Acute and Chronic Effects of Exercise in Health

Functional training versus Mat Pilates in motor and non-motor symptoms of individuals with Parkinson's disease: study protocol for a randomized controlled trial

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Abstract - Aim: This study aims to compare a functional training protocol and Mat Pilates for individuals with Parkinson's disease and to evaluate the effects on motor symptoms, as well as non-motor symptoms using a randomized controlled trial. **Methods:** Protocol for a randomized clinical trial in which 45 individuals with Parkinson's disease will be recruited and randomly allocated to one of three groups: (1) functional training; (2) Mat Pilates; (3) control group. Both intervention groups will have 60 min classes twice a week for 12 weeks. The primary outcome will be analyzed through motor symptoms, including balance, mobility, muscle strength, handgrip strength, flexibility, range of motion, and cardiorespiratory fitness. Secondary outcomes will include non-motor symptoms such as cognition, aging perspective, mood, anxiety, and depression. **Conclusion:** This will be the first randomized trial to compare the effects of functional training and Mat Pilates in a population with Parkinson's disease. It is hypothesized that improvements in motor and non-motor symptoms will be greater and more lasting after functional training and Mat Pilates interventions than those that maintain their routine activities, given the benefits of exercise and the unprecedented protocols in this disease.

Keywords: Parkinson's disease, physical exercise, training, Pilates.

Introduction

Parkinson's disease (PD) has been shown to promote motor symptoms of progressive physical limitation, such as stiffness, bradykinesia, tremor, postural instability, balance, gait difficulties, and disability in functional performance[1], as well as promoting non-motor symptoms such as mood swings, cognitive deficits, fatigue, depressive symptoms, and anxiety[2-4]. It is a disease characterized by the loss of dopaminergic neurons in the substantia nigra and accumulation of ill-folded alpha-synuclein, found in intracytoplasmic inclusions called Lewy Bodies[5]; PD incidence rates are estimated to range from 8 to 18 per 100,000 person-years[6].

In this way, it is noted that the practice of physical exercise has gained notoriety in the improvement of symptoms of the disease since the preventive and therapeutic effects of exercise are associated with its duration and intensity. Exercises of moderate to vigorous intensity, along with long duration and high frequency bring better benefits to this population [7]. In addition, exercise can also improve medication efficiency and medication side effects[8]. It is noted in experimental studies that used resistance training as an intervention that it is effective in reducing anxiety, and bradykinesia, improving quality of life, and increasing functional performance in this population[9,10], it also promotes changes in body composition and significant strength and functional gains[11]. Moreover, it is observed that light to moderate-intensity aerobic exercise also has positive benefits in PD, being able to attenuate symptoms, improve cardiovascular fitness, balance, functional capacity, and psychological aspects of individuals with PD[12,13].

Thus, it is noted that the resistance exercise, as well as the aerobic, is well accepted in individuals with PD alone, being able to associate both the functional training and the Mat Pilates, which has been gaining prominence among adults and the elderly. According to the American College of Sports Medicine - ACSM, functional training can be classified as neuromotor training that encompasses motor skills such as balance, coordination, agility, proprioception, and flexibility[14]. Functional training provides improvement of the psychobiological system through the application of integrated and multiarticular exercises directed to the improvement of the movement ability, improvement of strength and muscular endurance of the central region of the body (core), and increase the neuro-

muscular efficiency of the different tasks of daily life[15], bringing as a benefit the functional capacity to perform daily activities with autonomy and safety[16]. Like the study by Horne et al.[17], who observed in functional training a significant improvement in physical (gait, balance, and mobility) and psychosocial (depression, anxiety, and fatigue) aspects, in line with the study by Leal et al.[10] which promoted improvement in aerobic endurance, gait speed, balance, and handgrip compared to the control group.

The Pilates method, on the other hand, has as its main focus the quality, precision, and control of movement, in the activation of specific muscles in a functional sequence stimulating proprioception and strength[18]. This method generally favors an improvement in posture, strength gain, flexibility, motor control, and body awareness in its practitioners, as well as a connection between body and mind[18]. This method avoids the aggravation of a series of life-threatening symptoms of individuals with PD and can be a great ally to the well-being of the body and mind to maintain functional independence, as well as their reintegration into society[19].

Even with widespread dissemination of functional training and the Mat Pilates, few studies with results of its application in individuals with PD are found. These two modalities were listed so that from this protocol we can investigate not only the benefits of these in their individuality but also between them, by checking which can cause major improvements in motor and non-motor symptoms of the disease. Since few studies have analyzed these types of exercises in Parkinson's disease. Thus, the main objective of this study is to compare a functional training protocol and Mat Pilates for individuals with PD and to evaluate the effects on motor symptoms (balance, cardiorespiratory fitness, lower and upper limb strength, flexibility, and agility), as well as in non-motor symptoms (cognition, depressive symptoms, mood state, anxiety, and finitude) through a randomized controlled trial. As a hypothesis, the protocol will promote improvement in motor and non-motor symptoms and may be a new treatment option for these individuals.

Methods

Study design

A 12-week randomized clinical trial will be conducted to determine the effect of two exercise interventions on motor and non-motor symptoms in individuals with PD. The objectives will be to investigate the effect of a structured program of adapted functional training and a structured Mat Pilates program on the motor (balance, cardiorespiratory fitness, lower and upper limb strength, flexibility, and agility) and non-motor (cognition, depression, mood anxiety and finitude) in individuals with PD. The study will consist of three groups; Control Group (CG); Functional Training Group (FTR) and Pilates Group (PG). Ethical approval was granted through the Ethics Committee on Research in Human Beings (CEPSH) of UDESC -protocol 3.613.483 and registered with the Brazilian Registry of Clinical Trials (ReBEC) (RBR-6ckggn). All procedures followed the Helsinki declaration.

Figure 1 shows the Consolidated Standards of Reporting Trials (CONSORT) flowchart, enrollment schedules, interventions, and study evaluations. Additional file 1 shows the checklist using the SPIRIT used in the study (appendix).

Participants

Individuals of both sexes diagnosed with idiopathic PD, recruited in the city of Florianópolis and São José (Santa Catarina, Brazil), through the Santa Catarina Parkinson's Association (APASC) and newspaper, university website, and e-mail disclosures are invited to be part of the study. The individuals who will participate in the research will be included in the Rhythm and Movement Program and BPaRkI - Brazilian Parkinson's Rehabilitation Initiative, and the classes will take place at the Health and Sports Science Center of Santa Catarina State University (UDESC).

Inclusion and exclusion criteria

Inclusion criteria include (1) clinical diagnosis of PD following UK brain bank criteria[20]; (2) both sexes; (3) age greater than or equal to 50 years; (4) with stable doses and no change in antiparkinsonian medication within two weeks; (5) stage I to IV classified by Hoehn and Yahr; (6) data collection in the “on” phase; (7) without practicing any exercise program for at least two months. The study exclusion criteria include: (1) do not reach MMSE cutoff[21]; (2) classified in stage 5 PD (wheelchair users)[22]; (3) do not complete all stages of the study; (4) perform combined practice of any physical exercises; (5) who are not stable on medication doses; (6) not present in up to 75% of classes.

Intervention

Adapted functional training

Functional training classes will be held at the Health and Sports Science Center (CEFID) of the Santa Catarina State University (UDESC) in Florianópolis - SC, in a large gym with adequate facilities. Individuals assigned to this group will participate in a functional training program adapted for PD for 12 weeks. Each class will last 60 min and will be held twice a week in the afternoon. Individuals will need to complete at least 75% of the prescribed classes. This exercise modality was chosen because it is appropriate for individuals with PD who may have limited physical capacity. This exercise program will promote improvement in lower and upper body movements, as well

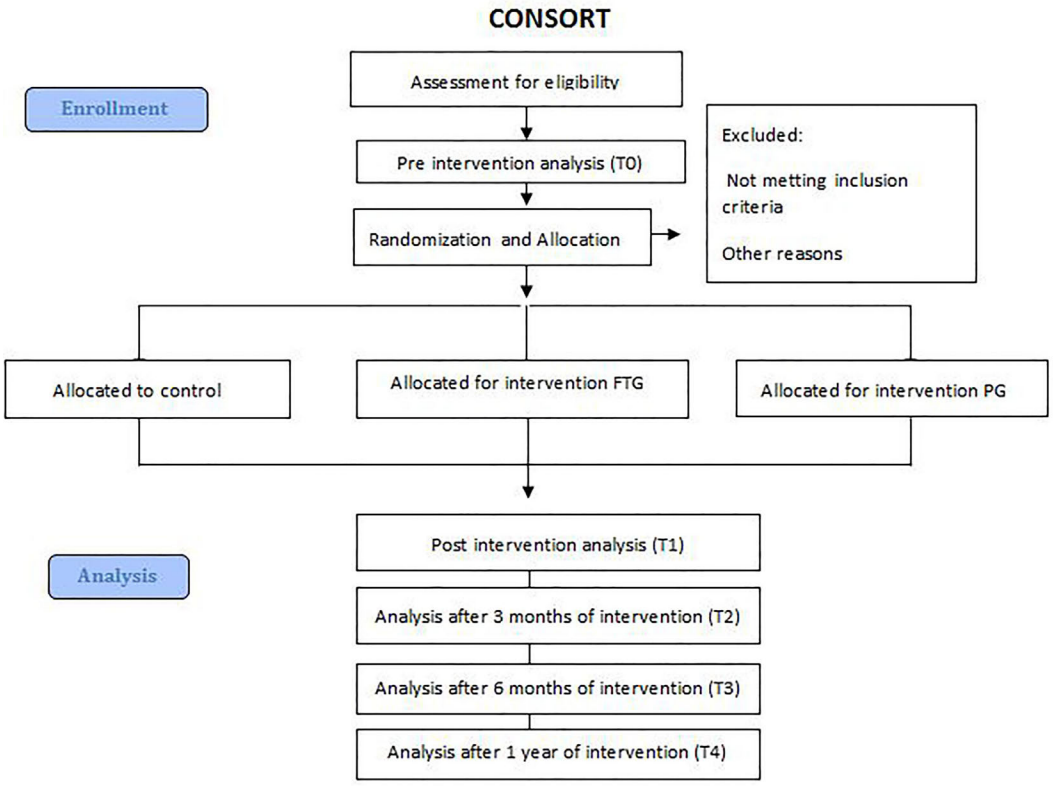

Figure 1 - Flowchart of the participant selection process and protocol steps, Consolidated Standards of Reporting Trials (CONSORT).

as stimulate balance, cardiorespiratory fitness, lower and upper limb strength, flexibility and agility, as well as motor coordination. In addition, functional training may promote psychological benefits, such as improved cognition, depressive symptoms, mood, anxiety, and finitude, among other possibilities[10,17].

Lessons will be divided into warming up (15 min) focused on joint warm-up with walking, moving, and running, and encompassing broad-to-specific joint movements, including flexion, extension, abduction, adduction, and rotation, initiated by the upper body until reaching the lower limbs. The main part (40 min) will stimulate the evolution of specific functional training exercises, including upper limb, trunk, and lower limb muscle strength, such as squats, advances, sitting and rising, abductions, adductions, extensions, and flexions in addition to focusing on the activation of the abdomen muscles, as well as trunk flexions, extensions and rotations. Also, exercises that enhance flexibility, endurance, power, balance, coordination, agility, and strength are the standard exercises of functional training.

Finally, stretching, slow walking, massage and myofascial releases (rest period) will be performed for 5 min to provide muscle relaxation. Both exercises will go from mild to vigorous intensities and with each week of intervention, the degree of difficulty of the exercises given will be greater, so that individuals have a progression over 12 weeks. In addition, music will be used according to the preference of participants during the classes as a motivational and playful factor. Detailed instructions for movements can be found in Table 1.

Mat Pilates

Mat Pilates classes will be held at the same venue, the Center for Health and Sports Sciences (CEFID) of the Santa Catarina State University (UDESC) in Florianópolis - SC, in a large room suitable for the practice of the sport. Individuals assigned to this group will participate in a Mat Pilates program aimed at individuals with PD for 12 uninterrupted weeks. Each class will last 60 min and will be held twice a week in the afternoon. Individuals in this group will need to complete at least 75% of the prescribed classes. This modality was chosen by a system of exercises that integrate the body, and mind and provide strength, flexibility, balance, body awareness, and postural control and seek physical and mental training that can improve the symptoms of the disease, although Pilates will promote improvement in depressive symptoms, anxiety, mood, cognition, among others.

The classes will be divided into warm-up (15 min) which will be explored the joint warm-up exercises, muscle activation, and Mat Pilates movements, such as breathing, imprint & release, hip release, spinal rotation,

Table 1 - Functional training intervention protocol adapted for individuals with Parkinson's disease.

	Training	Warming up	Main part	Winding down	Goal
1st week	1.	1- Joint warming 2- Quick walk 3- Offsets 4- Race in place 5- Agility Ladder	1- Free squats 2- Hip Lift 3- Up and down (step) 4- Ball around the body 5- Calf 6- Unilateral Leg Circles 7- Ball Salutation	General stretching	Flexibility Resistance Power
	2.	1- Joint warming 2- Good morning 3- Quick walk 4- Walking and running following commands	1- Triceps forehead 2- Walk the line (rope) 3- Take the weight off the floor 4- Bounce ball with cones 5- Unilateral Sinking 6- Jumping	Massage	Balance Coordination Agility
2nd week	3.	1- Light obstacle course 2- Lateral Agility Ladder 3- Palm forward / backward shifting 4- Past in the sink	1- Wall squats 2- Throwing wall ball 3- Hip extension / flexion 4- Direct thread 5- Abdominal bike 6- Unilateral leg lift 7- Stretching legs (elastic band)	General stretching	Flexibility Power Resistance
	4.	1- Walking circles arms 2- Half-Tip Walk 3- Ball walk between cones 4- Race in place	1- Pass the ball through the trunk 2- Hit the arc in the cone 3- Dumbbell Development 4- Take the ball in one foot and another 5- Squat weights 6- Balance on the rope 7- Jumping	Ball release	Coordination Flexibility Force
3rd week	5.	1- Joint warming 2- Good morning 3- Dance of the bows 4- Double race passing the ball	1- Climb to the step 2- Side with arm lift 3- Ball around the double task cone 4- Infrared Abdominal 5- Lying ball on feet up (side and other) 6- Ball Release	General stretching	Power Agility Resistance
	6.	1- Double task walk 2- Throwing wall ball 3- Throwing wall ball with offset	1- Squat by throwing the ball 2- Calf 3- Lateral abdominal weight 4- Alternating Thread 5- Switch legs weight with weight 6- I sink back 7- Unilateral Airplane	Massage	Balance Resistance Coordination
4th week	7.	1- Walking and running following commands 2- Side run to the cone 3- Jump in the bows	1- Pull arms with elastic 2- Hit the ball in the bows 3- Extension and flexion of knees with the weight 4- Stretching legs (elastic band) 5- Ball Salute 6- Sitting tighten balls with thighs	General stretching	Flexibility Coordination Force
	8.	1- Half-Tip Walk, Knees Up, Feet Behind 2- Hopscotch with bows 3- Agility Ladder	1- Laying touch the cones (small) 2- Unilateral Leg Circles 3- Take the weight off the floor 4- Elastic leg sidewalk 5- Free weight squats 6- Ball around the cone	Ball release	Coordination Agility Power
5th week	9.	1- Double task walk 2- Throwing wall ball 3- Throwing wall ball with offset	1- Rotation trunk with elastic in the feet 2- Abdominal Cradle 3- Weight lifting 4- Up and down lateral step	General stretching	Resistance Balance Power

(*continued*)

Table 1 - continued

	Training	Warming up	Main part	Winding down	Goal
			5- Deep displacement 6- Lying ball on feet up (side and other)		
	10.	1- Quick walk with rotation arms 2- Pass the ball in two groups (volleyball)	1- Squat with row 2- Lifting arms with weight 3- Static balance with one foot 4- Hip extension / flexion 5- Calf 6- Triceps forehead	Massage	Force Power Balance
6th week	11.	1- Living dead with arms 2- Dance of the bows 3- Double race passing the ball	1- Goal kick 2- Rotate arcs by the arm 3- Throwing wall ball with offset 4- Unilateral leg lift 5- Lateral abdominal weight 6- Direct thread 7- Jumping	General stretching	Coordination Resistance Agility
	12.	1- Walk up to the ball 2- Walk bouncing ball 3- Double task race	1- Pull arms with elastic 2- Hit the ball in the bows 3- Extension and flexion of knees with the weight 4- Collect mini cones 5- One-sided airplane 6- Sitting tighten balls with thighs 7- Ball Salutation	Ball release	Agility Force Balance
7th week	13.	1- Joint warming 2- Good morning 3- Half-Tip Walk, Knees Up, Feet Behind 4- Past in the sink	1- Weight wall squats 2- Up and down with knee lift (step) 3- Pull and push the wall 4- Hit the ball in the bows 5- Walking cuts toes 6- Stretching legs (elastic band)	General stretching	Flexibility Power Coordination
	14.	1- Hopscotch with bows 2- Jump in the bows 3- Hit the ball in the bows	1- Triceps with elastic in the grid 2- Legs with elastic in the grid 3- Infra Abdominal 4- Squat by throwing the ball 5- Static One-Step Balance 6- Ball around the cone	Massage	Balance Resistance Agility
8th week	15.	1- Walking with articulation 2- Pass the ball in two groups (volleyball)	1- Abdominal bike 2- Unilateral leg lift 3- Take the weight off the floor 4- Hip lift 5- Direct Thread 6- Lying ball on feet up (side and other) 7- Jumping	General stretching	Force Power Resistance
	16.	1- Double task walk 2- Double task race 3- Guided Displacement	1- Extension and flexion of knees with the weight 2- Unilateral airplane 3- Sitting tighten balls with thighs 4- Collect mini cones 5- Throw Ball Wall 6- Side lift with arms 7- Ball Salutation	Ball release	Balance Agility Force
9th week	17.	1- Walk ball throwing up 2- Walk bouncing ball 3- Agility Ladder	1- Throw small balls 2- Weighted row squats 3- Lifting side arms with weight 4- Elastic leg sidewalk 5- Leg circles with a ball 6- Switch weight of legs with weight	General stretching	Coordination Power Resistance

(*continued*)

Table 1 - continued

	Training	Warming up	Main part	Winding down	Goal
	18.	1- Jump in the bows 2- Hopscotch with bows 3- Throwing Ball Bows	1- Rotate arcs by the arm 2- Collect mini cones 3- Weighted rope balance 4- Spread arms with elastic 5- Abdominal Infrared 6- Stretching legs (elastic band)	Massage	Balance Flexibility Resistance
10th week	19.	1- Joint warming 2- Good morning 3- Pass the ball above and below 4- Pass side ball	1- Weight lifting 2- Wall weight squats 3- Unilateral leg lift 4- Rotation trunk with elastic in the feet 5- Triceps forehead 6- Go up and downside step 7- Jumping	General stretching	Force Resistance Power
	20.	1- Offsets 2- Walking following commands 3- Dance of the bows	1- Double Ball Release 2- Ball around the double cone 3- Hit the arc in the cone 4- Balancing cone balls 5- Offset sinking with ball up 6- Goal kick	Ball release	Agility Coordination Balance
11th week	21.	1- Half-Tip Walk, Knees Up, Feet Behind 2- Past in the sink 3- Side run to the cone	1- Extension and flexion of knees with the weight 2- Unilateral airplane 3- Throwing wall ball with offset 4- Abdominal bike 5- Dumbbell Development 6- Take the ball in one foot and another	General stretching	Balance Force Resistance
	22.	1- Quick walk with rotation arms 2- Walking following commands 3- Dead alive with arms	1- Arm-raising sinking 2- Triceps forehead with elastic 3- Weight lifting 4- Unilateral leg lift 5- Elastic leg walking 6- Take the weight off the floor	Massage	Force Resistance Power
12th week	23.	1- Walk ball throwing up 2- Walk bouncing ball 3- Ball walk between cones	1- Lateral abdominal weight 2- Squat by throwing the ball 3- Stretching legs (elastic band) 4- Switch legs weight with weight 5- Alternating Thread 6- Rotation trunk with elastic in the feet 7- Jumping	General stretching	Flexibility Force Coordination
	24.	1- Pass the ball in two groups (volleyball) 2- Kick a soccer ball	1- Abdominal Cradle 2- Static balance with one foot 3- Hit the ball in the bows 4- Balancing cone balls 5- Hopscotch double task 6- Ball Release	Ball release	Balance Agility Coordination

cat stretch, hip rolls, scapula isolation, arm circles, head nods e elevation & depression of scapula. The main part (40 min) with the evolution of specific movements of the Mat Pilates as breaststroke preparation (hand by hips), shell stretch, preparation abdomen, half rollback, roll up, single leg stretch, obliques, one leg circle, preparation shoulder bridge, hell squeeze prone, sidekick, spine twist, among others included in the protocol. Relaxation will consist of self-stretching exercises using the ball and talking about each participant's perception of the classes for 5 min. Both exercises will go from moderate to vigorous intensities and with each week of intervention, the degree of difficulty of the exercises given will be greater, so that individuals have a progression over the 12 weeks. Music will be used during the classes according to the preference of the participants, to stimulate and encourage them in the proposed exercises. Detailed photos of the exercises can be found in Bryan's (2011)[23] book. The details of the exercises that constitute the protocol are detailed in Table 2.

Table 2 - Pilates soil intervention protocol for individuals with Parkinson's disease.

	Training	Warming up	Main part	Winding down
1st week	1.	Muscle activation	Explanatory session: What is Pilates, the basic principles of Joseph Pilates: breathing, centering, control, precision, fluency, and concentration. Clarify the positions: positioning of the pelvis, positioning of the rib cage, stabilization and movement of the shoulder girdle, and positioning of the head and cervical spine.	Group massage (One behind the other)
	2	Muscle activation	1- Diaphragmatic breathing 2- Single-leg stretches, obliques (with feet flat on the floor) 3- Shoulders Circles 4- Obliques roll 5- One-leg Circles 6- Scissors 7 - Sidekick	Individual massage
2nd week	3	Muscle activation and Mat Pilates movements (breathing, imprint & release, hip release)	1- Single-leg stretches 2- Spine Stretch sitting 3- Obliques 4- Strengthening Pelvic Floor 5- Obliques roll 6- Saw 7- One leg circles	Group massage (Divided into two groups, all massage one at a time)
	4	Muscle activation and Mat Pilates movements (breathing, imprint & release, hip release)	1- The Hundred 2- Scissor leg stretch 3- Half-roll back 4- Sidekick 5- Roll up (pressing the magic circle with your hands) 6- Preparation of shoulder bridge 7- One-leg circle (with TheraBand around the thigh with both knees flexed) 8- Spine twist	Guided meditation
3rd week	5	Muscle activation and Mat Pilates movements (spinal rotation, cat stretch, hip rolls, scapula isolation)	1- Half-roll back 2- Roll up (pressing the magic circle with your hands) 3- One-leg circle (with TheraBand around the thigh with both knees flexed) 4- Preparation of shoulder bridge tightening the over ball between the knees and performing simultaneously exercises of biceps with the weight of 1 kg 5- Hell squeeze prone (pressing magic circle on ankles) 6- The sidekick kneeling 7- Spine twist	Myofascial Release
	6	Muscle activation and Mat Pilates movements (spinal rotation, cat stretch, hip rolls, scapula isolation)	1- The hundred 2- Obliques roll (with a magic circle on the knees) 3- Jackknife 4- Lateral flexion 5- Staggered legs (with the lower limbs within the magic circle) 6- Top-leg abduction 7- Top-leg circles 8- Preparation of shoulder bridge (with feet on top of the ball)	Massage in pairs
4th week	7	Muscle activation and Mat Pilates movements (arm circles, head nods e elevation & depression of scapula)	1- Half-roll back 2- Obliques (tightening the over the ball, and extending the lower member to the side of the rotation of the trunk) 3- Shoulder bridge (with magic circles) 4- Bend and Stretch (with Swiss ball) 5- Scissors (with over ball in the sacral region) 6- Top-leg circles	Group massage (One behind the other)

(*continued*)

Table 2 - continued

	Training	Warming up	Main part	Winding down
			7- Both legs together 8- Side kicking	
	8	Muscle activation and Mat Pilates movements (arm circles, head nods e elevation & depression of scapula)	1- Roll up 2- Single-leg stretches 3- Double-leg stretches 4- Preparation of shoulder bridge (with feet on top of the ball) 5- Top-leg abduction 6- Top-leg circles 7- Saw 8- Sidekick kneeling	Individual massage
5th week	9	Muscle activation and Mat Pilates movements (breathing, imprint & release, hip release, spinal rotation, cat stretch, hip rolls)	1- Roll up (with TheraBand on feet) 2- Obliques 3- Spine Twist 4- Preparation of shoulder bridge (with feet on top of the ball) 5- Preparation of shoulder bridge (with feet on top of the ball and performing extension and flexion of the knees) 6- Swimming 7- Sidekick (with ankle weights) 8- Saw	Group massage (Divided into two groups, all massage one at a time)
	10	Muscle activation and Mat Pilates movements (breathing, imprint & release, hip release, spinal rotation, cat stretch, hip rolls)	1- The Hundred 2- Single-leg stretches 3- Roll up (with TheraBand on feet), 4- Rolling like a ball 5- Saw 6- Preparation of shoulder bridge (with feet on top of the ball and performing extension and flexion of the knees) 7- Double-leg kick 8- Jackknife	Guided meditation
6th week	11	Muscle activation and Mat Pilates movements (spinal rotation, cat stretch, hip rolls; arm circles, head nods e elevation & depression of scapula)	1- Hundred (tightening magic circle between knees) 2- Obliques 3- Rollover 4- Hell squeeze prone (with a magic circle on ankles) 5- Spine stretch forward by pressing the magic circle with your hands 6- Preparation of shoulder bridge performing simultaneously exercises of biceps with the weight of 1 kg 7- Shoulder bridge 8- Double leg kicking	Myofascial Release
	12	Muscle activation and Mat Pilates movements (spinal rotation, cat stretch, hip rolls; arm circles, head nods e elevation & depression of scapula)	1- Single-leg stretches 2- Rollover 3- Side bend with knees supported 4- Hundred (with hip and knees flexed 90 degrees) 5- Scissors 6- Obliques roll (with the weight of 1 kg) 7- Single leg extension 8- Jackknife	Massage in pairs
7th week	13	Muscle activation and Double Walk with Obstacles	1- Hundred (with hip and knees flexed 90 degrees) 2- Obliques roll (with the weight of 1 kg) 3- Top-leg circles 4- Lateral flexion 5- Single-leg extension (with 1-kg ankle weights) 6- Hip twist 7- Side kicking 8- Corkscrew	Group massage (One behind the other)

(*continued*)

Table 2 - continued

	Training	Warming up	Main part	Winding down
	14	Muscle activation and Double Walk with Obstacles	1- Single leg stretch 2- Double leg stretch 3- Roll up tightening magic circle 4- Rollover 5- One-leg kick with 1-kg ankle weights 6- Sidekick with 1-kg ankle weights 7- Lateral flexion 8- Hip twist	Individual massage
8th week	15	Muscle activation and Dislocations with general joint movements	1- The Hundred (with hip and knees flexed 90 degrees) 2- Obliques 3- Preparation of shoulder bridge performing simultaneously exercises of biceps with the weight of 1 kg 4- Breaststroke with the weight of 1 kg 5- Roll up tightening magic circle 6- Criss-crossing 7- Seal 8- Open-leg rocker	Group massage (Divided into two groups, all massage one at a time)
	16	Muscle activation and Dislocations with general joint movements	1- Double-leg stretch 2- Open-leg rocker 3- Scissors in the air 4- Roll up with the weight of 1 kg 5- One-leg kick with 1-kg ankle weights 6- Corkscrew 7- Shoulder bridge 8- Teaser (with feet flat on the floor)	Guided meditation
9th week	17	Muscle activation and Mat Pilates movements (spinal rotation, cat stretch, hip rolls; arm circles, head nods e elevation & depression of scapula)	1- Spine Strech 2- Corkscrew 3- Seal 4- Open leg rocker 5- Bicycle in the air 6- Sidekick kneeling 7- Preparation of shoulder bridge performing simultaneously exercises of biceps with the weight of 1 kg 8- Staggered legs with 1-kg ankle weights	Myofascial Release
	18	Muscle activation and Mat Pilates movements (breathing, imprint & release, hip release, spinal rotation, cat stretch, hip rolls)	1- The hundred (with a Swiss ball in the feet) 2- Shoulder bridge 3- Swimming 4- Criss-crossing 5- Scissors with over ball in the sacral region 6- Sidekick with 1-kg ankle weights 7- The crab (with the Swiss ball behind the legs) 8- One-leg circle with 1-kg ankle weights	Massage in pairs
10th week	19	Muscle activation and Mat Pilates movements (spinal rotation, cat stretch, hip rolls; arm circles, head nods e elevation & depression of scapula)	1- Teaser 2- The hundred (with magic circles) 3- Obliques roll (with the weight of 1 kg) 4- Lateral flexion 5- Preparation of shoulder bridge performing simultaneously exercises of biceps with the weight of 1 kg 6- Spine stretch forward (with hands-on top of the magic circle) 7- Single-leg extension with 1-kg ankle weights 8- Swimming	Group massage (One behind the other)
	20	Muscle activation and Mat Pilates movements (breathing, imprint & release, hip release, spinal rotation, cat stretch, hip rolls)	1- Hell squeeze prone (with a magic circle on our ankles) 2- Criss-crossing 3- Open leg rocker 4- Bicycle in the air 5- One-leg circle with 1-kg ankle weights	Individual massage

(*continued*)

Table 2 - continued

	Training	Warming up	Main part	Winding down
			6- Staggered legs with 1-kg ankle weights 7- Side kicking 8- Shoulder bridge	
11th week	21	Muscle activation and Dislocations with general joint movements	1- Hundred 2- Breaststroke 3- Preparation of shoulder bridge (with the feet on the ball performing extension and flexion of the knees) 4- Scissors with over ball 5- Double-leg kick with 1-kg ankle weights 6- Top-leg abduction with 1-kg ankle weights 7- Top-leg circles with 1-kg ankle weights. 8 - Open leg rocker	Group massage (Divided into two groups, all massage one at a time)
	22	Muscle activation and ball joint movements	1- Obliques roll (with the weight of 1 kg) 2- Spine Stretch 3- Obliques roll with the weight of 1 kg 4- The double leg stretches (with the Swiss ball) 5- Side bend 6- top-leg abduction with 1-kg ankle weights 7- One-leg circle with 1-kg ankle weights 8- Preparation of shoulder bridge with the feet on the ball performing simultaneously exercises of biceps with the weight of 1 kg.	Guided meditation
12th week	23	Muscle activation and Dislocations with general joint movements	1- Mermaid 2- Scissors in the air 3- Teaser 4- Hundred 5- Single-leg stretch 6- Bicycle in the air 7- Swan dive 8- Staggered legs with 1-kg ankle weights	Myofascial Release
	24	Muscle activation and ball joint movements	1- The Hundred 2- Breaststroke 3- Rolling like a ball 4- Saw 5- Plank (with elbows on the Swiss ball) 6- Side kicking 7- Swan (with swiss ball) 8- Teaser	Massage in pairs

Control group

Participants assigned to the control group will be instructed to maintain their normal lifestyle and daily activities and not to engage in any other form of training during the 12 weeks. During this period, contact will be made by telephone every four weeks on the first day of the month, at a time previously set by the researchers, as well as motivational guidance by telephone and lectures highlighting the importance of physical exercise and training care for your general health. In addition, they will be invited to attend classes after the intervention period.

Adverse events

If any adverse events occur, they will be reported immediately to the principal investigator and, if appropriate, to the UDESC Human Research Ethics Committee (CEPSH). The principal investigator will be notified immediately of pressure drops, dizziness, chest pain, blurred vision, irregular pulse, fainting, shortness of breath, falls, or other adverse events.

Outcome measures

All measurements will be performed in five moments, namely the baseline period (T0) (pre-intervention), after the 12 weeks of intervention (T1) (post-intervention), and three follow-ups, three months after completion of the intervention (T2), six months after the intervention (T3) and one year after the intervention (T4). Measurements will be performed by three trained evaluators and all evaluators will be blinded to group allocation. Data collection, including the application of the questionnaire and physical tests, will take around 90 min at a time previously

set by the researchers. All evaluators will be trained to collect data by a specialized team, in order to avoid bias in the research and all measurements will be standardized. These will also receive calls from the main researcher during the study to maintain a follow-up and encourage continuity in the research. However, participants who drop out of the study will be called after the interventions to perform data collection and will be analyzed by intention to treat. Participant files will be stored in numerical order and a secure location. They will still be kept in storage for 3 years after completion of the study. A summary of all outcome measures that will be collected at each moment is shown in Figure 2 following SPIRIT.

Demographic and clinical information

Regarding age, gender, marital status, educational level, occupation, presence of clinically diagnosed diseases, use of medications for PD, depression and anxiety, initial symptoms, date of diagnosis of PD, duration of illness, dominant bodyside, bodyside most affected by the disease and anthropometric measurements (BMI). Body mass index (BMI) classification was based on the WHO protocol[24], that is, thinness (BMI < 18.5); eutrophy (BMI 18.5-24.9); overweight (BMI 25.0-29.9); pre-obesity and obesity (BMI > 30.0). Participants will be asked to report if there are any changes in medications during the study period.

		STUDY PERIOD					
	Enrolment	Allocation	Post-allocation				
TIMEPOINT	*-T1*	0	*T0*	*Intervention*	*T1*	*T2*	*T3*	*T4*
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
Randomization		X						
INTERVENTIONS:								
Functional Training			←	—	→			
Pilates			←	—	→			
Control Group			←	—	→			
ASSESSMENTS:								
Balance *Cognition* *Evaluation of PD* *General condition of the patient with PD* *Depression* *Anxiety* *Humor* *Aging Perspective* *Cardiorespiratory* *Range of motion* *Flexibility* *Handgrip* *Muscle Strenght* *Mobility*			X		X	X	X	X
Analysis of Study Outcomes								X

Figure 2 - Study evaluation schedule (SPIRIT).

Primary outcome assessment

Balance: The Mini-BESTest test, translated and validated in Brazil, is a 14-item test that focuses on dynamic balance, specifically early transitions, postural responses, sensory orientation, and dynamic gait. Its application takes 10 to 15 min and allows you to track balance changes quickly and reliably. Each item is scored from (0 to 2); A score of 0 indicates that a person is unable to perform the task while a score of 2 is normal. The best score is the maximum number of points, being 28[25].

Cardiorespiratory fitness: Ergospirometry will be used to conduct the submaximal stress test where you will assess cardiorespiratory fitness, indicated for populations with Parkinson's disease[26]. Exhaled gases and flow volume will be collected during the test and analyzed by the calibrated metabolic system (Quark CPET Ergo, Cosmed, Rome, Italy) to provide oxygen absorption measurements. The test will be terminated at the predetermined value.

Range of motion: To assess shoulder range of motion, the digital goniometer (Absolute Axis 360°) will be used for shoulder flexion and abduction movements[27]. The abduction movement will be performed with the individual sitting and the flexion movements with the same in the supine position.

Flexibility: For the lower limb flexibility test the Sit and Reach test will be used. The test begins with the individual sitting in a chair, one leg should be knee bent approximately 90° and the foot flat on the floor; the other leg should be extended. The measurement will be the distance between the middle toes and the tiptoe, being considered negative anterior to the tiptoe and positive the distance that the toes pass from the tiptoe[28].

Hand Grip Force: Will be measured with a hydraulic dynamometer, adjusted in the second position, due to hand size, measuring the force produced by an isometric contraction recorded in kilograms or pounds. The subject will be asked to sit in a chair without upper limb support, but with the back supported, shoulder addicted, elbow flexed at 90°, forearm in the neutral position, and wrist ranging from 0° to 30° in length and between zero and 15° ulnar deviation[29].

Muscle strength: Biodex System 4 PRO isokinetic dynamometer (BiodexTM Medical Systems Inc., Shirley, NY), used with individuals with Parkinson's disease[30], will be used to measure lower limb muscle strength. The isokinetic strength protocol will involve the knee extensors and flexors with the dominant limb, the range of motion will vary from 0° to 90°.

Mobility: Timed Up & Go (TUG) is a screening tool commonly used for fall hazards in the elderly. Translated and validated in Brazil, its main objective is to evaluate mobility. TUG measures the time it takes for an individual to perform some functional maneuvers, such as getting up, walking, walking, and sitting down[31].

Secondary outcome assessment

Cognition: Mini-Mental State Examination (MMSE), used as an exclusion criterion for those individuals who did not reach the cutoff points according to the criteria of Bertolucci et al.[21] - 13 points for illiterate people; 18 for average schooling; 26 for high schooling. Used for cognitive screening, MMSE provides information on different cognitive parameters containing questions grouped into categories designed to assess specific cognitive functions.

Disease severity: The Hoehn and Yahr Disability Scale (HY), developed in 1967 and validated, indicates the general condition of the PD patient. It comprises five stages of classification to assess the severity of PD and encompasses global measures of signs and symptoms that allow the individual to be classified according to the level of disability. Patients classified in stages I, II, and III have mild to moderate disability, while those in stages IV and V have more severe disability[22].

Unified Parkinson's Disease Assessment Scale (UPDRS): This scale assesses patients' signs, symptoms, and certain activities through self-report and observation. Consisting of 42 items, divided into four parts: mental activity, behavior, and mood; activities of daily living; motor exploration and complications of drug therapy. The maximum value indicates greater involvement by the disease and the minimum normality. The UPDRS is a reliable (r-0.96) and valid scale.

Depression: Beck Depression Inventory (BDI), is a self-report questionnaire originally developed by Beck et al.[32]. It contains 21 objective multiple-choice questions related to depressive symptoms such as hopelessness, irritation, cognition, guilt, and feelings of punishment, as well as physical symptoms such as fatigue, weight loss, and sexual interest. The sum of individual item scores gives a total score, where the highest score is 63, which indicates a high degree of depressive symptoms, and the lowest score is zero, which corresponds to the absence of depressive symptoms[32].

Anxiety: Beck Anxiety Inventory (BAI), this inventory was translated and validated in Brazil. It consists of 21 self-reported questions that highlight somatic, affective, and cognitive signs of anxiety symptoms. The total score is 63 points and indicates a high degree of anxiety[33].

Mood: Brunel's Mood Scale (BRUMS) assesses six mood states (tension, depression, anger, vigor, fatigue, and mental confusion). The questionnaire consists of 24 five-level scales, which must be answered by the participant considering how he feels at the moment of the evaluation. By summing up the answers for each aspect, a score ranging from 0 to 16 for each mood state is obtained. BRUMS has been validated for Brazil, with internal consistency values (Cronbach's alpha) greater than 0.70 for all aspects[34].

Aging Perspective: Sheppard Inventory adapted to Portuguese and validated by Neri[35]. The instrument consists of 20 questions divided into 4 subgroups, which allow evaluating the respondent's opinion regarding: a) the possibility of being happy in old age; b) if old age foreshadows dependency, death, and loneliness; c) if it is better to die early than to feel anguish and the loneliness of old age; d) if old age can provide feelings of integrity. Initially, through scores, it is possible to determine whether participants have a positive or negative perception of finitude (prevalence)[35].

Sample size calculation

The sample size calculation was performed using the G* Power 3.1.9.228 software, based on balance motor symptoms, assuming a moderate effect based on similar interventions, according to Cohen with 0.37 effect size, a significance level of 5%, 95% test power, and 20% sample loss. Thus, 15 individuals will be assigned to each group (FTG, PG, and CG) according to the sample calculation, in a total of 45 participants.

Randomization and Blinding

Upon consent of the study, survey participants will be randomly assigned to FTG, PG, and CG. The randomization process will be done through the program randomization.org, which will predict the allocation of individuals in the three groups. Two trained evaluators will be blind to group allocation and will not participate in the intervention. All individual information will be stored in an unidentifiable form.

In this study, it is not possible to blind participants from their assigned experimental groups, because the exercises of each intervention they perform will reveal their allocation to a particular group.

Statistical analysis

The data will be tabulated in the Microsoft Excel® program and transferred to the statistical package SPSS - IBM version 20.0. Descriptive statistics (mean, standard deviation, and percentage) will be performed, followed by the two-way ANOVA with repeated measures and the Sydak comparison test for comparative analysis of group results and pre and post-group comparisons in the three groups. Post hoc analysis using Bonferroni correction will be applied as appropriate. All subjects will be analyzed in the intent-to-treat analysis and in the per-protocol analysis, including all participants who have at least 75% compliance with the exercise. The significance level adopted of 5%.

Discussion

This protocol for randomized clinical trial aims to provide a program and exercise with two distinct modalities, functional training, and the Mat Pilates. In order to provide an answer as to which of these may bring major improvements in motor symptoms (balance, cardiorespiratory fitness, lower and upper limb strength, flexibility, and agility) and non-motor symptoms (cognition, depressive symptoms, mood state, anxiety, and finitude) in individuals with PD, positively influencing future non-pharmacological treatment approaches in these individuals.

The literature has benefits of functional training and the Mat Pilates as a non-pharmacological treatment, but there is still little evidence and non-randomized experimental studies. Functional training is an integrated and multiarticular exercise modality that according to Horne et al.[17] and Leal et al.[10] promotes improvement in muscle strength, 6-min walk test distance, motor function, quality of life, anxiety, and depression in individuals with PD. Mat Pilates can prevent the aggravation of a series of symptoms, both in motor and non-motor aspects, which make life difficult for these individuals and can be a great ally to the well-being of body and mind to maintain independence reintegration into society[19].

Furthermore, although pharmacological treatments seek to reduce the impact of some motor symptoms, they significantly decrease the quality of life of individuals living with PD[36]. Currently, the focus on investigations of different non-pharmacological interventions has increased due to side effects caused by medications such as bradykinesia and gait freezing[37]. Therefore, the importance of combining medication and concomitant physical exercise[38]. Thus, this will be the first randomized controlled trial designed with the benefits of functional training and the Mat Pilates in the non-pharmacological treatment of PD. This will help to identify the efficacy of both the motor and non-motor symptoms of the disease, besides being safe and economical approaches for this population, thus being a pioneer study when it comes to the comparison between these two modalities.

Conclusions

It is considered that the implementation of a functional training protocol, as well as the Mat Pilates for individuals with PD, may contribute to forming a parameter on which professionals can be based on the orientation and prescription of physical exercise for this population, bringing new knowledge for the literature in question. In addition, this protocol may have a positive impact on supporting the occurrence of new randomized controlled trials and the emergence of new evidence for performing a specific exercise protocol as a non-drug treatment.

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