5-2020

Effects of Pole Walking on Adults with Parkinson's Disease Following 6 Weeks of Training

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A Scholarly Project

Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine and Health Sciences

University of North Dakota

in partial fulfillment of the requirements

for the degree of

Doctor of Physical Therapy

Grand Forks, North Dakota

May

2020

This Scholarly Project, submitted by Kathleen Dennison and Taylor Jamison in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

Meridee Danks
(Graduate School Advisor)

David Relling
(Chairperson, Physical Therapy)

PERMISSION

Title Effects of Pole Walking on Adults with Parkinson's Disease Following 6 Weeks of Training

Department Physical Therapy

Degree Doctor of Physical Therapy

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Signatures Taylor Jamison
Kathleen Dennison

Date 12-3-19

TABLE OF CONTENTS

LIST OF FIGURES

Figure

LIST OF TABLES

Table

ACKNOWLEDGEMENTS

The authors acknowledge and comment the active participants for their voluntary contribution and dedication to this study. Support of our research was provided by the University of North Dakota Physical Therapy Department. We express great appreciation to our advising instructor, Meridee Danks, for this opportunity.

ABSTRACT

Introduction: Parkinson's Disease is a progressive neurodegenerative disorder that predominantly affects motor planning and motor function. Symptoms associated with this disease include bradykinesia, rigidity, tremor, and postural instability. These symptoms are often accompanied by gait disturbances including decreased step length, arm swing, and gait velocity, as well as diminished trunk rotation and postural instability all which make functional mobility increasingly difficult. Conventional walking has been shown to be an effective physical activity to maintain mobility and improve function and overall fitness. Specifically, walking speed has been identified as a crucial predictor for fall risk which is why clinicians have identified walking speed as the sixth vital sign. Pole walking has gained popularity over the years and may provide additional benefits when compared to conventional walking. These benefits include improved stride and step length, faster gait velocity and cadence, improved posture, flexibility, and strength, as well as improved cardiovascular responses following exercise.

Purpose: The purpose of this case series is to determine the effects of the use of walking poles in physical functioning, stability, balance, and posture in individuals with mild to moderate Parkinson's Disease.

Methods: Four individuals (3 males, 1 female) with mild to moderate Parkinson's Disease (Hoehn and Yarn Stages 1-3) participated and completed pre- and post-assessments and surveys. The assessments consisted of gait analysis through the use of the GAITRite, postural analysis, strength, flexibility, and a dynamic balance assessment.

All participants were provided and fit with walking poles, and were provided general instructions on walking technique. All subjects participated in a six week walking program two days per week for 45 minutes sessions including warm-up, pole walking, and cool-down.

Results: Data analysis consisted of improved percent change of pre-assessment and post-assessment examinations including posture, gait parameters, flexibility, and functional outcome measures. Overall, positive changes were evident in gait parameters such as gait velocity, cadence, step length, stride length, and stride width in all participants. Additional changes were evident in the DGI, 5xSTS, and flexibility. Subjectively, positive changes were noted among the PDQ-39, UPDRS-III, and perception of improved posture, and positive social engagement in all participants.

Conclusion: Based on the evidence provided from this case series, it can be concluded that the use of walking poles with individuals with Parkinson's Disease may be an effective intervention for maintenance of strength, range of motion, coordination, and multiple gait parameters. Pole walking is appropriate for improvement of these factors as well as enhanced quality of life for individuals with Parkinson's Disease, and allows for active participation and an optimistic approach to exercise. Due to the progressive nature of Parkinson's Disease, further research may be required with longer duration training, and larger study populations to verify whether or not walking poles may be included within conventional rehabilitation programs recommended for individuals with Parkinson's Disease.

CHAPTER I

INTRODUCTION

Parkinson's Disease (PD) is a chronic and progressive neurodegenerative disorder that predominantly affects dopamine-producing neurons in the brain. This is characterized by motor symptoms such as bradykinesia, rigidity, tremor, and postural instability, which are frequently associated with non-motor disturbances, which strongly affects physical, psychological, and social functions of patients.[1] These symptoms are often accompanied by gait disturbances such as shuffling steps, low walking speed, small stride length, reduced arm swing, rigidity in trunk movements, propulsion, and retropulsion,[2] making simple daily tasks and overall functional mobility increasingly difficult. Cugusi et al,[3] states that the optimal management of Parkinson's Disease requires a combination of pharmacologic and nonpharmacologic interventions such as physical activity. Tailored exercises for these individuals have shown to go well beyond the known benefits on cardiovascular, pulmonary, and musculoskeletal systems, and could optimize the motor abilities of Parkinson's Disease patients through delaying other disease complications such as dementia, depression, apathy and worsening quality of life.[1]

Many health care professionals have concluded that it is critical to observe walking speed as a functional vital sign or "sixth vital sign," when working with older adults. Walking speed is a valid, reliable, and sensitive measure appropriate for assessing and monitoring functional status and overall health in a wide range of populations and

diseases.[4] In addition, walking speed has been shown to be predictive of a range of outcomes including falls, hospitalizations, frailty, functional dependence, cognitive decline, cardiovascular-related events and mortality.[4] According to Parker et al,[5] gait disorder is the first complaint in individuals with Parkinson's Disease, and these individuals are at a greater risk for falls due to gait variability connected with the disease. This proves walking and balance training to be desired, and effective interventions for these specific individuals. Pole walking or also known as Nordic walking, is a safe form of physical activity for individuals with Parkinson's Disease, and offers further benefit as compared to conventional or normal unassisted walking when employed with the correct technique.[6-7] Additional benefits include: increased heart rate and oxygen consumption without an increase in perceived exertion and fatigue; greater activation of core, upper and lower extremity musculature, enhanced energy expenditure and aerobic effects; improved dynamic balance and stability; reduced load on articular surfaces; and promotion of asymmetric body movements.[6-7]

Nordic walking technique originated in Finland in the late 1900's in order to improve the health of sedentary populations. Since then, Nordic walking has gained international interest and has become a popular form of exercising and a leisure activity for a variety of populations.[8] In the United States, pole walking has termed the name "Exerstriding," exercising all the body's major muscles while striding.[8] In the Exerstriding technique, with the leading foot moving forward, the opposite arm will extend with the pole and will plant the pole when the arm is at the handshake position. The individual will then push into the pole while completing the step, similar to a pump handle.[9] In contrast with Nordic walking, individuals are asked to walk in an upright and

neutral position, with the poles held close to the body. When the leading foot is moving forward, the opposite arm swings forward with the pole in hand. The pole strikes the ground level with the heel of the leading foot. The poles remain pointing diagonally backward and the pole is pushed as far back as possible.[10] The key difference between these two techniques relays back to where the poles are planted. The Exerstriding method works by keeping the poles out in front of the body providing extra balance and stability, where the Nordic walking method keeps the poles at a diagonal more similar to a nordic skiing motion. According to Bumgardner,[9] the muscle engagement is similar in both pole walking methods as the triceps, pectorals, abdominals, latissimus dorsi, and erector spinae muscles are all engaged providing full body activation.[9] Additionally, the reciprocal motion of the arms and legs work to promote trunk rotation, which is something often lacking in individuals with Parkinson's Disease as rigidity of the trunk is a common characteristic of the disease.

While pole walking has gained popularity due to the proposed health benefits in all ages, research relating to the benefits of pole walking in individuals with Parkinson's Disease is limited. The purpose of this case series is to determine the effects of the use of walking poles in physical functioning, stability, balance, and posture in individuals with mild to moderate Parkinson's Disease. Specific aspects being identified and observed in this study included gait, posture, balance, flexibility, strength, and cardiovascular effects. It has been hypothesized that the use of walking poles in individuals with Parkinson's Disease can improve the efficiency of gait and balance, provide postural benefits, and impact cardiovascular response to exercise. Effects on physical functioning will be studied following a six-week program utilizing the Exerstrider technique to determine the

appropriateness of pole walking as a safe and effective exercise modality for individuals with mild to moderate Parkinson's Disease.

CHAPTER II

METHODOLOGY

This research received by the University of North Dakota approval through the International Review Board (IRB-201905-303) (Appendix A). Each participant was given a copy of and signed a consent form which included consent to videos and/or obtain photos (Appendix B).

Participants

Four participants (3 males, 1 female) were recruited through word of mouth and the local community health club to complete the study. The participants ranged in age from 63-66 years (m = 64.75), and the total number of years since initial Parkinson's diagnosis ranged from 1.5-17 years (m = 6.625). All participants met the inclusion criteria of: mild to moderate Parkinson's Disease, over the age of 18 years old, community ambulator, no health concerns that might impact their ability to perform pole walking, and no changes in Parkinson's Disease medication prior to participating in the walking pole study. Exclusion criteria restricted participation of individuals younger than 18 years of age, use of an assistive device, if they are not community ambulators, if they have any other neurological conditions or cognitive impairments that would impact participation in training and testing, or if there are cardiovascular diseases or concerns present of any health issues that would inhibit the use of walking poles or participating in a walking program.

Procedure

Following the consent process, the participants completed a pre-participation survey, and assessment consisting of a collection of tests designed to assess gait and balance, height and weight, strength, flexibility, vitals, and posture. All participants then completed a six-week, 2x/week, pole walking program. At the conclusion of the study reassessments of all tests and measures were performed and a post-participation survey was administered. Three out of four participants completed the pre- and post-intervention surveys and tests at the same time of day in order to optimize comparability of the results and ensure the timing of medication consumption did not influence the results.

Exerstrider® (Exerstrider, Madison, WI) walking poles with a "button lock" for stability were used in this study.[11] Each participant was fitted with walking poles before their initial assessment as per the Exerstrider manual by having each individual stand with normal posture, tips of poles to the sides of the body planted at the heel, and elbows bent to a 90-degree-angle, forearms parallel to the floor. After fitting, the participants were instructed in proper exerstriding technique using a reciprocal gait pattern at a comfortable pace. All participants used a boot-style tip (Figure 1), designed to provide a cushion from the forces applied through the poles, to provide traction, and assist in the push off.

Measures

Pre-Participation Survey

Following the participants completion of the consent form, they were given a pre-participation survey which consisted of demographic information including age, gender, employment status, activity level/involvement, and a list of current medications

living, emotional well-being, stigma, social support, cognition, communication, and bodily discomfort. Minimal detectable change (MDC) varies across each of the eight dimensions and are 12.24 points for mobility, 16.72 points for activities of daily living, 14.22 for emotional well-being, 21.21 for stigma, 24.50 for social support, 22.12 for cognition, 21.04 for communication, and 24.48 for bodily discomfort.[12] The sum score of raw data ranges from 0 to 156 points, with high scores indicating lower health-related quality of life. [10]

Unified Parkinson's Disease Rating Scale

Participants were asked to fill out Part III, Motor Examination, of the Unified Parkinson's Rating Disease Scale, both before and after completion of this study (Appendix F). This questionnaire addresses various concerns with motor functioning that are associated with Parkinson's Disease. At this time a MDC has not been established for the Unified Parkinson's Disease Rating Scale. The motor component includes fourteen questions including questions about gait, hand movements, posture, and rigidity. The sum score of raw data ranges from 0-56 points for the UPDRS-III, with higher scores indicating greater disability.[13]

Vitals

Vital signs which included oxygen saturation, blood pressure, and heart rate were taken at the beginning and upon completion of both the pre- and post-assessments. Oxygen saturation was taken using a Nellcor™ automated pulse oximeter. Blood pressure was completed by a researcher manually using an adult sized blood pressure cuff, and stethoscope. Heart rate was taken manually by a researcher for 60 seconds using the right sided radial pulse. Throughout the six-week walking program, oxygen saturation and

heart rate were taken both before and after the thirty-minute walk using the Nellcor™ automated pulse oximeter. In addition, RPE was subjectively recorded following each walking session. Any abnormal readings were reported to the participant.

Height and Weight

Height, in centimeters, was measured both with and without walking poles. First, participants were barefoot on a stadiometer and were instructed to stand normally and height was measured by the researcher. Next, the participant remained barefoot on the stadiometer and the researcher handed the participant walking poles. The participant was instructed to stand normally with the walking poles in hand, and height was measured once again by the same researcher. Weight was measured in pounds using a physician beam scale. The participant was barefoot, and any extra articles of clothing were removed during the measurement of weight.

Five Times Sit to Stand Test (5xSTS)

The 5xSTS is a reliable and valid measure that assesses lower extremity strength. It begins with the participant seated in a folding chair with a height of 16 inches with their arms folded across their chest. On "Go" the participant is instructed to stand up and sit back down five times as quickly as possible.[14] Researchers demonstrated the test to the participants prior to completion so they would have a better understanding of the instructions. The objective of this test is to complete 5xSTS repetitions as quickly as possible, while the researcher uses a stopwatch to time record the total time it takes to complete the test. The researcher begins timing on "Go," and stops timing when the participants buttocks touch the chair after the fifth repetition. According to Duncan et al,

an individual with Parkinson's Disease that takes greater than sixteen seconds to complete this test would be indicated as a fall risk.[15]

Chair Sit-and-Reach Test

The Chair Sit and Reach Test is used to assess hamstring flexibility.[14] The participant starts by sitting on the edge of a chair with one leg positioned in a 90-degree bend at the knee and the other extended forward with the knee straight. The participant then brings both arms in front with hands overlapping and middle fingers aligned. Then, they are instructed to reach forward toward the tip of their toes with their middle finger while keeping the knee straight. The distance between the middle finger and toes is measured in centimeters. A negative score was score was recorded if the participant cannot reach the toes and a positive score is given if passed toes. This test is performed bilaterally.

Back Scratch Test

The purpose of this test is to measure general shoulder flexibility.[14] In standing, the participant reach overhead and then down the back as far as possible with the palm toward the back. Then with the other arm, reach behind the back with palm side up. The distance was then measured between middle fingers and was recorded in centimeters. When fingers overlapped, a positive score was recorded. When fingers did not touch, a negative score was recorded. This test is performed bilaterally.

Standing Posture

During the pre- and post-assessments, photos were obtained to assess posture. Photos were taken of resting standing posture with and without walking poles. Three views were obtained including anterior, posterior, and right lateral view as seen in

(Appendix C). Additional questions were asked including report of health concerns or recent injury, prior use of walking poles, and participation in regular physical activity.

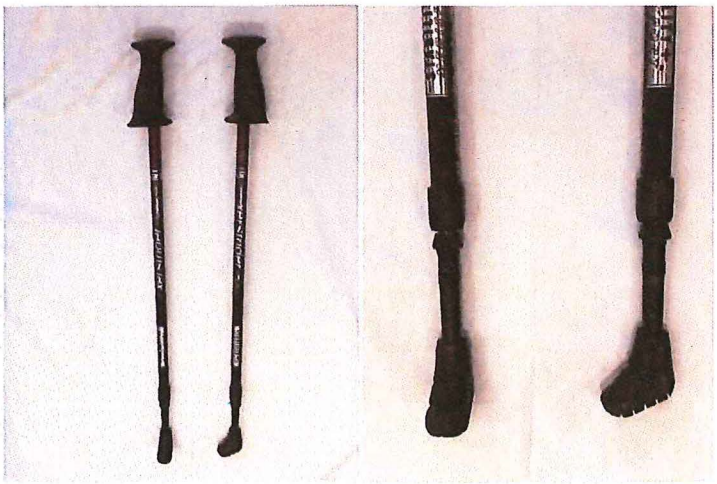

Figure 1. Walking Poles and Boot Tips

Post-Participation Survey

Following the completion of the study, a post-participation was filled out. Information collected included: general enjoyment of walking poles, perception of improvement of posture and walking, any changes in medication, and any changes in activity levels (Appendix D).

Parkinson's Disease Questionnaire - 39

Participants were asked to fill out the Parkinson's Disease Questionnaire - 39 (PDQ-39), both before and after completion of this study (Appendix E). The PDQ-39 is a reliable questionnaire with excellent validity.[12] This questionnaire assesses Parkinson's disease specific-health related quality over the past month, and the impact of Parkinson's Disease on difficulty pertaining to specific dimensions of function and well-being. The eight different dimensions assessed in this questionnaire are mobility, activities of daily

Figure 2. Posture Analysis Views without Poles (Post-Assessment)

Figure 3. Posture Analysis Views with Poles (Post-Assessment)

example Figure 2 and Figure 3. Each participant was asked to stand about 6-8 inches away from the grid for each picture and were told to "stand comfortably." When taking pictures with the walking poles, participants were asked to remain in their current position while a researcher handed them their walking poles so differences in posture could accurately be assessed. The photos were taken from a distance of 100 inches which was measured for consistency regardless of individuals height. Posture of each participant was analyzed using two independent reviewers and any disputes were settled by a third independent viewer.

Dynamic Gait Index

In order to assess balance in individuals with Parkinson's Disease, each participant completed the Dynamic Gait Index (DGI) during the pre- and post-assessments. The DGI is a reliable and valid measure that assesses an individual's ability to modify balance while walking in the presence of external demands.[16] Some of the tasks measured with this assessment include steady state walking, walking with changing speeds, walking with head turns both vertically and horizontally, walking while stepping over and around objects, pivoting while walking, and stair climbing. Video was obtained of each participant while they completed the DGI to allow researchers the opportunity to accurately score this assessment. Minimal detectable change (MDC) for individuals with Parkinson's Disease completing the DGI is 2.9 points.[16]

GAITRite

To allow researchers to assess changes in the participants gait, a GAITRite system was used. This allows detection of gait abnormalities and changes between trials and time. It is an instrumented walkway that detects spatial and temporal parameters of one's

gait.[17] By using the GAITRite, assessment of function gait is viable as well as assessment of one's gait with the use of an assistive device, such as walking poles. According to Uden and Besser,[18] the GAITRite has been proven to be reliable assessment of gait.[18] Each participant was given three trials walking at a normal pace and then three trials of walking with the walking poles. The trials were both repeated at the post-assessment screening.

Activity Log

At the start of the study, each participant was given a weekly activity log to complete throughout the duration of the study. This log consisted of frequency, duration, and type of activity that each participant participated in outside of the walks twice a week (Appendix G). This allowed researchers to assess the amount of weekly activity each participant participated in as well as if there were any significant changes in activity level throughout the study.

Intervention

Participants were encouraged to attend group exercise sessions consisting of warm-up, pole walking, and cool-down, twice per week. If unable to do so, participants rescheduled a separate time to complete the session at a time of their convenience. Prior to beginning the session, heart rate and oxygen consumption were recorded with a pulse oximeter. Warm up activities (Appendix H) performed included rhythmic knee bends, heel-toe rocking, mini squats with a power up, marching in place, diagonal reaching with knee bend, trunk rotation pivot with poles, shoulder rolls and neck stretching. Subjects then walked with poles at a self-paced speed with the researchers for 30 minutes. Participants were assisted with their pole walking technique through both verbal and

manual cuing. Researchers recorded the distance walked at each session. After each session, heart rate and oxygen consumption were recorded for a second time, along with rate of perceived exertion (RPE) using a 1-10 scale (Appendix I). A cool-down program (Appendix H) included standing trunk rotation, seated hamstring stretch, overhead triceps stretch, and a cross body arm stretch. Each stretch was held for a minimum of 30 seconds. In addition, participants were given an activity log to record all activities, pole walking or otherwise, which was completed on a weekly basis.

Data Analysis

Frequencies were calculated for subject demographics. Three trials were completed for all GAITRite data and measurements and the average of the three trials was utilized. Percent change was used to identify differences between times of measurement (Time1, Time 2) for the GAITRite data and all other measures.

CHAPTER III

RESULTS

The participants completed all components of this study including pre-participation and post-participation survey, questionnaires, functional assessments, and activity logs. Demographic information for each participant is given on Table 1 below. Each walking session was completed outside on a paved walking trail and was self-paced with the participants each session. Immediately after completing 30 minutes of walking, heart rate and oxygen saturation were recorded for each participant. The post participation evaluation and assessment were completed the following day after completion of the study. The overall compliance of this case series was excellent at 87.5%.

Pre-Participation Survey

The pre-participation survey included employment status, any health concerns, the use of an assistive device, previous walking pole use, fall history and activity level. The results of the pre-participation survey are listed below in Table 2. Two of the participants experienced a fall within the last year and three participants noted having difficulty with walking, and only one participant (participant 2), had prior experience using walking poles.

Table 3 depicts the values obtained for all tests and measures completed at both the pre- and post-assessments for each participant. Percent change was completed to identify differences between times of measurement for all data and measures.

Table 1. Participant Demographics

Participant	1	2	3	4
Age, y	66	65	65	63
Gender	Female	Male	Male	Male
Employment Status	Retired	Retired	Retired	Retired
Duration of PD, y	17	4	1.5	4
Medication Y/N	Y	Y	Y	N
Deep Brain Stimulator	Yes	No	No	No
Hoehn and Yahr Stage	3	2	2	1
Sessions attended	7/12	11/12	12/12	12/12
# of Falls in Last Year	1	2	0	0
Activity Level	Moderately Active	Lightly Active	Moderately Active	Very Active

Table 2. Pre-Participation Survey Results (n=4)

Survey Questions	Yes	No
Employed	0	4
Do you currently have difficulty walking?	3	1
Do you use a cane or walker to get around?	0	4
Have you fallen in the last year?	2	2
Do you have any health concerns or recent injuries that may impair your participation in a walking pole program?	0	4
Have you ever used walking poles prior to this study?	1	3
Do you participate in regular physical activity?	4	0

Table 3. Individual Outcomes for Participation

Measure			Participant 1			Participant 2			Participant 3			Participant 4		
			Pre	Post	Change (%)	Pre	Post	Change (%)	Pre	Post	Change (%)	Pre	Post	Change (%)
Weight (lbs)			123	120.5	-3.5	188	188	0 (0)	153	155	2.0 (1.31)	218	213	-5.0 (-2.29)
Height (cm)	w/ Poles		147.5	147.2	0.3 (-0.2)	166.6	166.4	-0.2 (0.12)	180	179.9	-0.1 (-0.06)	176.5	177.6	1.1 (0.62)
	w/o Poles		147	146	1.0 (-0.68)	166.5	166.4	-0.1 (0.06)	179.5	179.9	0.4 (0.22)	176.2	177.6	1.4 (0.79)
Chair Sit and Reach Test (cm)	R		-15	-13	2.0 (-13.33)	0	0	0 (0)	-20	-10	-10.0 (-50)	0	7	7 (12.5)
	L		-9.5	-9	0.5 (-5.26)	0	0	0 (0)	-15	-8	-7.0 (-46.67)	0	5	5 (16.6)
Back Scratch Flexibility Test (cm)	R over L		-11	-8	3.0 (-27.27)	-20	-13	7.0 (-35)	-40	-36	-4.0 (-10)	-32	-28	4.0 (-12.5)
	L over R		-22	-17	5.0 (-22.73)	-30	-18	12.0 (-40)	-37	-40	3.0 (8.11)	-43	-38	5.0 (-11.62)
5x Sit-to-Stand (sec)			6.93	6.84	-0.09 (-1.3)	7.57	6.87	-0.7 (-9.25)	10.82	9.63	-1.19 (-11)	10.65	9.15	-1.50 (-14.1)
DGI			20/24	21/24	1 (N/A)	23/24	24/24	1 (N/A)	20/24	23/24	3* (N/A)	22/24	24/24	2 (N/A)
PDQ-39			25/156	19/156	-6 (N/A)	66/156	56/156	-10 (N/A)	47/156	26/156	-21 (N/A)	21/156	13/156	-8 (N/A)
UPDRS-III			5/56	6/56	1 (N/A)	19/56	10/56	-9 (N/A)	12/56	3/56	-9 (N/A)	9/56	9/56	0 (N/A)
Gait Velocity (m/s)	w/ Poles		0.71	0.92	0.2 (28.17)*	1.15	1.32	0.17 (14.78)	1.12	1.16	0.04 (3.57)	1.37	1.45	0.08 (5.84)
	w/o Poles		1	0.9	-0.1 (-10)	1.22	1.37	0.15 (12.3)	1.32	1.55	-0.23 (17.42)*	1.37	1.51	0.14 (10.22)
Cadence (steps/min)	w/ Poles		79.1	88.3	9.2 (11.63)	102.7	106.5	3.8 (3.7)	93	88.4	-4.6 (-4.95)	103.7	110.1	6.4 (6.72)
	w/o Poles		109.8	107.9	-1.9 (-1.73)	106	109.4	3.4 (3.21)	108.8	115.2	6.4 (5.88)	107.4	114	6.6 (6.15)
Step Length (cm)	w/ Poles	R	50.5	58.2	7.7 (15.25)	66.6	74.6	8.0 (12.01)	72.4	81.5	9.1 (12.57)	76.2	77.3	1.1 (1.44)
		L	57.8	65.7	7.9 (13.67)	67.8	74.8	7.0 (10.32)	72.6	77.1	4.5 (6.2)	82.0	81.1	-0.9 (-1.1)
	w/o Poles	R	45.8	46.8	1 (2.18)	68.5	76.0	7.5 (10.95)	73.5	82.9	9.4 (12.8)	74.3	77.6	3.3 (4.44)
		L	53.5	54.1	0.6 (1.12)	69.3	74.3	5.0 (7.22)	72.5	78.6	6.1 (8.41)	78.9	82.1	3.2 (4.1)
Stride Length (cm)	w/ Poles	R	109	125.1	16.1 (14.77)	134.0	150.7	16.7 (12.46)	144.8	159.2	14.4 (9.94)	158.1	158.4	0.3 (0.19)
		L	108.1	122.2	14.1 (13.04)	136.0	149.3	13.3 (9.78)	144.6	158.4	13.8 (9.54)	158.7	158.4	-0.3 (-0.19)
	w/o Poles	R	99.1	100.7	1.6 (1.61)	138.4	150.6	12.2 (8.82)	146.4	162.2	15.8 (10.79)	153.1	159.4	6.3 (4.11)
		L	99.7	100.9	1.2 (1.2)	137.2	149.9	12.7 (9.26)	145.5	161.5	16.0 (11)	153.8	159.7	5.9 (3.84)
Stride Width (cm)	w/ Poles	R	7.6	13.5	5.9 (77.63)	8.3	7.5	-0.8 (-9.64)	10.1	8.5	-1.6 (-15.84)	13.4	10.0	-3.4 (-25.37)
		L	6.7	14.8	8.1 (120.9)	8.3	7.3	-1.0 (-12.05)	10.1	9.0	-1.1 (-10.89)	12.9	11.5	-1.4 (-10.85)
	w/o Poles	R	8	9.4	1.4 (17.5)	8.5	8.9	0.4 (4.71)	7.0	7.1	0.1 (1.43)	11.8	10.8	-1.0 (-8.47)
		L	7.9	9.7	1.8 (22.78)	8.5	9.4	0.8 (9.30)	5.9	7.3	1.4 (23.73)	12.0	11.3	-0.7 (-5.83)

*Significant change

Post-Participation Survey

All participants in this study also completed a post-participation survey. In this survey, participants were asked to rate whether or not they felt the use of walking poles improved their balance and posture. In addition, participants reported whether or not they began any new activities during the study, and if they would continue to use walking poles following this study. The results of this survey can be identified in Table 4.

Table 4. Post-Participation Survey Results (n=4)

Survey Questions	Yes	No
Do you feel that walking poles improved your balance?	3	1
Do you feel that walking poles improved your posture?	4	0
Would you continue to use walking poles outside of this study?	2	2
Have you started any new activities since the start of the study?	1	3

PD Specific Disability and Quality of Life

Participants in this case series showed consistency or decreases in scores on the Motor subscale of the UPDRS over time (Fig. 4A). At this time a MDC has not been established for the UPDRS-III, although two participants subjectively indicated a decrease of 9 points on this assessment indicating decreased disease impairment.

All participants had consistent decreases in scores on the PDQ-39 over time (Fig. 4B). This decrease in score indicates a higher self-perceived quality of life for individuals with Parkinson's Disease. However, the participant with a greater Hoehn and Yahr stage displayed a smaller change in this score, whereas participants at an earlier Hoehn and Yahr stage showed greater changes.

Strength and Balance

All participants demonstrated a decreased time in the 5xSTS assessing lower extremity strength (Fig. 4C). For individuals with Parkinson's Disease, time to complete this test that is 16 seconds or greater indicates a high fall risk. This was not evident in any of the participants prior or at the end of completing this study. The participant with a greater Hoehn and Yahr stage showed less of a change in time to complete this test compared to participants at an earlier Hoehn and Yahr stage.

All participants showed an improvement in score on the DGI at 6-weeks as compared to their baseline score (Fig. 4D). Participant 3 exceeded the MDC of a 2.9-point increase at 6 weeks which was recorded to be statistically significant. Participants demonstrated greater ease in various categories of this assessment including gait with horizontal and vertical head turns, gait and pivot turn, stepping over obstacles, and steps.

Flexibility

All participants displayed a general trend in an improvement of their upper extremity flexibility through the Back Scratch Test. The mean for the Back Scratch Test at the post-assessment was -24.75 centimeters. These improvements remained to be below average for their gender and age group (Appendix J). Each participant also completed the Chair Sit and Reach Test in order to assess lower extremity flexibility. Participant 1 and 3 values were below average while participants 2 and 4 were within the average range. All participants either improved in their lower extremity flexibility or remained the same. The mean value for hamstring flexibility was -3.5 centimeters when evaluating the post-assessment. See Appendix K for normal ranges for the Chair Sit and Reach Test. These deviations from age related normal values is likely to be expected with

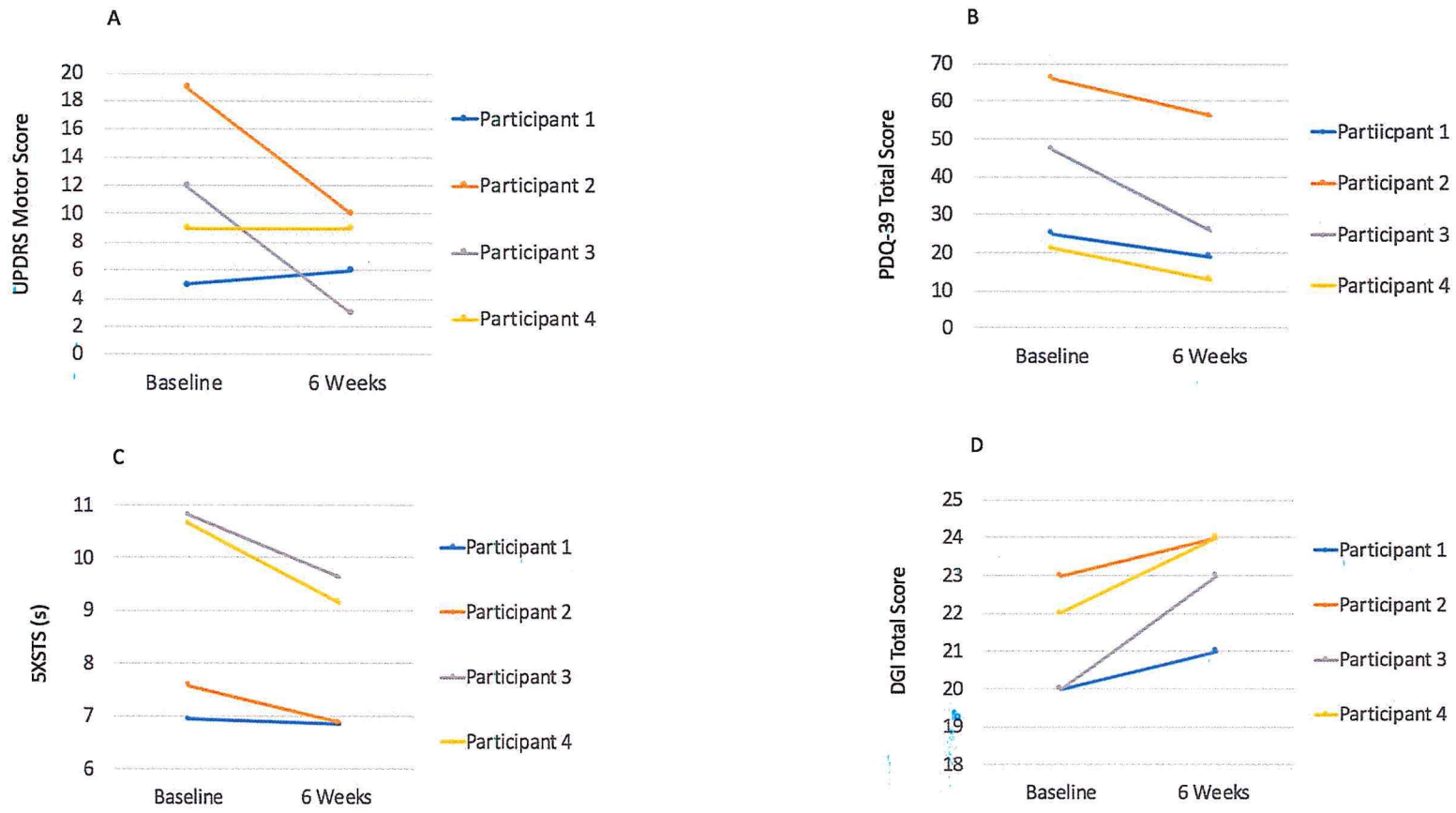

Figure 4.
Changes over time in outcomes for Parkinson's Disease. (A) Unified Parkinson's Disease Rating Scale Motor Part (UPDRS-III), total score of 56 points lower score indicates decreased disease impairment. (B) Five Times Sit to Stand (5xSTS), higher score indicates increased fall risk. (C) Dynamic Gait Index (DGI), total score of 24 points scores <19 indicate increased risk for falls. (D) Parkinson's Disease Questionnaire (PDQ-39), total score of 156 points, lower score indicated increased quality of life.

individuals with Parkinson's Disease as rigidity is commonly seen with this disease limiting the amount of flexibility available.

Posture

Out of the four participants, no changes were noted except in one participant in which reviewers noted that posture appeared to slightly worsen at the post-assessment. All participants subjectively reported in their post-assessment survey that they felt they had an overall improvement of their posture following the six-week period.

GAITRite Analysis

Upon comparison of pre- and post-assessment of gait changes were noted in the majority of areas. All participants recorded improved cadence without poles as compared to the beginning of this study, and three out of the four participants recorded improved cadence with poles. In addition, while these changes were not ruled statistically significant, general improvements were made among all participants in both step length and stride length. Furthermore, three out of the four participants showed a decrease in their stride width with the addition of walking poles indicating decreased base of support during ambulation. All participants improved in velocity both with and without walking poles, and when walking without walking poles, participant 3's increase in velocity was of significance (0.18 m/s). Table 3 illustrates the GAITRite data while reporting respected percent change from pre- and post-assessment testing as well as significant and non-significant values.

Vital Signs

Vital signs which included oxygen saturation, blood pressure, and heart rate were recorded at both the pre- and post-assessments. All vital signs remained similar in their

pre-and post-assessment. The change was not significant, and this can be attributed to the continuous levels of activities and the fact that significant change was not noted for exercise levels between any of the participants.

Activity Logs

On the pre-participation survey, each participant noted their activity level as seen in the patient demographic information, Table 2 above. Two participants rated their pre-participation activity levels as moderately active, one reported lightly active, and the last participant reported being very active. Each participant reported the same level of activity at their post-participation assessment. Throughout the use of the self-reported activity logs, researchers were able to see outside activity level as all participants were involved in various Parkinson's Disease exercise programs at the local fitness facility. Each participant was involved in routine activity and no significant changes were reported between the start and completion of the study. Participant 4 was significantly more active than the rest reported 90+ minutes of activity every day.

CHAPTER IV

DISCUSSION

The purpose of this study was to determine the effects of the use of walking poles in physical functioning, stability, balance, and posture in individuals with mild to moderate Parkinson's Disease. Specific aspects under investigation included: range of motion, gait, posture, strength, and cardiovascular endurance. Parkinson's Disease is a progressive neurodegenerative disorder, the goal of treatment is to delay disease progression and maintain function and quality of life as best as possible. While the majority of changes in this present study were not found to be statistically significant, improvements were still seen throughout this training program. These improvements were evident in the PDQ-39 (Fig. 4B), 5xSTS (Fig. 4C), DGI (Fig. 4D), and GAITRite analysis (gait velocity, cadence, step length, stride length and stride width). These positive changes may be indicative of the whole-body approach with the use of walking poles which incorporates dynamic balance activity, trunk rotation, and functional range of motion throughout the upper and lower extremities. In addition, outdoor training focused on initiation and multidirectional movement while ambulating on uneven terrain. Initiation of the activities included in this whole-body training program promoted overall maintenance as well as positive changes in the participants of this case series.

All participants reported not having participated in a recent walking program in general prior to this study, and only one participant had prior experience with the use of walking poles. Interestingly, participants with mild to moderate Parkinson's Disease.

demonstrated greater ease initiating use with the walking poles than the participant with moderate to severe Parkinson's Disease. This difference may have been due to the decreased ability to demonstrate coordinated movement in the participant with greater severity of the disease due to its progressive nature. This observation supports research suggesting that disease severity affects training capacity.[19]

In addition, although participants had busy daily schedules, they all demonstrated compliance and finished this study. They were interested in the research behind the use of walking poles and how they can be of benefit, especially to those with Parkinson's Disease. This appeared to serve as a great motivator as Parkinson's is a progressive disease, and all participants wanted to remain as active and functional as they possibly can. As evident on the PDQ-39, participants perceived positive changes in areas of mobility, activities of daily living, social, and communication. Participant three perceived the greatest change in regard to mobility with a change of 8 points in this category. Overall, these positive changes signify that the participants had an improved quality of life by participating in this study. Participants were eager to partake in this study and mentioned how much they enjoyed attending training sessions and getting together to socialize with one another.

This case series was able to demonstrate that pole walking training was feasible for all participants regardless of the level of Parkinson's Disease severity. All four participants were able to tolerate 30 minutes of pole walking two days per week for a total of six weeks. The participants were also able to partake in other aspects of the training program such as warm-up and cool-down activities accompanied by each session, as well as social interaction and conversation between one another during the

pole walking activity. This demonstrates that participants were able to utilize dual task training through engaging with one another throughout each session.

As shown above in the results, flexibility was overall improved within the participants of this study. This may be due to the increased amplitude required with both upper and lower extremity movements while ambulating with walking poles, as well as the stretching completed as a part of the warm-up and cool-down at each session (Appendix H). However, the results were greatly decreased when compared to age related normal values (Appendices J and K).

Study Comparisons

In this present study, all subjects increased their DGI score, with one participant showing clinical significance in their improvement. Musiał et al[6] concluded that Nordic walking improved gait patterns in individuals with Parkinson's Disease. These researchers implemented therapy classes in which Nordic walking activities were completed for one and a half hours, once a week, for six months. In addition to Nordic walking, these researchers also included breathing, coordination, flexing, and resistive exercises. This study differs from the current study in that the current study completed Exerstriding training twice per week for 6 weeks and did not include any other additional exercises along with the pole walking. Both studies completed a warm-up and cool-down before and after training at each session. While these studies differ in their methods, they yielded similar results as both the current study and Musiał et al[6] concluded that Nordic walking works to improve gait and functional mobility through clinically significant improvements in score in the Dynamic Gait Index (DGI) as the MDC for this measure is 2.9 points.

In this present study, all participants showed improvements with score on either the Parkinson's Disease Questionnaire-39 (PDQ-39), or the Unified Parkinson's Disease Rating Scale Part III (UPDRS-III). Baatile et al[20] completed a study to determine if an eight-week supervised Exerstriding exercise program for individuals with Parkinson's Disease would undergo significant improvements in cognitive skills, activities of daily living, motor function, and quality of life. The PDQ-39 and UPDRS were used to measure functional independence and quality of life. This study consisted of supervised PoleStriding three days per week for eight weeks, with around 40-minute sessions, where the present study completed supervised pole walking twice a week, for 30-minute sessions. The results from Baatile et al[20] yielded statistically significant improvements in both the PDQ-39 and UPDRS. While not statistically significant, all participants within the present study showed an improved score in at least one of these measures which are evident in Figures 3A and 3D. Similarly, this indicates that pole walking has the ability to improve perceived functional independence and quality of life in individuals with Parkinson's Disease.

Increased step length and gait velocity are consistent findings within current literature regarding the use of walking poles. A study by van Eijkeren et al[21] where individuals with Parkinson's Disease completed a six-week Nordic walking exercise program. The observed increased gait velocity through completion of the 10-meter walk test which yielded statistically significant results was measured through a reduction in time to complete this test following the training program.[21] The present study measured gait velocity with the use of the GAITRite both before and after the six-week training program. Within the present study, one participant showed a statistically significant

increase in their walking speed without the use of poles. The remainder of the present study participants also showed an increase in speed either with or without the use of walking poles although these results were not found to be statistically significant. Significant improvements with step length in individuals with Parkinson's Disease who complete Nordic walking has been noted across many studies as noted in Bombieri et al.[22] The present study recognizes improvements in step length among all four participants either with the use of walking poles, or without walking poles.

Post-participation surveys indicated that two out of four subjects reported they enjoyed using the walking poles noting that they would continue to use them. Participants also indicated that they perceived improved health, fitness, and balance during and after practice with the walking poles. Fritschi et al[23] addressed the factors related to walking pole participation and concluded that this activity aided in the perception of heightened health benefits. Additionally, the use of walking poles presumably provided an increased sense of stability, therefore, decreasing the fear of falling. For these reasons, pole walking has been deemed as an appropriate alternative to conventional walking and health promotion programs geared towards older adults and individuals with Parkinson's Disease.

Limitations

Limitations of this study include small sample size (n=4), no control group, male dominant sample, and all participants were already involved in regular physical activity at the local fitness center. Due to the nature of Parkinson's Disease and the increased risk for falling, maintaining a small sample size was beneficial. However, in order to further

investigate the effectiveness of the improvement in function with walking poles for Parkinson's Disease clients, a larger more diverse sample should be identified.

The small sample size limited the ability to create a control group. Absence of this group disallowed comparison of traditional walking or other interventions to pole walking. Participants had a Parkinson's diagnosis ranging from Level I-III on the Hoehn and Yahr Scale and were all regular participants in a Parkinson's Disease program at the local fitness center. Due to this, all participants reported their physical activity prior to the study was lightly active to very active. All levels of activities remained the same throughout the study allowing reported results to be directly related to the pole walking intervention. Additional studies should consider a larger study group with increased female inclusion to address gender differences and fitness benefits.

Due to previous engagements and commitments, two participants were unable to meet at every session. If participants were unable to attend a session for any reason, make-up session times were attempted at the participants convenience. Lastly, an additional limitation noted was the absence of external cuing. This includes verbal cues with mention to increase push back through the poles into the ground during walking, incorporating both arms at increased volume and amplitude for increased trunk rotation, and external speed cuing.

Recommendations

The small sample size included in this pilot study helped achieve 87.5% compliance. Group instruction and walking sessions fostered a sense of community for the subjects and may have boosted individual motivation to keep attending sessions and increase physical activity. Two out of four participants indicated on their post-

participation survey that they would willingly continue walking pole activities following the completion of the study as a way to increase physical activity through a unique activity that improves their coordination and posture.

Due to the limitation of this small pilot study, it would be worthwhile for other studies to evaluate the maintenance of improvements over time, a longer duration of the study, and 6-months to a year following intervention. Involving a larger group with more diverse activities levels and duration of disease would provide a better insight to individual differences and fitness benefits. As stated previously, the study was performed with three men and one woman, so additional efforts to recruit female subjects may allow for identification of gender differences and further hypothesize fitness benefits for that particular group as a whole. Implementation of a control group that does not use walking poles would provide evidence that supports the outcomes of training with walking poles with Parkinson's Disease specific participants. Another way to accurately measure the effects of pole walking would be to limit structured activities outside of the program to identify effects specifically from the walking poles.

Another recommendation of this study would be to attempt Nordic Walking rather than the Exerstriding, which was performed in this study. This may show increased improvements as the intensity is increased with this technique. Nordic walking shows a greater propulsion as poles are used to push forward whereas exerstriding has the poles extended in front of the individual for balance. Nordic walking may allow the individual to get increased muscle activation as well as trunk rotation.

Additional recommendations for this program would be to increase early external and tactile cueing during the course of the study including amplitude of movements of

speed to increase the challenge to drive increased neuroplasticity. While completing the pole walking, researchers allowed the participants to carry the pace, and the group preferred to walk together rather than individually. Although distance and speed increased throughout the study, it might be beneficial to pace the individuals to increase velocity on an individual basis at an increased intensity. It is also recommended that the walking pole study be increased in length as Parkinson's Disease is a progressive disease and changes may take longer to be apparent. Due to the progressive nature of the disease, participants may demonstrate maintenance rather than statistically significant improvements in measures.

CHAPTER V

CONCLUSION

Based on the evidence collected throughout this study, it can be concluded that in individuals with Parkinson's Disease level 1-3 on the Hoehn and Yahr Scale, pole walking two times per week can improve balance, strength, endurance, and posture. Although there were not many statistically significant findings noted, there were overall general improvements found in gait parameters such as the DGI, gait velocity, cadence, stride width, step, and stride length. All participants noted self-reported improvements in posture following the study. This study helped to display the positive health benefits for individuals with a neurological condition, Parkinson's Disease. While overall improvements are more difficult to see with a progressive disease, this study helped demonstrate the overall maintenance of these individuals which suggests that the use of walking poles is a viable physical therapy intervention for individuals with Parkinson's Disease. In addition, the versatility of walking pole's use and appropriateness for all ages, genders, diagnoses, and fitness levels allow for this practice to be incorporated into physical therapy intervention for a wide variety of individuals.

Pole walking was found to be a beneficial exercise for individuals in our study as it not only allowed participants the opportunity to engage in additional exercise beyond their previous activities, it also allowed them to integrate into a social environment with individuals with similar disease processes. This allowed for participants to feel motivated and enjoy the pole walking which in turn can improve overall quality of life for these

individuals. When used for physical therapy intervention, a positive mindset and view regarding walking poles can increase individuals' overall compliance and quality of life for diagnoses such as Parkinson's Disease.

APPENDIX A – IRB APPROVAL

UND UNIVERSITY OF NORTH DAKOTA

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DIVISION OF RESEARCH & ECONOMIC DEVELOPMENT

Institutional Review Board
Tech Accelerator, Suite 2050
4201 James Ray Dr Stop 7134
Grand Forks, ND 58202-7134
Phone: 701.777.4279
Fax: 701.777.2193
UND.irb@UND.edu

May 21, 2019

Principal Investigator:	Meridee Danks, D.P.T.
Project Title:	Effects of Pole Walking on Adults with Parkinson's Disease Following 6 Weeks of Training
IRB Project Number:	IRB-201905-303
Project Review Level:	Expedited 4, 6
Date of IRB Approval:	05/20/2019
Expiration Date of This Approval:	05/19/2020
Consent Form Approval Date:	05/20/2019

The application form and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the University of North Dakota Institutional Review Board.

Attached is your original consent form that has been stamped with the UND IRB approval and expiration dates. Please maintain this original on file. ***You must use this original, stamped consent form to make copies for participant enrollment. No other consent form should be used.*** It must be signed by each participant prior to initiation of any research procedures. In addition, each participant must be given a copy of the consent form.

Prior to implementation, submit any changes to or departures from the protocol or consent form to the IRB for approval. No changes to approved research may take place without prior IRB approval.

You have approval for this project through the above-listed expiration date. When this research is completed, please submit a termination form to the IRB. If the research will last longer than one year, an annual review and progress report must be submitted to the IRB prior to the submission deadline to ensure adequate time for IRB review.

The forms to assist you in filing your project termination, annual review and progress report, adverse event/unanticipated problem, protocol change, etc. may be accessed on the IRB website: http://und.edu/research/resources/human-subjects/

Sincerely,

Michelle L. Bowles, M.P.A., CIP
IRB Manager

MLB/sb
Enclosures

Cc: Chair, Physical Therapy

Human Subjects Research Protocol: Application for Expedited or Full Board Review

- *Please provide the information requested below.*
- *Handwritten forms are not accepted – responses must be typed on the form.*
- *All students, medical residents, and post-docs must list a research advisor.*

Please check one of the options below:

☒ Initial submission

☐ Revised application in response to reviewer requests

⚠ *All revisions must be in UPPER CASE.*

Principal Investigator: Meridee Danks

Telephone: 701-777-2831 **E-mail Address:** meridee.danks@med.und.edu

Complete Mailing Address: 1301 North Columbia Road Stop 9037

School/College: University of North Dakota **Department:** Physical Therpay

Research Advisor (if applicable):

Telephone: **E-mail Address:**

Address or Box #:

School/College: **Department:**

*** ***All IRB applications must include a Key Personnel Listing.***

Project Title: Effects of Pole Walking on Adults with Parkinson's Disease Following 6 Weeks of Training

Proposed Project Dates: **Beginning Date:** April 2019 **Completion Date:** Ongoing (Including data analysis)

Funding agencies supporting this research: N/A

Did the grant proposal with the funding entity go through UND Grants & Contracts Admin.? ☐ YES or ☒ NO

Attach a copy of the grant proposal. Do not include any budgetary information. The IRB will not be able to review the study without a copy of the grant proposal submitted to the funding agency.

☐ YES or ☒ NO Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

☒ YES or ☐ NO Will any research participants be obtained from another organization outside the University of North Dakota (e.g., hospitals, schools, public agencies, American Indian tribes/reservations)?

☒ YES or ☐ NO Will any data be collected at or obtained from another organization outside the University of North Dakota?

If yes to either of the previous two questions, list all organizations: YMCA- Grand Forks

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands its involvement and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on organizational letterhead.

Does any external site where the research will be conducted have its own IRB? ☐ YES ☐ NO ☒ N/A

If yes, does the external site plan to rely on UND's IRB for approval of this study? ☐ YES ☐ NO ☐ N/A
(If yes, contact the UND IRB at 701 777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

_____ Date submitted: _____ Status: ☐ Approved ☐ Pending

_____ Date submitted: _____ Status: ☐ Approved ☐ Pending

(include the name and address of the IRB, contact person at the IRB, and a phone number for that person)

Type of Project: Check "Yes" or "No" for each of the following.

☒ YES or ☐ NO New Project

☐ YES or ☒ NO Continuation/Renewal

☐ YES or ☒ NO Dissertation/Thesis/Independent Study

☐ YES or ☒ NO Student Research Project

☐ YES or ☒ NO Is this a Protocol Change for previously approved project? If yes, submit a signed Protocol Change Form, along with a signed copy of this form with the changes bolded or highlighted.

☐ YES or ☒ NO Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.

☐ YES or ☒ NO Does your project include Genetic Research?

Subject Classification: Check all that apply, or check here if N/A ☐

☐ Children (< 18 years)

☐ Prisoners

☐ Cognitively impaired persons or persons unable to consent

☒ Other Individuals with Parkinson's Disease

☐ UND Students

☐ Pregnant Women/Fetuses

This study will involve: Check all that apply, or check here if N/A ☒

☐ Deception (Attach Waiver or Alteration of Informed Consent Requirements)

☐ Stem Cells

☐	Radiation	☐	Discarded Tissue
☐	New Drugs (IND) IND # _____Attach Approval	☐	Fetal Tissue
☐	Investigational Device Exemption (IDE) # _____Attach Approval	☐	Human Blood or Fluids
☐	Non-approved Use of Drug(s)	☐	Other _____

I. Project Overview

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

Individuals with Parkinson's Disease often have difficulty with walking by exhibiting a slow, shuffling type gait with limited trunk mobility. Physical activity such as walking has shown to be beneficial for people with Parkinson's Disease Walking is a popular and convenient exercise to perform. Pole walking is a new and simple type of fitness walking using specially designed poles. Two poles are used while walking, each pole coordinating movements with the opposite leg similar to cross country skiing. Walking poles provide stability and encourage a natural rotation during gait. The aim of this study is to examine the effects of pole walking on physcial functioning and mobility of individuals with Parkinson's Disease after completing a training program.

II. Protocol Description

Please provide a thorough description of the procedures to be used by addressing the instructions under each of the following categories.

1. Subject Selection.

a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects.

The researchers will recruit from the local Grand Forks community and/or local health clubs (YMCA). Recruitment will be completed during Spring 2019, pending IRB approval, until a sufficient number of participants are recruited. Principle investigator will be recruiting through word of mouth.

b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the "Subject Classification" section above.

Individuals with mild to moderate Parkinson's Disease (Hoehn and Yahr stages I-III) who are over the age of 18 and are community ambulators. A pre-participation survey will be used to identify any health concerns or injuries that may impair the individuals ability to participate in the walking pole program. Individuals must be able to pass a health pre-screen of vital signs (blood pressure, heart rate, O2 sats). Any abnormal readings would exclude the individual from participating in the study until physician approval is obtained. Constant medications relating to Parkinson's Disease must be established four weeks prior to initiation of study. Individuals must cognitively agree to participate in the study and have the ability to be compliant for the 6 week training program.

c) Describe your exclusionary criteria and provide a rationale for excluding subject categories.

Individuals that are younger than 18 years of age, use of an assistive device, if they are not community ambulators, if they have any other neurological conditions or cognitive impairments that would impact participation in training and testing, or if there are cardiovascular diseases or concerns present or any health issues that would inhibit the use

of walking poles or participating in a walking program (as identified in pre-participation survey).

d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects.
This will be a pilot study/case series. The goal is to have at least 2-6 subjects per training session. This will allow one-on-one instruction and supervision with the walking program. Training sessions may be repeated at another time to collect progressive data.

e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.
N/A this is pilot study.

2. Description of Methodology.

a) Describe the procedures used to obtain informed consent.
Participants will be asked if they would like to participate in the study. If they are interested they will receive a written informed consent to review. Questions will be addressed and then signatures will be obtained. Each participant will receive a copy of informed consent.

b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research.
Pre- and Post- testing and survey's will be performed at UNDSHMS Physical Therapy Department. If weather is cooperative training may be performed outside. If weather is poor, walking will be performed inside at UNDSMHS.

c) Indicate who will carry out the research procedures.
University of North Dakota faculty, Meridee Danks DPT and two University of North Dakota Physical Therapy graduate students assisting her. Renee Mabey PT, DPT, UND-PT faculty, will be the statistician.

d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.
Participants will be asked to do a short survey/questionnaire to determine demographics, health status and activity levels. Pre-screening of vital signs (blood pressure, heart rate, O2 sats) will be performed prior to initial assessment. Pre-test and post-test will be completed (1 session each of approximately 45 minutes) with the following commonly used physical therapy assessments:

1. GAITRite (an instumented 16' walkway), to analyze gait parameters such as walking speed, step length, cadence, etc. The participant will be asked to walk over the electronic carpeted walkway at a comfortable speed with and without poles, three times each. Average of three trials will be recorded. Video will be taken during each of these trials to analyze posture/gait. Hudl app may be used to help measure angles during gait analysis. Gait Abnormality Rating Scale (GARS) or GARS-modified will be used as a guide for the gait analysis (see attached). The 10 Meter Walk Test (10 MWT) will be used as a back up if GAITRite is not available. Time to complete ~ 5 minutes.
2. Height will be measured with Stadiometer both with and without walking poles. This will be used to measure if there is posture change with use of walking poles. Time to complete ~ 2 minutes.

3. Five Times Sit to Stand Test - participant is asked to stand up and sit back down five times as fast as they can. Time it takes to complete this will be recorded. Testing balance and lower body strength. Functional moility test. Total time to complete ~1 minute.
4. Back Stratch Test- participant asked to reach one hand over the shoulder and other up the middle of their back, the number of inches between middle fingers is measured. Testing upper body flexibility. Time to complete ~ 2 minutes.
5. Chair Sit-and-Reach Test- participant is asked to reach had to tip of toe while sitting on a chair, measurement taken from tip of fingers to tip of toe. Testing hamstring tightness. Total time to complete ~5 minutes. (see attached)
6. Posture standing will be recorded by use of the IPad, photographs/video will be taken from front and side views with a posture grid in the background. Time to complete ~2 minutes.
7. Participants will complete a weekly activity log during training program to monitor any changes in activity.
8. Dynamic Gait Index- assess individual's ability to modify balance while walking in the presence of external demands. DGI is a commonly used test in physical therapy for balance and gait in people with Parkinson's Disease. Video will be taken during this assessment to analyze posture/gait. Total time to complete ~10 minutes
9. PDQ-39 Quality of Life survey specific to indivuduals with Parkinson's Disease (see attached). Total time to complete ~ 10 minutes.
10. Unified Parkinson's Disease Rating Scale (UPDRS) very commonly used outcome measure for Parkinson's Disease.

Walking Pole Training Protocol - participants will meet as a group 2x/week for 6 weeks. At first session, walking poles will be properly fitted to each participant and instruction given on proper use of walking poles. Each training session will include 5-10 minutes of warmup stretching activities, 30 minutes of pole walking, and 5-10 minutes cool down/stretching period. Total class time should take ~45 minutes. Heart rate, oxygen saturation and rate of perceived exertion (RPE) will be monitored at each training session. Participants will be allowed to choose his/hers comfortable walking pace during training sessions. Each training session, distance walked and timed walk will be measured. Walking poles will be provided by researcher. If participant is unable to attend class they will be asked to perform 30 minutes of pole walking on his/her own.

e) Describe audio/visual procedures and proper disposal of tapes.

We will use an IPad to record participants during gait and posture analysis (arm swing, step length, trunk rotation, etc.). Consent form will indicate whether or not participant will allow videotaping to be completed. Videotapes will be downloaded to a secure computer and subjects will give permission for the downloading and keeping of videos for future analysis. Hudl app may be used to help measure angles during gait analysis.

f) Describe the qualifications of the individuals conducting all procedures used in the study.

Meridee Danks has been a practicing physcial therapist for 34 years and has a specialty certification in Neurological Physical Therapy. UND PT graduate students will be supervised and trained appropriately.

g) Describe compensation procedures (payment or class credit for the subjects, etc.).
Participants will be put in a drawing to receive a pair of walking poles following completion of research. A single pair of walking poles will be given out.

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

3. Risk Identification.

a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.
There is a minimal risk of losing balance or falling during gait assessment and training sessions. For all mobility assessments, a gait belt and a spotter will be used to ensure safety. The subject will be instructed that they are able to quit the activity at any time if they do not feel safe. Patients will be trained properly to ensure safety while using walking poles prior to initiation of training program. All training sessions will be supervised by principal investigator and UND PT graduate students.

b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.
There will be an initial link between data sheet and consent form. All data sheets will be coded and consent forms will be stored seperately. Link will be used to help with initial data processing and will destroyed once data analysis is completed.

c) Provide a description of the data monitoring plan for all research that involves greater than minimal risk.
N/A

d) If the PI will be the lead-investigator for a multi-center study, or if the PI's organization will be the lead site in a multi-center study, include information about the management of information obtained in multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications.
N/A

4. Subject Protection.

a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).
We will ensure a safe environment with limited distractions, adequate space, and a clear walking path minimizing obstacles. Subjects will be informed that they are able to stop any activity they do not feel safe performing. All walking activity will be directly supervised by research personnel. Group will remain smaller for one-on-one instruction and supervision.

b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.
All data will be coded and identifying information will be removed once all data is gathered. Any reporting will be in aggregate form. On the consent form the participant will identify whether or not they give permission to photographed or video recorded.

c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.
Each subject will be provided with a copy of consent from prior to participation.

d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.
Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)
2) who will have access to the data
3) how the data will be destroyed
4) the storage location of consent forms and personal data (separate from research data)
5) how the consent forms will be destroyed

1) The research data will be stored separately from the consent form and other personal data
2) Only researchers and people who aduit IRB procedures will have access to the data.
3) The data will be kept a minimum of three years and will be shredded once data analysis is completed.
4) Consent forms and data will be stored in separate filed in a locked office (E341 in UNDSMHS) of the researcher.
5) Consent forms will be kept a minimum of three years and will be shredded once data analysis is completed.

e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.).
Suggestions to contact a physician will be made if subjects have any concerns arise.

f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.
Subject will be referred for medical treatment if required for any injury that may occur during assessment. The responsibility of cost related to any treatment will be the responsibility of the subject.

III. Benefits of the Study

Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). **Please note:** extra credit and/or payment are not benefits and should be listed in the Protocol Description section under Methodology.

Subjects will be able to have their strength, posture, and gait assessed at no cost. They will also be able to experiment with walking poles. They will be able to determine if there is any benefit of using walking poles to improve their gait and posture. The research will provide benefit to the general society by seeing the effectiveness of walking poles on posture and gait in individuals with Parkinson's Disease.

IV. Consent Form

Clearly describe the consent process below and be sure to include the following information in your description (Note: Simply stating 'see attached consent form' is not sufficient. The items listed below must be addressed on this form.):

1) The person who will conduct the consent interview
2) The person who will provide consent or permission
3) Any waiting period between informing the prospective participant and obtaining consent
4) Steps taken to minimize the possibility of coercion or undue influence
5) The language (English, French, German, etc.) to be used by those obtaining consent
6) The language (English, French, German, etc.) understood by the prospective participant or the legally authorized representative

7) The information to be communicated to the prospective participant or the legally authorized representative

1) Meridee Danks will supervise the informed consent interview.
2) The individual that is volunteering for the study will provide consent to participate.
3) Participants will be given the consent form to read and will be allowed to ask any questions prior to obtaining consent.
4) Prospective subjects will be told research is voluntary and if they do participate, that they will be able to stop at any time without penalty.
5) English language will be used in obtaining consent.
6) English speaking prospective participants will be recruited.
7) The consent form will indicate the assessments to be performed and the amount of time to perform them and who will be performing the assessments.

A copy of the consent form must be attached to this proposal.

Necessary attachments:

- ☒ Signed Student Consent to Release of Educational Record Form (below) (students only);
- ☒ Investigator Letter of Assurance of Compliance (below) (all researchers)
- ☒ Consent form, or Waiver or Alteration of Informed Consent Requirements
- ☒ Key Personnel Listing
- ☒ Surveys, interview questions, assessments, etc. (if applicable);
- ☐ Printed web screens (if survey is over the Internet); and
- ☐ Advertisements (flyer, social media postings, email/letters, etc.).

V. Signatures:

Principal Investigator:
I certify that the information provided on this form is accurate and that this research will be conducted in accordance with the statements provided above. I understand that if I want to make changes to the research protocol after IRB approval, I must submit a protocol amendment to the IRB for review prior to implementing any changes.

I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.

Meridee Danks 05/14/19

(Principal Investigator) Date:

Research Advisor:
As the advisor for this research, I understand that I am responsible for the ethical conduct of this research as described in the protocol. I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.

UNIVERSITY OF NORTH DAKOTA
INSTITUTIONAL REVIEW BOARD
KEY PERSONNEL LISTING

	Names of Research Personnel		Position	Highest Academic Degree	Responsibilities (check all that apply)				
	First Name	Last Name	(select from drop-down menu)	(High School, B.S, M.A., Ph.D., M.D., etc.)	Consent Subjects	Recruit Subjects	Research Design	Intervention	Data Analysis
1	Meridee	Danks	Faculty	DPT	☒	☒	☒	☒	☒
2	Kathleen	Dennison	Graduate student	BS	☒	☒	☒	☒	☒
3	Taylor	Jamison	Graduate student	BS	☒	☒	☒	☒	☒
4	Renee	Mabey	Faculty	PhD	☐	☐	☐	☐	☒
5					☐	☐	☐	☐	☐
6					☐	☐	☐	☐	☐
7					☐	☐	☐	☐	☐
8					☐	☐	☐	☐	☐
9					☐	☐	☐	☐	☐
10					☐	☐	☐	☐	☐

* *Attach proof of education in human subjects research for all non-UND personnel*

Revised 03/15/2017

May 15, 2019

To Whom It May Concern:

The Grand Forks YMCA offers physical activity programs to promote wellness for people with Parkinson's disease, such as Rock Steady Boxing and PWR! Exercise. We always welcome the UND Physical Therapy Department faculty and students to assist as volunteers with such programming.

We welcome the UND Physical Therapy Department in recruiting participants who attend our Parkinson classes for their study, "Effects of Pole Walking on Adults with Parkinson's Disease following 6 Weeks of Training." This study is led by UND Physical Therapy faculty member, Meridee Danks, DPT.

The YMCA fully supports the efforts of the UND Physical Therapy faculty and will assist as needed in encouraging participation in this study.

Sincerely,

Adam Sorum
Healthy Living Director
YMCA
215 N 7th Street
Grand Forks, ND 58203

GAIT ASSESSMENT RATING SCALE (GARS)

A. General Categories

1. **Variability** - a measure of inconsistency and arrhythmicity in steps and arm movements
   0 = Fluid and predictably paced limb movements.
   1 = Occasional interruptions (changes in velocity) approximately < 25% of the time.
   2 = Unpredictability of rhythm of movement > 25% of the time.
   3 = Random timing of limb movements.

2. **Guardedness** -- hesitancy, slowness, diminished propulsion and lack of commitment stepping and arm swing.
   0 = Good forward momentum and lack of apprehension in propulsion.
   1 = Center of gravity of head, arms and trunk (HAT) projects only slightly in front of push off, but still good arm - leg coordination.
   2 = HAT held over anterior aspect of foot, and some moderate loss of smooth reciprocation.
   3 = HAT held over rear aspect of stance phase foot, and great tentativeness in stepping.

3. **Weaving** -- an irregular line of progression.
   0 = Straight line of progress on frontal view.
   1 = Single deviation from straight line of progression.
   2 = Two to three deviations from straight line of progression.
   3 = Four or more deviations from straight line of progression.

4. **Waddling** -- A broad based gait characterized by excessive truncal crossing of the midline and bending.
   0 = Narrow base of support and body held nearly vertically over feet.
   1 = Slight separation of medial aspects of feet and just perceptible lateral movements of head trunk.
   2 = 3" to 4" separation of feet and obvious bending of trunk to side so that cog of head lies well over ipsilateral stance foot.

5. **Staggering** -- sudden and unexpected laterally directed partial losses of balance.
   0 = No losses of balance to side.
   1 = A single lurch to the side.
   2 = Two lurches to the side.
   3 = Three or more lurches to the side.

B. Lower Extremity Categories

1. **Percent of time in swing** -- loss of percentage in the gait cycle constituted by the swing phase.
   0 = Approximately 3:2 ratio of stance:swing.
   1 = 1:1 or less ratio of stance:swing.
   2 = Markedly prolonged stance phase but with some obvious swing time remaining.
   3 = Barely perceptible portion of cycle spent in swing phase.

2. Foot Contact -- the degree to which the heel strikes the ground before the forefoot.
   0 = Very obvious angle of impact of heel on ground.
   1 = Barely visible contact of heel before forefoot.
   2 = Entire foot lands on ground.
   3 = Anterior aspect of foot strikes ground before heel.

3. Hip ROM -- the degree of loss of hip ROM seen during a gait cycle.
   0 = Obvious angulation of thigh backwards during double support (~ 10 deg.)
   1 = Just barely visible angulation of thigh backwards from vertical.
   2 = Thigh in line with vertical projection from ground.
   3 = Thigh angled forward from vertical at maximum posterior excursion.

4. Knee ROM -- the degree of loss of knee ROM seen during the gait cycle.
   0 = Knee moves from complete extension at heel strike (and late stance) to 70 or nearly 90 deg during swing.
   1 = Slight bend in knee seen at heel strike and late stance and maximal flexion at midswing is closer to 45 deg. than 90 deg.
   2 = Knee flexion at late stance more obvious than at heel strike, very little clearance seen for toe during swing.
   3 = Toe appears to touch ground during swing, knee flexion appears constant during stance, and knee angle during stance, and knee angle during swing appears 45 deg or less.

C. Trunk, Head and Upper Extremity Categories

1. Elbow Extension -- a measure of the decrease in elbow range of motion.
   0 = large peak to peak excursion of forearm (approximately 20 deg.), with distinct maximal flexion at end of anterior trajectory.
   1 = 25 deg. decrement of extension during maximal posterior excursion of upper extremity.
   2 = almost no change in elbow angle.
   3 = no apparent change in elbow angle (held in flexion).

2. Shoulder Extension -- a measure of the decrease in shoulder range of motion.
   0 = clearly seen movement of upper arm anterior (15 deg) and posterior (20 deg) to vertical axis of trunk.
   1 = shoulder flexes slightly anterior to vertical axis.
   2 = shoulder comes only to vertical axis or slightly posterior to during flexion.
   3 = shoulder stays well behind vertical axis during entire excursion.

3. Shoulder Abduction -- a measure of pathological increase in shoulder range of motion laterally.
   0 = shoulders held almost parallel to trunk.
   1 = shoulders held 5 to 10 deg. to side.
   2 = shoulders held 10 to 20 deg. to side.
   3 = shoulders held greater than 20 deg. to side.

4. Arm - Heel strike Snychrony -- the extent to which the contralateral movements of an arm and leg are out of phase.

0 = good temporal conjunction of arm and contralateral leg at apex of shoulder and hip excursions all of the time.

1 = arm and leg slightly out of phase 25% of the time.

2 = arm and leg moderately out phase 25 - 50% of the time.

3 = little or no temporal cadence of arm and leg.

5. Head Held Forward -- a measure of the pathological forward projection of the head relative to the trunk.

0 = earlobe vertically aligned with shoulder tip.

1 = earlobe vertical projection falls 1" anterior to shoulder tip.

2 = earlobe vertical projection falls 2" anterior to shoulder tip.

3 = earlobe vertical projection falls 3" anterior to shoulder tip.

6. Shoulders Held Elevated -- the degree to which the scapular girdle is held higher than normal.

0 = tip of shoulder (acromion) markedly below level of chin (1 - 2").

1 = tip of shoulder slightly behind level of chin.

2 = tip of shoulder at level of chin.

3 = tip of shoulder above level of chin.

7. Upper Trunk Flexed Forward -- a measure of kyphotic involvement of the trunk.

0 = very gentle thoracic convexity, cervical spine flat, or almost flat.

1 = emerging cervical curve, more distant thoracic convexity.

2 = anterior concavity at mid chest level apparent.

3 = anterior concavity at mid chest level very obvious.

> 9 = at risk for falling.

Gait Abnormality Rating Scale - modified (GARS-M) -- VanSwearingen, et al, 1996

1. Variability-a measure of inconsistency and arrhythmicity of stepping and/or arm movements
   - 0 = fluid and predictably paced limb movements
   - 1 = occasional interruptions (changes in speed) approximately 25% of the time
   - 2 = unpredictability of rhythm approximately 25%-75% of the time
   - 3 = random timing of limb movements
2. Guardedness-hesistancy, slowness, diminished propulsion, and lack of commitment in stepping and arm swing
   - 0 = good forward momentum and lack of apprehension in propulsion
   - 1 = center of gravity of head, arms, and trunk (HAT) projects only slightly in front of pushoff, but still good arm-leg coordination
   - 2 = HAT held over anterior aspect of foot and some moderate loss of smooth reciprocation
   - 3 = HAT held over rear aspect of stance phase foot and great tentativeness in stepping
3. Staggering-sudden and unexpected laterally directed partial losses of balance
   - 0 = no losses of balance to side
   - 1 = a single lurch to side
   - 2 = two lurches to side
   - 3 = three or more lurches to side
4. Foot contact-the degree to which heel strikes the ground before the forefoot
   - 0 = very obvious angle of impact of heel on ground
   - 1 = barely visible contact of heel before forefoot
   - 2 = entire foot lands flat on ground
   - 3 = anterior aspect of foot strikes ground before heel
5. Hip ROM-the degree of loss of hip range of motion seen during a gait cycle
   - 0 = obvious angulation of thigh backward during double support (10°)
   - 1 = just barely visible angulation backward from vertical
   - 2 = thigh in line with vertical projection from ground
   - 3 = thigh angled forward from vertical at maximum posterior excursion
6. Shoulder extension-a measure of the decrease of shoulder range of motion
   - 0 = clearly seen movement of upper arm anterior (15°) and posterior (20°) to vertical axis of trunk
   - 1 = shoulder flexes slightly anterior to vertical axis
   - 2 = shoulder comes only to vertical axis or slightly posterior to it during flexion
   - 3 = shoulder stays well behind vertical axis during entire excursion
7. Arm-heel-strike synchrony-the extent to which the contralateral movements of an arm and leg are out of phase
   - 0 = good temporal conjunction of arm and contralateral leg at apex of shoulder and hip excursions all of the time
   - 1 = arm and leg slightly out of phase 25% of the time
   - 2 = arm and leg moderately out of phase 25%-50% of the time
   - 3 = little or no temporal coherence of arm and leg

"Sensitivity (62.3%) and specificity (87.1%) for recurrent fall risk have been determined for community-dwelling older men (64–96 years of age), including a cutoff score of 9 for recurrent fall risk." (Brach, 2002)

- VanSwearingen JM, Paschal KA, Bonino P, Yang JF. (1996). The Modified Gait Abnormality Rating Scale and recognizing recurrent fall risk of community-dwelling, frail older veterans. Phys Ther. 76:994–1002.
- VanSwearingen JM, Paschal KA, Bonino P, Chen TW. (1998). Assessing recurrent fall risk of community-dwelling, frail older veterans using specific tests of mobility and the physical performance test of function. J Gerontol A Biol Sci Med Sci. 1998;53:M457–M464.
- Brach JS, VanSwearingen JM. (2002). Physical Impairment and Disability: Relationship to Performance of Activities of Daily Living in Community-Dwelling Older Men. Physical Therapy 82:8, 752-761.

The original GARS is a 16 item measure (Wolfson, 1990)

Wolfson L., Whipple R. Amerman P, Tobin JN. (1990). Gait assessment in the elderly: gait abnormality rating scale and its relation to falls. J Gerontol. 45:M12-M19.

APPENDIX B – CONSENT FORM

INFORMED CONSENT DOCUMENT TEMPLATE
IC 701-B 01/21/2019

THE UNIVERSITY of NORTH DAKOTA
INSTRUCTIONS FOR WRITING AN INFORMED CONSENT DOCUMENT

INSTRUCTIONS:

- ☐ This consent document template is recommended for non-medical studies because it contains all required elements of consent.
- ☐ The highlighted text throughout this document offers suggestions and guidance. It should be deleted and replaced with information specific to your study and then un-highlighted. All other text on the document should remain.

CONSENT DOCUMENT INSTRUCTIONS:

- ☐ Consent documents should be written in the second person (e.g., "You are invited to participate"). Use of the first person (e.g., "I understand that…") can be interpreted as suggestive and can constitute coercive influence over a subject.
- ☐ The consent form should be written at about an eighth grade reading level. Clearly define complicated terms and put technical jargon in lay terms.

CONSENT DOCUMENT FORMAT:

- ☐ To facilitate the IRB review process, the sample format below is recommended for consent forms.
- ☐ Prepare the entire document in 12 point type, with no blank pages or large blank spaces/paragraphs.
- ☐ ***Do not change the margins on the document.*** They are set to allow room for the IRB approval stamp.
- ☐ Multiple page consent documents should contain page numbers and a place for the subject to initial each page.

CONCISE SUMMARY FOR ANY CONSENT FORM OVER 6 PAGES:

If your consent is more than 6 pages, provide a brief explanation of the project that is concise and focused, and that will most likely assist a prospective subject to understand the research and choose to participate. This presentation of information is to be short, and can summarize information explained later in greater detail. This summary should include:

- ☐ The purpose and expected duration
- ☐ Major requirements of the study
- ☐ The most important risks and/or benefits
- ☐ Other alternatives to participating, if appropriate
- ☐ Time commitment

ASSISTANCE

- ☐ If you have questions about or need assistance with writing an informed consent please call the Institutional Review Board office at 701 777-4279 or UND.irb@UND.edu.

THE UNIVERSITY OF NORTH DAKOTA
CONSENT TO PARTICIPATE IN RESEARCH

Project Title: Effects of Pole Walking on Adults with Parkinson's Disease Following 6 Weeks of Training

Principal Investigator: *Meridee Danks, DPT*

Phone/Email Address: *701-777-3861 / meridee.danks@und.edu*

Department: *Physical Therapy*

What should I know about this research?
- ☐ Someone will explain this research to you.
- ☐ Taking part in this research is voluntary. Whether you take part is up to you.
- ☐ If you don't take part, it won't be held against you.
- ☐ You can take part now and later drop out, and it won't be held against you
- ☐ If you don't understand, ask questions.
- ☐ Ask all the questions you want before you decide.

How long will I be in this research?
We expect that your taking part in this research will last ~7-8 weeks (pre-/post-testing/6 weeks training).

Why is this research being done?
The purpose of this research is to determine the effects of the use of walking poles on physical functioning, stability, balance, and posture in individuals with mild to moderate Parkinson's Disease. Pole walking is a new and simple type of fitness walking using specially designed poles. Two poles are used while walking, each pole moving with the opposite leg (left pole with the right leg and right pole with the left leg). The poles help with your balance and exercise your arms while you walk. Your participation will allow the researchers to evaluate the walking pole benefits among individuals with Parkinson's Disease. The aim of this study is to examine the effects of pole walking on physical functioning in individuals with Parkinson's Disease after completing a walking program.

What happens to me if I agree to take part in this research?
If you decide to take part in this research study, demographic/general health information, a Unified Parkinson's Disease Rating Scale (UPDRS), and a Parkinson's Disease Quality of Life (PDQ) survey will be taken. Following, you will participate in a pre-study assessment, lasting approximately 45 minutes. Prior to completing this assessment, your blood pressure, heart rate,

Date: _____
Subject Initials: _____

and oxygen saturation will be tested. If any abnormal readings are found, you will be asked to get your doctors approval to participate in the study. You will then move through a series of 6 stations of commonly used Physical Therapy assessments that evaluate strength, endurance, and walking - the first being an instrumented walkway (GAITRite) that will record walking measures (such as footprints, velocity measure, etc); followed by height and weight measurements, Five Times Sit-to-Stand test, Chair Sit-and Reach Test, Back Scratch Test, and Dynamic Gait Index (DGI). Vital signs will be re-checked following completion of the tests above. Picture and/or video recordings via iPads may be used to document your standing and walking posture.

Following the assessment, you will be fitted with a set of walking poles that will be used for the duration of the pole walking training program. You will receive thorough instruction (~30-60 minutes) regarding use of the walking poles prior to starting this 6 week walking program. The group walking program will meet 2 times per week for 6 weeks. Each session will include 5-10 minutes of warm-up stretching activities, 30 minutes of pole walking, with rest breaks as needed, and a 5-10 minute of cool down/stretching period at the end. Total class time is estimated to be ~45 minutes. Walking poles will be provided. Each participant will fill out a weekly activity log during the 6-week training program. If you are unable to make it to a session you will be asked to try and complete the training session on your own. Following the 6 weeks of training, a one time post-training survey and assessment will be completed (~45 minutes). Pictures and videos via iPads will be taken in this study to analyze your posture and gait. Permission to use these pictures and videos in a written report or article will be requested prior to use.

Could being in this research hurt me?
The most important risks or discomforts that you may expect from taking part in this research include losing your balance or falling during gait assessments and training sessions, although the risk is minimal. Risk will be minimized through proper instruction and assistance during assessments and training sessions. This study requires you to complete aerobic exercise. Pre-screening will be completed and vital signs (heart rate, oxygen saturation and rate of perceived exertion) will be monitored during each session. Only subjects that are community walkers with Parkinson's Disease will be allowed to participate. Your participation is voluntary and you will be able to quit the activity at any time if you do not feel safe.

Will being in this research benefit me?
The most important benefits that you may expect from taking part in this research include that you will be able to have your strength, posture, and gait assessed at no cost. Also, you will be able to experiment with walking poles and partake in a 6-week walking program. You will be able to assess whether or not you personally benefit from the use of walking poles to improve your posture, gait, and balance.
The research will also provide benefit to the general public by determining the effectiveness of walking poles on posture and gait in individuals with Parkinson's Disease during community ambulation.

Date: _____
Subject Initials: _____

How many people will participate in this research?
Approximately 2-4 individuals with mild to moderate Parkinson's Disease will take part in training sessions at one time in this study. Participants need to be over the age of eighteen, are community ambulators, and have no recent health concerns that might impact their ability to perform pole walking training. Pre- and post-assessments will be performed at University of North Dakota Medical School (UNDSMHS). Pole walking training sessions will be performed outside on community walking paths or sidewalks.

Will it cost me money to take part in this research?
You will not have any costs for being in this research study. You will be required to travel to the pre- and post-assessment and to each training session held twice per week for 6 weeks. Parking permits will be provided for lots at UNDSMHS.

In the event that this research activity results in an injury, treatment will be available including first aid, emergency treatment and follow-up care as needed. Payment for any such treatment is to be provided by you (you will be billed) or your third-party payer, if any (such as health insurance, Medicare, etc.) No funds have been set aside to compensate you in the event of injury. Also, the study staff cannot be responsible if you knowingly and willingly disregard the directions they give you.

Will I be paid for taking part in this research?
You will not be paid for being in this research study. Your name will be entered into a drawing for a free pair of walking poles following the group walking program.

Who is funding this research?
The University of North Dakota and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.

What happens to information collected for this research?
The records of this study will be kept private to the extent permitted by the law. Your private information may be shared with individuals and organizations that conduct or watch over this research, including:

- The Institutional Review Board (IRB) that reviewed this research
- Researcher graduate student assistants and research statistician.

We may publish the results of this research. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy. Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified. Pictures and videos via iPads will be taken in this study to analyze your posture and

Date: _____
Subject Initials: _____

gait. Permission to use these pictures and videos in a written report or article will be requested prior to use. Recordings will be stored on a password protected computer for a minimum of three years for data analysis purposes by researchers. Data or specimens collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

We may publish the results of this research. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

What if I agree to be in the research and then change my mind?
If you decide to leave the study early, we ask that you call the study coordinator. Your participation is voluntary. You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your current or future relations with the University of North Dakota. There will be no penalty if you choose not to participate in this study.

Who can answer my questions about this research?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 701.777.4279 or UND.irb@UND.edu if:

- ☐ You have questions, concerns, or complaints that are not being answered by the research team.
- ☐ You are not getting answers from the research team.
- ☐ You cannot reach the research team.
- ☐ You want to talk to someone else about the research.
- ☐ You have questions about your rights as a research subject.
- ☐ You may also visit the UND IRB website for more information about being a research subject: http://und.edu/research/resources/human-subjects/research-participants.html

Date: _____
Subject Initials: _____

Your signature documents your consent to take part in this study. You will receive a copy of this form.

Subject's Name: _____

_____ _____
Signature of Subject Date

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative.

_____ _____
Signature of Person Who Obtained Consent Date

Date: _____
Subject Initials: _____

APPENDIX C – PRE-PARTICIPATION SURVEY

Walking Pole Pre-Participation Screen

ID#____

Age:_____ **Gender** (circle one): M F

Employment: Retired Employed Volunteer
Please specify: (# hrs/week & type)

Duration of Parkinson's Disease:_____
List your major problems secondary to Parkinson's:

Present Medications:

1. Do you currently have difficulty walking? Yes No
If "yes," please specify:

2. Do use a cane or walker to get around? Yes No
If yes, indicate type:

3. Have you fallen in the past year? Yes No
If yes, how many times? _____

What caused the falls?

4. Do you have any health concerns or recent injuries that may impair your participation in a walking pole program? Yes No
If "yes," please list and explain:

5. Have you ever used walking poles prior to this study? Yes No
If "yes," how often?

6. Do you participate in regular physical activity? Yes No
If "yes," please specify type of exercise and how often you engage in this activity:

7. How would you describe your activity level? (please check one)

_____ Sedentary = little to no regular activity
_____ Lightly Active = at least 20 minutes of exercise 1-3 times per week
_____ Moderately Active = at least 30-60 minutes of exercise 3-4 times per week
_____ Very Active = 60 minutes of exercise 5-7 times per week

APPENDIX D – POST-PARTICIPATION SURVEY

Post-Participation Survey ID#_____

1. Please rate how much you liked using walking poles on a scale from 0-10, 0 indicating not at all, 10 being the highest score. (circle one)

   0 1 2 3 4 5 6 7 8 9 10

2. What did you like the most about walking with poles?

3. What did you like least about walking with poles?

4. Do you feel that walking poles improved your balance? Yes No

5. Do you feel that walking poles improved your posture? Yes No
   Comments:

6. Would you continue to use walking poles outside of this study? Yes No
   If yes, when would you use them?

7. Have you started any new activities since the start of the study? Yes No
   If yes, explain.

8. How would you describe your activity level? (please check one)
   _____ Sedentary = little to no regular activity
   _____ Lightly Active = at least 20 minutes of exercise 1-3 times per week
   _____ Moderately Active = at least 30-60 minutes of exercise 3-4 times per week
   _____ Very Active = 60 minutes of exercise 5-7 times per week

APPENDIX E – PDQ-39

PDQ-39 QUESTIONNAIRE

Please complete the following

Please tick one box for each question

Due to having Parkinson's disease, how often during the last month have you....		**Never**	**Occasionally**	**Sometimes**	**Often**	**Always** or cannot do at all
1	Had difficulty doing the leisure activities which you would like to do?	☐	☐	☐	☐	☐
2	Had difficulty looking after your home, e.g. DIY, housework, cooking?	☐	☐	☐	☐	☐
3	Had difficulty carrying bags of shopping?	☐	☐	☐	☐	☐
4	Had problems walking half a mile?	☐	☐	☐	☐	☐
5	Had problems walking 100 yards?	☐	☐	☐	☐	☐
6	Had problems getting around the house as easily as you would like?	☐	☐	☐	☐	☐
7	Had difficulty getting around in public?	☐	☐	☐	☐	☐
8	Needed someone else to accompany you when you went out?	☐	☐	☐	☐	☐
9	Felt frightened or worried about falling over in public?	☐	☐	☐	☐	☐
10	Been confined to the house more than you would like?	☐	☐	☐	☐	☐
11	Had difficulty washing yourself?	☐	☐	☐	☐	☐
12	Had difficulty dressing yourself?	☐	☐	☐	☐	☐
13	Had problems doing up your shoe laces?	☐	☐	☐	☐	☐

*Please check that you have ticked **one box for each question** before going on to the next page*

Due to having Parkinson's disease, how often <u>during the last month</u> have you....		***Please tick <u>one</u> box for each question***				
		Never	**Occasionally**	**Sometimes**	**Often**	**Always** or cannot do at all
14	Had problems writing clearly?	☐	☐	☐	☐	☐
15	Had difficulty cutting up your food?	☐	☐	☐	☐	☐
16	Had difficulty holding a drink without spilling it?	☐	☐	☐	☐	☐
17	Felt depressed?	☐	☐	☐	☐	☐
18	Felt isolated and lonely?	☐	☐	☐	☐	☐
19	Felt weepy or tearful?	☐	☐	☐	☐	☐
20	Felt angry or bitter?	☐	☐	☐	☐	☐
21	Felt anxious?	☐	☐	☐	☐	☐
22	Felt worried about your future?	☐	☐	☐	☐	☐
23	Felt you had to conceal your Parkinson's from people?	☐	☐	☐	☐	☐
24	Avoided situations which involve eating or drinking in public?	☐	☐	☐	☐	☐
25	Felt embarrassed in public due to having Parkinson's disease?	☐	☐	☐	☐	☐
26	Felt worried by other people's reaction to you?	☐	☐	☐	☐	☐
27	Had problems with your close personal relationships?	☐	☐	☐	☐	☐
28	Lacked support in the ways you need from your spouse or partner?	☐	☐	☐	☐	☐
	If you do not have a spouse or partner tick here		☐			
29	Lacked support in the ways you need from your family or close friends?	☐	☐	☐	☐	☐

*Please check that you have ticked **one box for each question** before going on to the next page*

Due to having Parkinson's disease, how often <u>during the last month</u> have you....		***Please tick <u>one</u> box for each question***				
		Never	**Occasionally**	**Sometimes**	**Often**	**Always**
30	Unexpectedly fallen asleep during the day?	☐	☐	☐	☐	☐
31	Had problems with your concentration, e.g. when reading or watching TV?	☐	☐	☐	☐	☐
32	Felt your memory was bad?	☐	☐	☐	☐	☐
33	Had distressing dreams or hallucinations?	☐	☐	☐	☐	☐
34	Had difficulty with your speech?	☐	☐	☐	☐	☐
35	Felt unable to communicate with people properly?	☐	☐	☐	☐	☐
36	Felt ignored by people?	☐	☐	☐	☐	☐
37	Had painful muscle cramps or spasms?	☐	☐	☐	☐	☐
38	Had aches and pains in your joints or body?	☐	☐	☐	☐	☐
39	Felt unpleasantly hot or cold?	☐	☐	☐	☐	☐

*Please check that you have ticked **one box for each question** before going on to the next page*

Thank you for completing the PDQ 39 questionnaire

APPENDIX F – UPDRS – III

Unified Parkinson's Disease Rating Scale

III. Motor Examination

18. Speech
0 = Normal.
1 = Slight loss of expression, diction and/or volume.
2 = Monotone, slurred but understandable; moderately impaired.
3 = Marked impairment, difficult to understand.
4 = Unintelligible.

19. Facial Expression
0 = Normal.
1 = Minimal hypomimia, could be normal "Poker Face."
2 = Slight but definitely abnormal diminution of facial expression
3 = Moderate hypomimia; lips parted some of the time.
4 = Masked or fixed facies with severe or complete loss of facial expression; lips parted 1/4 inch or more.

20. Tremor at Rest (head, upper and lower extremities)
0 = Absent.
1 = Slight and infrequently present.
2 = Mild in amplitude and persistent. Or moderate in amplitude, but only intermittently present.
3 = Moderate in amplitude and present most of the time.
4 = Marked in amplitude and present most of the time.

21. Action or Postural Tremor of Hands
0 = Absent.
1 = Slight; present with action.
2 = Moderate in amplitude, present with action.
3 = Moderate in amplitude with posture holding as well as action.
4 = Marked in amplitude; interferes with feeding.

22. Rigidity (Judged on passive movement of major joints with patient relaxed in sitting position. Cogwheeling to be ignored.)
0 = Absent.
1 = Slight or detectable only when activated by mirror or other movements.
2 = Mild to moderate.
3 = Marked, but full range of motion easily achieved.
4 = Severe, range of motion achieved with difficulty.

23. Finger Taps (Patient taps thumb with index finger in rapid succession.)
0 = Normal.
1 = Mild slowing and/or reduction in amplitude.
2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.
3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.
4 = Can barely perform the task.

24. Hand Movements (Patient opens and closes hands in rapid succesion.)
0 = Normal.
1 = Mild slowing and/or reduction in amplitude.
2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.
3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.
4 = Can barely perform the task.

25. Rapid Alternating Movements of Hands (Pronation-supination movements of hands, vertically and horizontally, with as large an amplitude as possible, both hands simultaneously.)
0 = Normal.
1 = Mild slowing and/or reduction in amplitude.
2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.
3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.
4 = Can barely perform the task.

Fahn S, Elton R, Members of the UPDRS Development Committee. In: Fahn S, Marsden CD, Calne DB, Goldstein M, eds. Recent Developments in Parkinson's Disease, Vol 2. Florham Park, NJ. Macmillan Health Care Information 1987, 153-163, 293-304.

Unified Parkinson's Disease Rating Scale

26. Leg Agility (Patient taps heel on the ground in rapid succession picking up entire leg. Amplitude should be at least 3 inches.)
0 = Normal.
1 = Mild slowing and/or reduction in amplitude.
2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.
3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.
4 = Can barely perform the task.

27. Arising from Chair (Patient attempts to rise from a straightbacked chair, with arms folded across chest.)
0 = Normal.
1 = Slow; or may need more than one attempt.
2 = Pushes self up from arms of seat.
3 = Tends to fall back and may have to try more than one time, but can get up without help.
4 = Unable to arise without help.

28. Posture
0 = Normal erect.
1 = Not quite erect, slightly stooped posture; could be normal for older person.
2 = Moderately stooped posture, definitely abnormal; can be slightly leaning to one side.
3 = Severely stooped posture with kyphosis; can be moderately leaning to one side.
4 = Marked flexion with extreme abnormality of posture.

29. Gait
0 = Normal.
1 = Walks slowly, may shuffle with short steps, but no festination (hastening steps) or propulsion.
2 = Walks with difficulty, but requires little or no assistance; may have some festination, short steps, or propulsion.
3 = Severe disturbance of gait, requiring assistance.
4 = Cannot walk at all, even with assistance.

30. Postural Stability (Response to sudden, strong posterior displacement produced by pull on shoulders while patient erect with eyes open and feet slightly apart. Patient is prepared.)
0 = Normal.
1 = Retropulsion, but recovers unaided.
2 = Absence of postural response; would fall if not caught by examiner.
3 = Very unstable, tends to lose balance spontaneously.
4 = Unable to stand without assistance.

31. Body Bradykinesia and Hypokinesia (Combining slowness, hesitancy, decreased arm swing, small amplitude, and poverty of movement in general.)
0 = None.
1 = Minimal slowness, giving movement a deliberate character; could be normal for some persons. Possibly reduced amplitude.
2 = Mild degree of slowness and poverty of movement which is definitely abnormal. Alternatively, some reduced amplitude.
3 = Moderate slowness, poverty or small amplitude of movement.
4 = Marked slowness, poverty or small amplitude of movement.

Fahn S, Elton R, Members of the UPDRS Development Committee. In: Fahn S, Marsden CD, Calne DB, Goldstein M, eds. Recent Developments in Parkinson's Disease, Vol 2. Florham Park, NJ. Macmillan Health Care Information 1987, 153-163, 293-304.

APPENDIX G – ACTIVITY LOG

Activity Record **Week of May 27** **Name** _____

Record number of minutes per day of each activity below:

Activity	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Pole Walking: Goal is for 2x/week							
Lifestyle activity: Indicate any moderately strenuous housework, yard work, recreation, sports & so on.							
Structured Aerobic Exercise: Brisk walking, jogging, cycling, treadmill, & so on							
Structured exercise: Strengthening: Resistive tubing hand weights, weight machines, or calisthenics.							
TOTAL Min/DAY of Mod Exercise							
Flexibility and Stretching Activities							
Agility & Balance Activities							

APPENDIX H – WARM-UP & COOL-DOWN

Warm-Up ~ 7 minutes

- Butt kicks
  - 10 reps bilaterally
- Heel-toe rocks
  - 10 reps
- Mini squats with power ups (poles in front)
  - 10 reps
- Marching (poles in front)
  - 30 seconds
- Rotation pivot with poles
  - 10 reps bilaterally
- Diagonal reaching with dynamic knee bend
  - 10 reps bilaterally
- Shoulder rolls
  - Forwards and backwards, 10 reps each direction
- Arm stretch across body
  - 15 seconds bilaterally
- Neck flexion/extension/side-bending/rotation
  - 5 reps each direction

Cool-Down ~ 5 minutes

- Hamstring stretch (seated)
  - 30 seconds bilaterally
- Arm stretch across body
  - 15 seconds bilaterally
- Triceps stretch
  - 15 seconds bilaterally
- Trunk rotation (holding poles)
  - 10 reps bilaterally

APPENDIX I – RATE OF PERCEIVED EXERTION SCALE

RPE SCALE	
1	Nothing
2	Very Easy
3	Easy
4	Comfortable
5	Somewhat Difficult
6	Difficult
7	Hard
8	Very Hard
9	Extremely Hard
10	Maximal/Exhaustion

APPENDIX J – BACKSCRATCH TEST NORMAL VALUES

Men's Normal Values (cm)

Age	Below Average	Average	Above Average
60-64	> 16.51	16.51 to 0	< 0
65-69	> 19.05	19.05 to -2.54	< -2.54
70-74	> 20.32	20.32 to -2.54	< -2.54
75-79	> 22.86	22.86 to -5.08	< -5.08
80-84	> 24.13	24.13 to -5.08	< -5.08
85-89	> 25.40	25.40 to -7.62	< -7.62
90-94	> 26.67	26.67 to -10.16	< -10.16

Women's Normal Values (cm)

Age	Below Average	Average	Above Average
60-64	> 7.62	7.62 to 3.81	< 3.81
65-69	> 8.89	8.89 to 3.81	< 3.81
70-74	> 10.16	10.16 to 2.54	< 2.54
75-79	> 12.7	12.7 to 1.27	< 1.27
80-84	> 13.97	13.97 to 0	< 0
85-89	> 17.78	17.78 to -2.54	< -2.45
90-94	> 20.32	20.32 to -2.54	< -2.54

APPENDIX K – CHAIR SIT AND REACH NORMAL VALUES

Men's Normal Values (cm)

Age	Below Average	Average (in inches)	Above Average
60-64	< -6.3	-6.35 to 10.16	> 10.16
65-69	< -7.62	-7.62 to 7.62	> 7.62
70-74	< -8.89	-8.89 to 6.35	> 6.35
75-79	< -10.16	-10.16 to 5.08	> 5.08
80-84	< -13.97	-13.97 to 3.81	> 3.81
85-89	< -13.97	-13.97 to 1.27	> 1.27
90-94	< -16.51	-16.51 to -1.27	> -1.27

Women's Normal Values (cm)

Age	Below Average	Average	Above Average
60-64	< -1.27	-1.27 to 12.7	> 12.7
65-69	< -1.27	-1.27 to 11.43	> 11.43
70-74	< -2.54	-2.54 to 10.16	> 10.16
75-79	< -3.81	-3.81 to 8.89	> 8.89
80-84	< -5.08	-5.08 to 7.62	> 7.62
85-89	< -6.35	-6.35 to 6.35	> 6.35
90-94	< -11.43	-11.43 to 2.54	> 2.54

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