randomized trial. Based on those findings, it was determined to halt the trial as the treatment effect was not sufficiently strong enough to warrant continued allocation of resources to recruitment and treatment of the second half of subjects. The following results are from that interim futility analysis.

Primary analysis: comparing the four groups over time

In the ITT analysis, no interactions were noted among the 4 groups over time for the SOT ($p = .135$, $\eta_p^2 = .094$, power = .659), BBS ($p = .527$, $\eta_p^2 = .057$, power = .433), SSGV ($p = .624$, $\eta_p^2 = .050$, power = .380), DGI ($p = .402$, $\eta_p^2 = .066$, power = .485), ABC ($p = .249$, $\eta_p^2 = .080$, power = .578), and obstacle course ($p = .654$, $\eta_p^2 = .048$, power = .330) (see table 4 for means and standard deviations).

Insert table 4 here

The main effect for time was significant for SOT ($p = .003$, $\eta_p^2 = .101$), BBS ($p = .003$, $\eta_p^2 = .097$), DGI ($p = .006$, $\eta_p^2 = .091$), ABC ($p = .002$, $\eta_p^2 = .114$), and obstacle course ($p < .001$, $\eta_p^2 = .189$). Post hoc analyses revealed a trend of significant improvement in several outcomes from baseline to post intervention and from baseline to 2-weeks post intervention; overall, no other changes among the rest of the measurement times were observed (table 5). The main effect for time was not significant for SSGV ($p = .121$, $\eta_p^2 = .042$, power = .500). The main effect for group was not significant for any of the outcome measures: SOT ($p = .566$, $\eta_p^2 = .044$, power = .183); BBS ($p = .126$, $\eta_p^2 = .010$, power = .076); SSGV ($p = .816$, $\eta_p^2 = .020$, power = .106); DGI ($p = .851$, $\eta_p^2 = .017$, power = .096); ABC ($p = .424$, $\eta_p^2 = .060$, power = .243); and, obstacle course ($p = .863$, $\eta_p^2 = .017$, power = .093). The results of the PP analysis were similar to the ITT analysis.

Insert table 5 here

Secondary analysis: comparing intervention to control over time

Table 6 illustrates the means and standard deviations for the secondary analysis. In the ITT analysis, no interactions were noted when comparing the intervention to control over time for the SOT (p =.193, η_p^2 = .033, power = .399), BBS (p =.207, η_p^2 = .032, power = .392), SSGV (p =.356, η_p^2 = .023, power = .290), DGI (p =.605, η_p^2 = .012, power = .161), ABC (p =.918, η_p^2 = .003, power = 074), and obstacle course (p =.675, η_p^2 = .010, power = .133). For the SOT, the main effect for time was significant (p = .034, η_p^2 = .061, power = .682), BBS (p = .022, η_p^2 = .067, power = .741), ABC (p = .007, η_p^2 = .086, power = .835), and obstacle course ($p < .001$, η_p^2 = .156, power = .983). The main effect for time was not significant for SSGV (p = .085, η_p^2 = .046, power = .559) and DGI (p = .105, η_p^2 = .044, power = .502). The main effect for group was not significant for SOT (p = .938, $\eta_p^2 < .001$, power = .051), BBS (p = .567, η_p^2 = .007, power = .087), SSGV (p = .685, η_p^2 = .004, power = .068), DGI (p = .398, η_p^2 = .015, power = .133), ABC (p = .426, η_p^2 = .014, power = .123), and obstacle course (p = .769, η_p^2 = .002, power = .060). The results of the PP analysis were similar to the ITT analysis.

Insert table 6 here

DISCUSSION

Our results suggest that attentional focus instructions did not enhance outcomes in subjects with PD undergoing a standardized balance training program. These results are not consistent with the literature, which suggests that an external focus of attention is more effective than an internal or no focus of attention for balance in individuals with PD (Landers et al., 2005; Wulf et al., 2009). In addition, it is not consistent with the plethora (Landers et al., 2005; Wulf et al., 2009; Wulf et al., 1999; Prinz., 1990) of studies that have shown a beneficial effect of the external focus relative to an internal focus or no focus for many different motor tasks. The standardized balance training intervention used in the present study did not drive significant improvements compared to those not receiving any intervention. These results are again not consistent with the literature, which suggests that balance training is effective in patients with PD.

In previous studies measuring the effects of attentional focus, only those with a history of falls experienced a significant improvement as a result of responding to external or distal focus instructions (Landers et al., 2005). Landers et al. (Landers et al., 2005) found that the use of external focus was ineffective for those without a history of falls presumably because the balance task was not challenging enough for them. The external focus group in our study may not have been effective because our study included both fallers and non-fallers (i.e., those presumably without significant balance impairment). Another factor to note when considering our study is that tasks being performed may not have been challenging enough, and were therefore already under automatic control, indicating that external or internal focus instructions may have been redundant or distracting when attempting to accomplish a task (Landers et al., 2005). The improvements noted in previous PD studies were also not to the magnitude that we hypothesized to see in our participants (Landers et al., 2005; Wulf et al., 1999). The changes that were observed in those studies were only in postural sway and not in gait and balance function as a whole or balance confidence, which were of interest in our study. Additionally, it has been noted that the benefits of external focus become greater as the focus becomes more external or distal (Prinz., 1990). The attentional foci in our study may not have been sufficiently external or distal. These differences in methodology may account for some of the variance in our results.

No differences were found when comparing the intervention group to the control group. These outcomes disagree with current literature (Dibble et al., 2009a; Allen et al., 2010; Ashburn et al., 2007; Hackney et al., 2010; Morris et al., 2009; Qutubuddin et al., 2005; Rossi-Izquierdo et al., 2009; Smania et al., 2010) which supports the application of physical therapy strategies to improve balance. Additionally, studies show that physical therapy interventions can improve outcomes such as timed sit to stand (Allen et al., 2010), the Freezing of Gait Questionnaire (Allen et al.,2010), quality of life (Dibble et al., 2009b; Ashburn et al., 2007), activities of daily living (Crizzle et al., 2006), and gait (Morris et al., 2010; Mehrholz Jan et al., 2010) in subjects with PD. These outcomes are commonly thought to impact balance indirectly, and are therefore also relevant to support the argument that physical therapy can improve balance in people with PD.

There are several possible explanations for the results obtained. The primary explanation is that attentional focus instructions do not differentially affect balance impairment; however, it is also important to consider the possibility of error especially since our results are not consistent with previous findings. Another logical reason for our findings is that the interventions were not individualized. The protocol was slightly altered to accommodate the different balance capabilities of the individual, but it was not structured to target specific participant impairments; therefore, certain parts of the intervention may have been too easy or too difficult to achieve improvements. That is, there was no specific attention to each participants balance deficits; all participants received the same balance tasks.

Another explanation is that we did not have a strengthening component in our protocol. Lower extremity strength can be an important factor to consider when applying balance training (Pijnappels et al., 2008). Ribeiro et al. (Ribeiro et al., 2009) showed that in the elderly, balance can improve as a result of strengthening the ankle dorsiflexors and plantarflexors. A study by Dibble et al. (Dibble et al., 2009b) demonstrated positive effects of eccentric strength training on bradykinesia and quality of life. Improving bradykinesia could lead to improved balance by providing a smoother cadence with ambulation and less hesitation that can lead to falls. In addition, the specific exercises used in our study were selected primarily because the nature of the exercise made it relatively easy to select external and internal focus instructions. There were many other exercises that could not be used simply because internal and external focus instructions were not appropriate or would not have made sense. It could also be argued that failure to exclude individuals with dementia would render our results invalid. However, we used the Mini-Mental State Exam as a screening tool for our study and found that running the final statistics with and without the participants classified with dementia revealed no change in overall results. Therefore, the final results reflect data collected from those with and without dementia. Overall, current evidence still supports the use of physical therapy for balance in people with PD, but our results show that the standardized training protocol used in our study was not effective for driving changes in balance.

It is also important to consider the possibility of the placebo effect in people with PD in light of our findings. This was brought to attention during data collection when two of the control subjects (blinded to group assignment) voluntarily stated their enthusiasm for the improvement from the "treatment" they had received. This was, of course, erroneous since they had not received any training at all; however, these two subjects perceived that the outcome measurements were, in fact, balance treatment. Several studies observing the effects of drug therapy (Goetz et al., 2000; Leentjens et al.,

2009) and transplantation surgery (Watts et al., 2001) in people with PD have demonstrated that subjects in the control group experience improved symptoms following a trial. A controlled trial testing the effects of monotherapy ropinerole reported that 16% of subjects receiving placebo treatment showed objective motor function improvement (Goetz et al., 2000). Furthermore, a meta-analysis examining the effects of pramipexole on the mood and motivational symptoms of PD found that while 63.2% of subjects receiving pramipexole had an improvement of symptoms, 45% of subjects receiving a placebo treatment also reported an improvement of symptoms (Leentjens et al., 2009). This evidence suggests that the placebo effect on individuals with PD is strong, and may partially explain the lack of difference between the results of the intervention and control groups. This is even more plausible since we did not have a large number of participants in the control group. We did not ask the other subjects in the control group if they too felt that they were receiving treatment.

Our subjects were asked to be on their ON phase of medication during the intervention sessions if using dopaminergic medications. Dopaminergic therapy is a common treatment for patients with Parkinson's disease, and these medication types are accompanied by ON and OFF periods throughout the day which are associated with a cyclic pattern of decreased and increased motor symptoms as the dose is highest within the body and as it wears off before the next scheduled dose. The length of ON periods and decrease in symptoms varies among patients, so there is no way to ensure that they were in fact on their ON phase for the duration of each testing session. On the other hand, while decreased symptoms during these ON times is generally thought of as being positive for function, the increased dosage during this period may actually have a negative affect on motor *learning* as was a focus of the current study. Kwak and colleagues (Kwak et al., 2010) found that during ON times, there was obvious impairment in motor sequence learning in the early stages of learning. Our study attempted to measure attentional focus while subjects were on their ON period in order to achieve optimal motor performance; however, those in the early stages of PD (Hoehn and Yahr 1-2.5) may have been experiencing impairment to the anterior and ventral portions of the striatum through over-dosing to these structures (Kwak et al., 2010). This may explain why there were not any significant increases in outcome measures.

The results of this current study should be interpreted with caution due to its limitations. During the intervention phase, there was one subject who began another exercise program (drop-in), which was discovered after completion of the study, and there were subjects who experienced significant weight loss, were injured, or dropped out before the intervention was complete. While no injuries occurred as a result of our study, these historical events may have affected the findings of the study. Additionally, we must consider type II error when interpreting the results. The data reflect mostly low effect sizes and power calculations. We consider any result with low power to be at risk for a type II error, and in committing such error we could have been reporting that there was no change when there actually was a change. Researchers may consider using the effect sizes from our study to power future trials of a similar nature. In addition, researchers should aim to conduct a study in which the intervention protocol is more individualized and impairment-based. Because the population of subjects recruited for this study presented with mild Hoehn & Yahr scores, higher than expected baseline SSGV scores were achieved, which decreased the scope of improvement for this outcome measure. Improvement may have been detected using a more challenging outcome measure for gait velocity. Also, in light of current knowledge, future studies on balance training should include a strengthening component. Another limitation is that all subjects in the intervention groups received the same month-long intervention period. An intervention lasting longer may have produced different outcomes. Additionally, investigators should ensure that a clear delineation of external versus internal instructions is made and verify that the subject understands what he or she should be doing and concentrating on during the tasks.

CONCLUSION

Despite early evidence in improving balance in individuals with PD and considerable evidence for various motor tasks using healthy adults in the motor learning literature, it does not appear that an external focus of attention has any positive long-term benefits in PD in terms of improved balance performance. While an external focus may cause an immediate improvement in balance, it may not be sufficient to drive clinically relevant improvements in long-term balance performance. In addition, the standardized balance training used in this study was not better than the control group which may be because the program was not individualized and impairment-based.

Table 1. Subject characteristics.

Characteristic	Group A (n=10)	Group B (n=11)	Group C (n=10)	Group D (n=10)
Age (years)				
Mean ± SD	72.20 ± 4.417	70.18 ± 4.355	70.12 ± 9.473	74.30 ± 8.795
Standard Error	1.397	1.313	2.996	2.781
Gender				
Male	4	8	7	6
Female	6	3	3	4
Hoehn & Yahr Score				
Mean ± SD	2.250 ± .8580	2.864 ± .8090	2.450 ± .4378	2.750 ± .6346
Standard Error	.2713	.2439	.1384	.2007
Mini-Mental State Exam				
Mean ± SD	27.60 ± 1.075	26.55 ± 3.882	29.60 ± .516	28.50 ± 2.121
Standard Error	.340	1.171	.163	.671
UPDRS Score				
Mean ± SD	26.70 ± 13.557	39.45 ± 10.885	37.30 ± 8.341	33.30 ± 10.688
Standard Error	4.287	3.282	2.638	3.380

Table 2. Exercise protocol and instructions for Groups A-C.

Exercise protocol	**GROUP A** **External focus**	**GROUP B** **Internal focus**	**GROUP C** **No focus**
1. Treadmill training in harness *("no hands on rails")* Treadmill speed = 25% increase from normal walking speed 1-2 weeks = 10 min 3-4 weeks = 12 min	*"Concentrate on keeping equal pressure on both halves of the treadmill belt"*	*"Concentrate on putting equal pressure on the right and left foot"*	*"Concentrate on keeping your balance"*
3 minute sitting break (pulse and blood pressure checked)			
2. Obstacle course negotiation (3 x 8 meters in harness – 5 minutes, 30 second breaks between each set) **a. step over 3, 5-inch obstacles** **b. walk over balance beam** **1st time –forward** **2nd time – backward** **3rd time – side-stepping** **c. weave way through 5 cones** **d. turn 180 degrees and return through course**	***a**. "Concentrate on clearing the hurdle"* ***b.** "Concentrate on the beam"* ***cd.** "Concentrate on the cones"*	***a.** "Concentrate on lifting your leg high"* ***b.** "Concentrate on your feet"* ***cd.** "Concentrate on your feet"*	*"Concentrate on keeping your balance"*
3 minute sitting break			
3. Compliant surface training (15 minutes total, 30 second breaks between each) **a. Rocker board** (2 minutes) • 1-2 weeks = easy • 3-4 weeks = difficult **b. Balance disc** (2 minutes) • 1-2 weeks = normal stance width • 3-4 weeks = narrow stance width **c. Balance pad** (7 minutes) • 1-2 weeks = single leg stance (eyes open and closed) (hard pad week 1, soft pad week 2) • 3-4 weeks = external perturbations (eyes open and closed) (hard pad week 1, soft pad week 2)	***ab.** "Concentrate on keeping the platform level"* ***c.** "Move the pad as little as possible"*	***ab**. "Concentrate on keeping an equal amount of pressure on the bottom of both feet"* *c. "Move your feet as little as possible"*	*"Concentrate on maintaining your balance"*

Table 3. Description of outcome measures and the corresponding psychometric properties.

Measure	Construct	Number of items	Evidence for reliability	Evidence for validity
Berg Balance Scale (BBS) (Berg et al., 1989)	Clinician rated assessment of balance tasks	14 tasks, total score 0 (greatest fall risk)- 56 (least fall risk)	ICC=.98 (Berg et al., 1989) (Qutubudding et al., 2005)	Validated for populations who had PD (Qutubuddin et al., 2005) and to predict future falls (Muir et al., 2008).
Dynamic Gait Index (DGI) (Chiu et al., 2006)	Clinician rated assessment of ability to modify gait under various conditions	Eight tasks, total score ranging 0 (greatest fall risk) to 24 (least fall risk)	ICC=.84 (Huang et al., 2011)	Demonstrated an AUC value of 0.84 indicating a high probability of predicting whether a person with PD will fall (Dibble et al., 2006).
Sensory Organization Test (SOT)	Computerized posturography used to challenge the three sensory components of balance	Composite score of six scenarios ranges from 0-100 based off age and height adjusted averages	ICC=.66 (Ford-Smith et al., 1995) CI: (0.49, 0.79)	Found to possibly provide effective screening for PD in addition to its potential in assisting in providing individualization of exercise programs for patients with PD (Bansal et al., 2005).
Activities-Specific Balance Confidence Scale (ABC) (Powell et al., 1995)	Self-administered assessment of confidence with balance during various ADLs	16 items, scores ranging from 0 (not confident) to100% (very confident)	Cronbach's α = .97 (Oude Nijhuis et al., 2007), ICC = 0.94 (CI = 64-77) (Steffen et al., 2008)	Discriminative validity found with the area under the ROC curve = 0.79 (Oude Nijhuis et al., 2007) indicating the test's ability to distinguish between individuals with PD (exhibiting the entire spectrum of PD characteristics) and their age-matched controls (without dementia or comorbidities).
Self Selected Gait Velocity (SSGV) (Montero-Odasso et al., 2005)	Timed comfortable walking pace over 10 meters	N/A	ICC= .95 (Marchetti et al., 2008)	Slow walking speed was associated with a greater risk of falls in individuals with PD (Morris et al., 1994), (Lohnes et al., 2011).

Table 4. Means and standard deviations for the intent-to-treat analysis of all of the outcome variables for the primary analysis.

	Group	Baseline	Post	2-week post	8-week post
Sensory Organization Test[a]	A	66.67 SD 13.39	68.42 SD 15.08	67.42 SD 12.75	68.50 SD 13.73
	B	69.31 SD 12.07	72.69 SD 14.61	74.23 SD 13.19	75.08 SD 12.93
	C	57.92 SD 17.89	68.50 SD 11.32	71.08 SD 12.97	67.67 14.04
	D	68.08 SD 9.31	65.50 SD 18.87	71.92 SD 10.87	69.50 SD 14.44
Berg Balance Scale	A	45.00 SD 8.84	47.92 SD 6.76	46.75 SD 6.77	47.42 SD 8.72
	B	44.69 SD 7.61	48.00 SD 6.98	47.92 SD 9.37	46.38 SD 10.04
	C	45.50 SD 6.60	47.25 SD 7.29	49.42 SD 5.73	48.42 SD 8.01
	D	44.83 SD 4.59	44.50 SD 7.53	46.33 SD 4.94	47.58 SD 4.89
Self-Selected Gait Velocity[b]	A	1.22 SD 0.46	1.27 SD 0.48	1.19 SD 0.41	1.21 SD 0.43
	B	1.26 SD 0.40	1.32 SD 0.36	1.35 SD 0.33	1.34 SD 0.41
	C	1.26 SD 0.41	1.36 SD 0.52	1.35 SD 0.46	1.35 SD 0.46
	D	1.18 SD 0.30	1.19 SD 0.27	1.32 SD 0.32	1.30 SD 0.37
Dynamic Gait Index	A	17.83 SD 4.61	19.17 SD 4.82	19.33 SD 5.19	17.83 SD 6.95
	B	17.23 SD 3.27	19.85 SD 3.08	19.69 SD 3.38	17.92 SD 5.29
	C	18.00 SD 2.99	18.58 SD 3.75	19.58 SD 3.34	19.75 SD 4.86
	D	19.33 SD 2.31	19.92 SD 3.37	19.92 SD 2.78	19.75 SD 2.63
Activity Balance Confidence Scale	A	67.10 SD 28.99	68.24 SD 26.35	72.57 SD 24.99	63.76 SD 28.81
	B	73.08 SD 20.83	82.83 SD 14.97	77.50 SD 17.90	81.31 SD 15.99
	C	71.23 SD 18.52	79.13 SD 17.45	77.86 SD 20.26	77.44 SD 20.76
	D	65.56 SD 18.26	73.29 SD 11.46	70.06 SD 15.88	68.64 SD 13.63
Obstacle Course[c]	A	72.62 SD 54.35	62.27 SD 57.16	59.55 SD 58.16	60.74 SD 60.19
	B	60.99 SD 32.12	43.06 SD 26.84	46.04 SD 37.69	52.98 SD 59.39
	C	83.89 SD 59.37	63.36 52.76	51.81 SD 33.78	59.13 SD 53.97
	D	78.42 SD 69.37	65.32 SD 58.49	55.60 SD 39.36	56.55 SD 41.14

[a]*Sensory Organization Test measures sway on a scale of 0-100; a score of 100 represents no sway.*
[b]*Self-Selected Gait Velocity is measured in meters per second.*
[c]*Obstacle course is measured in seconds it took to complete the course.*

Table 5. P-values for the post hoc analyses of the outcome measures over time.

	Baseline to Post	Baseline to 2-week post	Baseline to 8-week post	Post to 2-week post	Post to 8-week post	2-week post to 8-week post
Intent to Treat Data						
SOT	.407	.006	.034	1.00	1.00	1.00
BBS	.171	.005	.032	1.00	1.00	1.00
DGI	.100	.002	1.00	1.00	1.00	.598
ABC	.002	.082	.537	1.00	.177	1.00
Obstacle	.001	<.005	.008	.860	1.00	1.00
Per Protocol Data						
SOT	.498	.013	.060	1.00	1.00	1.00
BBS	.238	.008	.035	1.00	1.00	1.00
DGI	.014	.001	.973	1.00	1.00	.764
ABC	.006	.069	.632	1.00	.366	1.00
Obstacle	.003	.001	.040	1.00	1.00	1.00

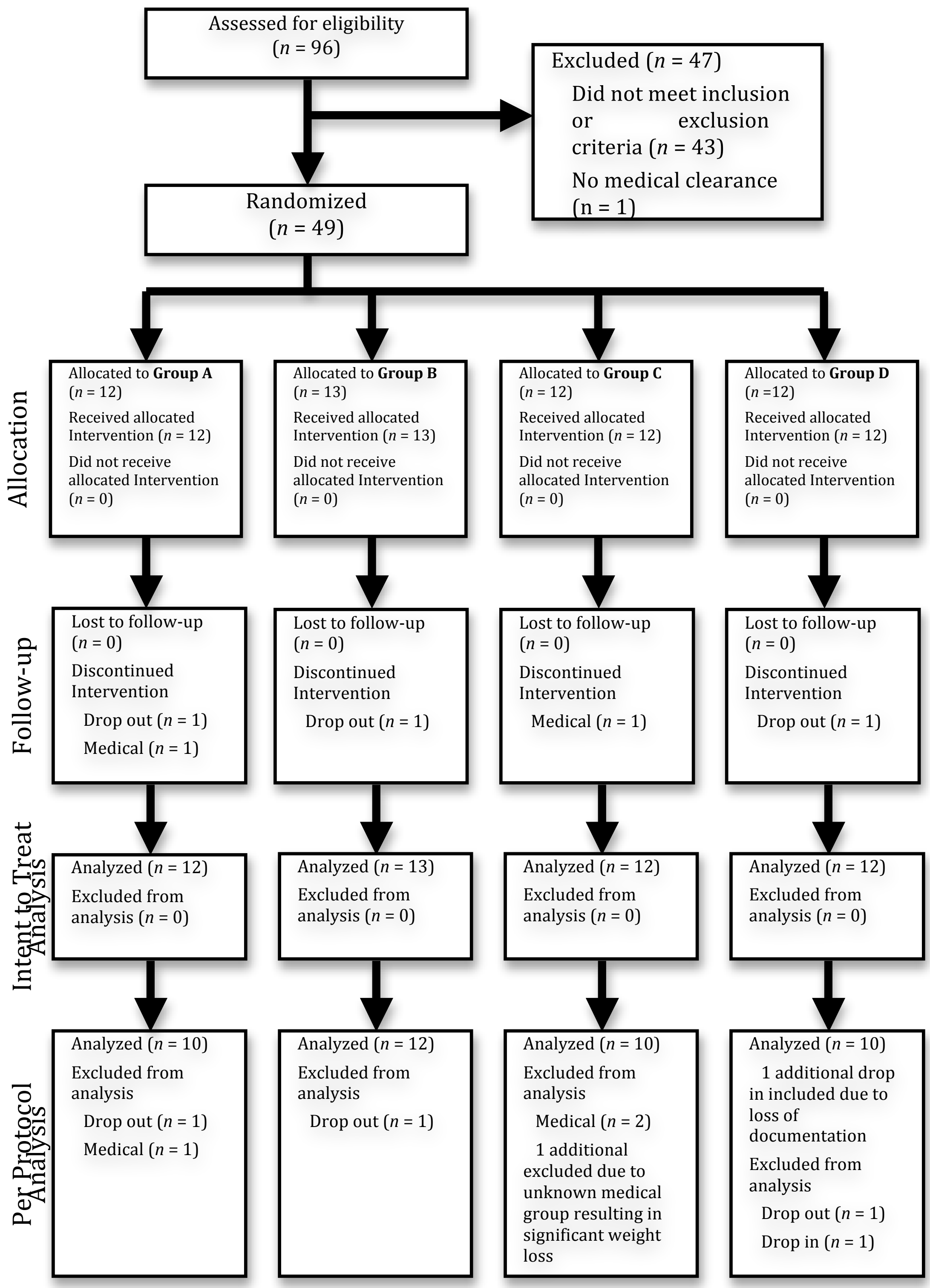
Post hoc analyses completed for significant main effects only
SOT, Sensory Organization Test; BBS, Berg Balance Scale; DGI, Dynamic Gait Index; ABC, Activity Balance Confidence Scale

Table 6. Means and standard deviations for the intent-to-treat analysis of all of the outcome variables for the secondary analysis.

	Group	Baseline	Post intervention	2-week post intervention	8-week post intervention
SOT	Intervention	64.76 SD 15.01	69.95 SD 13.57	71.00 SD 12.92	70.54 SD 13.61
	Control	68.08 SD 9.31	65.50 SD 18.87	71.92 SD 10.87	69.50 SD 14.44
BBS	Intervention	45.05 SD 7.52	47.73 SD 6.82	48.03 SD 7.38	47.38 SD 8.78
	Control	44.83 SD 4.59	44.50 SD 7.53	46.33 SD 4.94	47.58 SD 4.89
SSGV	Intervention	1.25 SD 0.41	1.32 SD 0.44	1.30 SD 0.40	1.33 SD 0.46
	Control	1.18 SD 0.30	1.19 SD 0.27	1.32 SD 0.32	1.30 SD 0.37
DGI	Intervention	17.68 SD 3.59	19.22 SD 3.85	19.54 SD 3.93	18.49 SD 5.67
	Control	19.33 SD 2.31	19.92 SD 3.37	19.92 SD 2.78	19.75 SD 2.63
ABC	Intervention	70.54 SD 22.64	76.90 SD 20.48	76.02 SD 20.71	74.36 SD 22.99
	Control	65.56 SD 18.26	73.29 SD 11.46	70.06 SD 15.88	68.64 SD 13.63
Obstacle Course	Intervention	72.18 SD 48.98	55.70 SD 46.35	52.09 SD 42.93	57.40 SD 56.31
	Control	78.42 SD 69.37	65.32 SD 58.49	55.60 SD 39.36	56.55 SD 41.14

SOT, Sensory Organization Test; BBS, Berg Balance Scale; DGI, Dynamic Gait Index; ABC, Activity Balance Confidence Scale

Figure 1. Flow diagram of subject recruitment, allocation and analysis.



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- Big Stone Therapies • Outpatient Orthopedic Clinic • June 2010 – Aug 2010 • Baxter, MN

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- Combined Sections Meeting of the APTA, 2010 • San Diego, California

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- National Student Conclave, Miami, FL (10/2009)

RESEARCH

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