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

Functional training versus Mat Pilates in Parkinson's disease

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Study protocol

Keywords: Parkinson's disease, Physical exercise, Functional training, Pilates, Randomized clinical trial.

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Abstract

Background: Motor and non-motor symptoms affect the life of those living with Parkinson's disease, and it is clear that exercise offers benefits in these aspects. However, the effects of adapted functional training interventions and the Mat Pilates as a form of rehabilitation for the disease in question have not yet been established. Thus, this study aims to propose an adapted functional training protocol and Mat Pilates for individuals with Parkinson's disease and to evaluate the effects on motor symptoms (balance, cardiorespiratory fitness, lower and upper limb strength, flexibility and agility), as well as non-motor symptoms (cognition, depressive symptoms, mood state, anxiety and finitude) by means of 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-minute classes twice a week for 12 weeks. The primary outcome will be analyzed by balancing with the Mini-BESTest test. Secondary outcomes will include cognition, aging perspective, mood, anxiety, depression, mobility, muscle strength, handgrip strength, flexibility, range of motion, and cardiorespiratory fitness. The evaluations will be performed in the pre-intervention period (baseline), after 12 weeks of intervention, after 3 months, 6 months and 1 year of intervention.

Discussion: 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.

Trial registration

Registry name: Registro Brasileiro de Ensaios Clínicos (ReBEC)

Registration number: RBR-6ckggn

Date of registration: September 29, 2020. Trial was prospectively registered

Background

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 [2,3,4]. 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].

Thus, 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, 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 in the functional training and in the Mat Pilates, that has been gaining prominence in adults and elderly, because it provides Improvement of the human 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 of the neuromuscular efficiency for the different tasks of daily life [14], bringing as a benefit the functional capacity to perform daily activities with autonomy and safety [15]. Like the study by Horne et al. (2019) [16], 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., (2019) [10] which promoted improvement in aerobic endurance, gait speed, balance and handgrip compared to the control group. Similarly, the Mat Pilates 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 body and mind to maintain functional independence, as well as their reintegration into society [17].

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. Thus, the main objective of this study is to propose an adapted 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/design
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 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 schedule, 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 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 [18]; (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 [19]; (2) classified in stage 5 PD (wheelchair users) [20]; (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.

Sample size calculation

The sample size calculation was performed using the G * Power 3.1.9.228 software, based on the study's primary outcome, the balance, assuming a moderate effect based on similar interventions, according to Cohen with 0.37 effect size, 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.

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 minutes 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 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.

Lessons will be divided into: warming up (15 minutes) 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 minutes) that 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 minutes 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.

Functional training intervention protocol adapted for individuals with Parkinson’s disease.
<table>
<thead>
<tr>
<th>RAINING</th>
<th>WARMING UP</th>
<th>MAIN PART</th>
<th>WINDING DOWN</th>
<th>GOAL</th>
</tr>
</thead>
</table>
| 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 |
| 1.      | 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 weight off the floor  
4- Bounce ball with cones  
5- Unilateral Sinking  
6- Jumping | Massage | Balance  
Coordination  
Agility |
| 1.      | 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 |
| 1.      | 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 |
| 1.      | 1- Joint warming  
2- Good morning  
3- Dance of the bows  
4- Double race passing the ball | 1- Climb on 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 |
| 1.      | 1- Double task walk  
2- Throwing wall ball  
3- Throwing wall ball with offset | 1- Squat with throwing 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 |
| 1. | 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 weight  
4- Stretching legs (elastic band)  
5- Ball Salute  
6- Sitting tighten balls with thighs | General stretching | Flexibility  
Coordination  
Force |
|---|---|---|---|---|
| 1. | 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 weight off the floor  
4- Elastic leg sidewalk  
5- Free weight squats  
6- Ball around the cone | Ball release | Coordination  
Agility  
Power |
| 1. | 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  
5- Deep displacement  
6- Lying ball on feet up (side and other) | General stretching | Resistance  
Balance  
Power |
| 1. | 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 |
| 1. | 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 |
| 1. | 1- Walk up 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 weight  
4- Collect mini cones  
5- One-sided airplane  
6- Sitting tighten balls with thighs | Ball release | Agility  
Force  
Balance |
| 7- Ball Salutation | 1. | 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 wall  
4- Hit the ball in the bows  
5- Walking cuts toes  
6- Stretching legs (elastic band) | General stretching  
Flexibility  
Power  
Coordination |
| --- | --- | --- | --- | --- |
| 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 with throwing ball  
5- Static One-Step Balance  
6- Ball around the cone | Massage  
Balance  
Resistance  
Agility |
| 1- Walking with articulation  
2- Pass the ball in two groups (volleyball) | 1- Abdominal bike  
2- Unilateral leg lift  
3- Take 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 |
| 1- Double task walk  
2- Double task race  
3- Guided Displacement | 1- Extension and flexion of knees with 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 |
| 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 side walk  
5- Log circles with ball  
6- Switch weight of legs with weight | General stretching  
Coordination  
Power  
Resistance |
| 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 | Massage  
Balance  
Flexibility  
Resistance |
<table>
<thead>
<tr>
<th>6. Stretching legs (elastic band)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Joint warming</td>
</tr>
<tr>
<td>2. Good morning</td>
</tr>
<tr>
<td>3. Pass the ball above and below</td>
</tr>
<tr>
<td>4. Pass side ball</td>
</tr>
<tr>
<td>1. Weight lifting</td>
</tr>
<tr>
<td>2. Wall weight squats</td>
</tr>
<tr>
<td>3. Unilateral leg lift</td>
</tr>
<tr>
<td>4. Rotation trunk with elastic in the feet</td>
</tr>
<tr>
<td>5. Triceps forehead</td>
</tr>
<tr>
<td>6. Go up and downside step</td>
</tr>
<tr>
<td>7. Jumping</td>
</tr>
<tr>
<td>General stretching</td>
</tr>
<tr>
<td>Force</td>
</tr>
<tr>
<td>Resistance</td>
</tr>
<tr>
<td>Power</td>
</tr>
</tbody>
</table>

| 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 |

| 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 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 |

| 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 weight off the floor |
| Massage |
| Force |
| Resistance |
| Power |

| 1. Walk ball throwing up |
| 2. Walk bouncing ball |
| 3. Ball walk between cones |
| 1. Lateral abdominal weight |
| 2. Squat with throwing 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 |

| 1. Pass the ball in two groups (volleyball) |
| 2. Kick soccer ball |
| 1. Abdominal Cradle |
| 2. Static balance with one foot |
| 3. Hit the ball in the bows |
| Ball release |
| Balance |
| Agility |
| Coordination |
Mat Pilates

Mat Pilates classes will be held at the same venue, 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 minutes 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, 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 minutes) in which will be explored the joint warm-up exercises, muscle activation and Mat Pilates movements, such as, breathing, imprint & release, hip release, spinal rotation, cat stretch, hip rolls, scapula isolation, arm circles, head nods e elevation & depression of scapula. The main part (40 minutes) with evolution of specific movements of the Mat Pilates as breast stroke preparation (hand by hips), shell stretch, preparation abdomen, half roll back, roll up, single leg stretch, obliques, one leg circle, preparation shoulder bridge, hell squeeze prone, side kick, spine twist, among others included in the protocol. Relaxation will consist of self-stretching exercises using the ball and talk about each participant’s perception of the classes for 5 minutes. 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. The details of the exercises that constitute the protocol are detailed in Table 2.
<table>
<thead>
<tr>
<th>WARMING UP</th>
<th>MAIN PART</th>
<th>WINDING DOWN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong></td>
<td>Muscle activation</td>
<td>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.</td>
</tr>
</tbody>
</table>
| **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- Side kick | Group massage (One behind the other) |
| **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 | Individual massage |
| **4**      | Muscle activation and Mat Pilates movements (breathing, imprint & release, hip release) | 1- The Hundred  
2- Scissors leg stretch  
3- Half-roll back  
4- Side kick  
5- Roll up (pressing the magic circle with hands)  
6- Preparation shoulder bridge  
7- One-leg circle (with TheraBand around the thigh with both knees flexed)  
8- Spine twist | Guided meditation |
| **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 hands)  
3- One-leg circle (with TheraBand around the thigh with both knees flexed)  
4- Preparation shoulder bridge tightening the over ball between the knees and performing simultaneously exercises of biceps with weight of 1 kg  
5- Hell squeeze prone (pressing magic circle on ankles)  
6- The side kick 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 magic circle the knees)  
3- Jackknife  
4- Lateral flexion  
5- Staggered legs (with the lower limbs within the magic circle)  
6- Top-leg abduction | Massage in pairs |
|   | Muscle activation and Mat Pilates movements (arm circles, head nods e elevation & depression of scapula) | 1- Half-roll back  
2- Obliques (tightening the over 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 sacral region)  
6- Top-leg circles  
7- Both legs together  
8- Side kicking | Group massage (One behind the other) |
|---|---|---|---|
| 7 | 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 shoulder bridge (with feet on top of the ball)  
5- Top-leg abduction  
6- Top-leg circles  
7- Saw  
8- Sidekick kneeling | Individual massage |
| 8 | 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 shoulder bridge (with feet on top of the ball)  
5- Preparation shoulder bridge (with feet on top of the ball and performing extension and flexion of the knees)  
6- Swimming  
7- Side kick (with ankle weights)  
8- Saw | Group massage (Divided into two groups, all massage one at a time) |
| 9 | 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 shoulder bridge (with feet on top of the ball and performing extension and flexion of the knees)  
7- Double-leg kic  
8- Jackknife | Guided meditation |
| 10 | 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- Roll over  
4- Hell squeeze prone (with magic circle on ankles)  
5- Spine stretch forward with pressing the magic circle with hands  
6- Preparation shoulder bridge performing simultaneously exercises of biceps with weight of 1 kg  
7- Shoulder bridge | Myofascial Release |
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<td>13</td>
<td>1- Single-leg stretches</td>
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<td></td>
<td>2- Roll over</td>
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<td></td>
<td>3- Side bend with knees supported</td>
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<td></td>
<td>4- Hundred (with hip and knees flexed 90 degrees)</td>
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<td></td>
<td>5- Scissors</td>
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<td></td>
<td>6- Obliques roll (with weight of 1 kg)</td>
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<td>7- Single leg extension</td>
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<td>8- Jackknife</td>
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<td>13</td>
<td>Muscle activation and Double Walk with Obstacles</td>
<td>Massage in pairs</td>
<td>Group massage (One behind the other)</td>
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<td>Muscle activation and Double Walk with Obstacles</td>
<td>Individual massage</td>
<td>Group massage (Divided into two groups, all massage one at a time)</td>
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<tr>
<td>15</td>
<td>Muscle activation and Dislocations with general joint movements</td>
<td>Guided meditation</td>
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</tr>
<tr>
<td>16</td>
<td>Muscle activation and Dislocations with general joint movements</td>
<td>Guided meditation</td>
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<tr>
<td>17</td>
<td>Muscle activation and Mat Pilates movements (spinal rotation, cat stretch, hip rolls; arm circles, head nods elevation &amp; depression of scapula)</td>
<td>Guided meditation</td>
<td>Myofascial Release</td>
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<tr>
<td>18</td>
<td>Muscle activation and Mat Pilates movements (breathing, imprint &amp; release, hip release, spinal rotation, cat stretch, hip rolls)</td>
<td>Muscle activation and Mat Pilates movements (breathing, imprint &amp; release, hip release, spinal rotation, cat stretch, hip rolls)</td>
<td>Massage in pairs</td>
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<tr>
<td>8- Staggered legs with 1-kg ankle weights</td>
<td>1- The hundred (with Swiss ball in the feet)</td>
<td>1- The hundred (with Swiss ball in the feet)</td>
<td>1- The hundred (with Swiss ball in the feet)</td>
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<tr>
<td></td>
<td>2- Shoulder bridge</td>
<td>2- Shoulder bridge</td>
<td>2- Shoulder bridge</td>
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<td></td>
<td>3- Swimming</td>
<td>3- Swimming</td>
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<tr>
<td></td>
<td>4- Criss-crossing</td>
<td>4- Criss-crossing</td>
<td>4- Criss-crossing</td>
</tr>
<tr>
<td></td>
<td>5- Scissors with over ball in the sacral region</td>
<td>5- Scissors with over ball in the sacral region</td>
<td>5- Scissors with over ball in the sacral region</td>
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<tr>
<td></td>
<td>6- Side kick with 1-kg ankle weights</td>
<td>6- Side kick with 1-kg ankle weights</td>
<td>6- Side kick with 1-kg ankle weights</td>
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<td></td>
<td>7- The crab (with the Swiss ball behind the legs)</td>
<td>7- The crab (with the Swiss ball behind the legs)</td>
<td>7- The crab (with the Swiss ball behind the legs)</td>
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<td></td>
<td>8- One-leg circle with 1-kg ankle weights</td>
<td>8- One-leg circle with 1-kg ankle weights</td>
<td>8- One-leg circle with 1-kg ankle weights</td>
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<tr>
<th>19</th>
<th>Muscle activation and Mat Pilates movements (spinal rotation, cat stretch, hip rolls; arm circles, head nods elevation &amp; depression of scapula)</th>
<th>Muscle activation and Mat Pilates movements (spinal rotation, cat stretch, hip rolls; arm circles, head nods elevation &amp; depression of scapula)</th>
<th>Group massage (One behind the other)</th>
</tr>
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<tbody>
<tr>
<td>1- Teaser</td>
<td>1- Teaser</td>
<td>1- Teaser</td>
<td>1- Teaser</td>
</tr>
<tr>
<td>2- The hundred (with magic circles)</td>
<td>2- The hundred (with magic circles)</td>
<td>2- The hundred (with magic circles)</td>
<td>2- The hundred (with magic circles)</td>
</tr>
<tr>
<td>3- Obliques roll (with weight of 1 kg)</td>
<td>3- Obliques roll (with weight of 1 kg)</td>
<td>3- Obliques roll (with weight of 1 kg)</td>
<td>3- Obliques roll (with weight of 1 kg)</td>
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<tr>
<td>4- Lateral flexion</td>
<td>4- Lateral flexion</td>
<td>4- Lateral flexion</td>
<td>4- Lateral flexion</td>
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<tr>
<td>5- Preparation shoulder bridge performing simultaneously exercises of biceps with weight of 1 kg</td>
<td>5- Preparation shoulder bridge performing simultaneously exercises of biceps with weight of 1 kg</td>
<td>5- Preparation shoulder bridge performing simultaneously exercises of biceps with weight of 1 kg</td>
<td>5- Preparation shoulder bridge performing simultaneously exercises of biceps with weight of 1 kg</td>
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<tr>
<td>6- Spine stretch forward (with hands on top of the magic circle)</td>
<td>6- Spine stretch forward (with hands on top of the magic circle)</td>
<td>6- Spine stretch forward (with hands on top of the magic circle)</td>
<td>6- Spine stretch forward (with hands on top of the magic circle)</td>
</tr>
<tr>
<td>7- Single-leg extension with 1-kg ankle weights</td>
<td>7- Single-leg extension with 1-kg ankle weights</td>
<td>7- Single-leg extension with 1-kg ankle weights</td>
<td>7- Single-leg extension with 1-kg ankle weights</td>
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<td>8- Swimming</td>
<td>8- Swimming</td>
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<tr>
<th>20</th>
<th>Muscle activation and Mat Pilates movements (breathing, imprint &amp; release, hip release, spinal rotation, cat stretch, hip rolls)</th>
<th>Muscle activation and Mat Pilates movements (breathing, imprint &amp; release, hip release, spinal rotation, cat stretch, hip rolls)</th>
<th>Individual massage</th>
</tr>
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<tbody>
<tr>
<td>1- Hell squeeze prone (with magic circle on our ankles)</td>
<td>1- Hell squeeze prone (with magic circle on our ankles)</td>
<td>1- Hell squeeze prone (with magic circle on our ankles)</td>
<td>1- Hell squeeze prone (with magic circle on our ankles)</td>
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<tr>
<td>2- Criss-crossing</td>
<td>2- Criss-crossing</td>
<td>2- Criss-crossing</td>
<td>2- Criss-crossing</td>
</tr>
<tr>
<td>3- Open leg rocker</td>
<td>3- Open leg rocker</td>
<td>3- Open leg rocker</td>
<td>3- Open leg rocker</td>
</tr>
<tr>
<td>4- Bicycle in air</td>
<td>4- Bicycle in air</td>
<td>4- Bicycle in air</td>
<td>4- Bicycle in air</td>
</tr>
<tr>
<td>5- One-leg circle with 1-kg ankle weights</td>
<td>5- One-leg circle with 1-kg ankle weights</td>
<td>5- One-leg circle with 1-kg ankle weights</td>
<td>5- One-leg circle with 1-kg ankle weights</td>
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<tr>
<td>6- Staggered legs with 1-kg ankle weights</td>
<td>6- Staggered legs with 1-kg ankle weights</td>
<td>6- Staggered legs with 1-kg ankle weights</td>
<td>6- Staggered legs with 1-kg ankle weights</td>
</tr>
<tr>
<td>7- Side kicking</td>
<td>7- Side kicking</td>
<td>7- Side kicking</td>
<td>7- Side kicking</td>
</tr>
<tr>
<td>8- Shoulder bridge</td>
<td>8- Shoulder bridge</td>
<td>8- Shoulder bridge</td>
<td>8- Shoulder bridge</td>
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<table>
<thead>
<tr>
<th>21</th>
<th>Muscle activation and Dislocations with general joint movements</th>
<th>Muscle activation and Dislocations with general joint movements</th>
<th>Group massage (Divided into two groups, all massage one at a time)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1- Hundred</td>
<td>1- Hundred</td>
<td>1- Hundred</td>
<td>1- Hundred</td>
</tr>
<tr>
<td>2- Breaststroke</td>
<td>2- Breaststroke</td>
<td>2- Breaststroke</td>
<td>2- Breaststroke</td>
</tr>
<tr>
<td>3- Preparation shoulder bridge (with the feet on the ball performing extension and flexion of the knees)</td>
<td>3- Preparation shoulder bridge (with the feet on the ball performing extension and flexion of the knees)</td>
<td>3- Preparation shoulder bridge (with the feet on the ball performing extension and flexion of the knees)</td>
<td>3- Preparation shoulder bridge (with the feet on the ball performing extension and flexion of the knees)</td>
</tr>
<tr>
<td>4- Scissors with over ball</td>
<td>4- Scissors with over ball</td>
<td>4- Scissors with over ball</td>
<td>4- Scissors with over ball</td>
</tr>
<tr>
<td>5- Double-leg kick with 1-kg ankle weights</td>
<td>5- Double-leg kick with 1-kg ankle weights</td>
<td>5- Double-leg kick with 1-kg ankle weights</td>
<td>5- Double-leg kick with 1-kg ankle weights</td>
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<tr>
<td>6- Top-leg abduction with 1-kg ankle weights</td>
<td>6- Top-leg abduction with 1-kg ankle weights</td>
<td>6- Top-leg abduction with 1-kg ankle weights</td>
<td>6- Top-leg abduction with 1-kg ankle weights</td>
</tr>
<tr>
<td>7- Top-leg circles with 1-kg ankle weights.</td>
<td>7- Top-leg circles with 1-kg ankle weights.</td>
<td>7- Top-leg circles with 1-kg ankle weights.</td>
<td>7- Top-leg circles with 1-kg ankle weights.</td>
</tr>
<tr>
<td>8 - Open leg rocker</td>
<td>8 - Open leg rocker</td>
<td>8 - Open leg rocker</td>
<td>8 - Open leg rocker</td>
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</tbody>
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<table>
<thead>
<tr>
<th>22</th>
<th>Muscle activation and ball joint movements</th>
<th>Muscle activation and ball joint movements</th>
<th>Guided meditation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1- Obliques roll (with weight of 1 kg)</td>
<td>1- Obliques roll (with weight of 1 kg)</td>
<td>1- Obliques roll (with weight of 1 kg)</td>
<td>1- Obliques roll (with weight of 1 kg)</td>
</tr>
<tr>
<td>2- Spine Stretch</td>
<td>2- Spine Stretch</td>
<td>2- Spine Stretch</td>
<td>2- Spine Stretch</td>
</tr>
<tr>
<td>3- Obliques roll with weight of 1 kg</td>
<td>3- Obliques roll with weight of 1 kg</td>
<td>3- Obliques roll with weight of 1 kg</td>
<td>3- Obliques roll with weight of 1 kg</td>
</tr>
<tr>
<td>4- The double leg stretches (with the Swiss ball)</td>
<td>4- The double leg stretches (with the Swiss ball)</td>
<td>4- The double leg stretches (with the Swiss ball)</td>
<td>4- The double leg stretches (with the Swiss ball)</td>
</tr>
<tr>
<td>5- Side bend</td>
<td>5- Side bend</td>
<td>5- Side bend</td>
<td>5- Side bend</td>
</tr>
<tr>
<td>6- top-leg abduction with 1-kg ankle weights</td>
<td>6- top-leg abduction with 1-kg ankle weights</td>
<td>6- top-leg abduction with 1-kg ankle weights</td>
<td>6- top-leg abduction with 1-kg ankle weights</td>
</tr>
<tr>
<td>7- One-leg circle with 1-kg ankle weights.</td>
<td>7- One-leg circle with 1-kg ankle weights.</td>
<td>7- One-leg circle with 1-kg ankle weights.</td>
<td>7- One-leg circle with 1-kg ankle weights.</td>
</tr>
<tr>
<td>8- Preparation shoulder bridge with the feet on the ball performing simultaneously exercises of biceps with weight of 1 kg.</td>
<td>8- Preparation shoulder bridge with the feet on the ball performing simultaneously exercises of biceps with weight of 1 kg.</td>
<td>8- Preparation shoulder bridge with the feet on the ball performing simultaneously exercises of biceps with weight of 1 kg.</td>
<td>8- Preparation shoulder bridge with the feet on the ball performing simultaneously exercises of biceps with weight of 1 kg.</td>
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<thead>
<tr>
<th>23</th>
<th>Muscle activation and Dislocations with general joint movements</th>
<th>Muscle activation and Dislocations with general joint movements</th>
<th>Myofascial Release</th>
</tr>
</thead>
<tbody>
<tr>
<td>1- Mermaid</td>
<td>1- Mermaid</td>
<td>1- Mermaid</td>
<td>1- Mermaid</td>
</tr>
<tr>
<td>2- Scissors in air</td>
<td>2- Scissors in air</td>
<td>2- Scissors in air</td>
<td>2- Scissors in air</td>
</tr>
<tr>
<td>3- Teaser</td>
<td>3- Teaser</td>
<td>3- Teaser</td>
<td>3- Teaser</td>
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<tr>
<td>4- Hundred</td>
<td>4- Hundred</td>
<td>4- Hundred</td>
<td>4- Hundred</td>
</tr>
<tr>
<td>5- Single-leg stretch</td>
<td>5- Single-leg stretch</td>
<td>5- Single-leg stretch</td>
<td>5- Single-leg stretch</td>
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</tbody>
</table>
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 of 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, and 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 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 minutes at a time previously set by the researchers. A summary of all outcome measures that will be collected at each moment is shown in Figure 2 following 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 minutes and allows you to quickly and reliably track balance changes. Each
item is scored from (0-2); 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 amount of points, being 28 [21].

Secondary outcome assessment

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 body side, body side most affected by the disease and anthropometric measurements (BMI). Body mass index (BMI) classification was based on the WHO protocol (2016) [22], 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.

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. (1994) [19] - 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, indicate 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 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 [20].

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), this is a self-report questionnaire originally developed by Beck et al. (1961) [23]. 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 [23].

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 indicate a high degree of anxiety [24].
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 [25].

Aging Perspective: Sheppard Inventory adapted to Portuguese and validated by Neri (1991) [26]. The instrument consists of 20 questions divided into 4 subgroups, which allow to evaluate the respondent's opinion regarding: a) 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, by means of scores, it is possible to determine whether participants have a positive or negative perception of finitude (prevalence) [26].

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 [27]. Exhaled gases and flow volume will be collected during the test and analyzed by 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 [28]. 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 [29].

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 neutral position and wrist ranging from 0 ° to 30 ° in length and between zero and 15 ° ulnar deviation [30].

Muscle strength: Biodex System 4 PRO isokinetic dynamometer (BiodexTM Medical Systems Inc., Shirley, NY), used with individuals with Parkinson's disease [31], 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 [32].

**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 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 primary intention-to-treat analysis and protocol analysis will also be performed including all participants who have at least 75% compliance with the exercise. 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. (2019) [16] and Leal et al. (2019) [10] promotes improvement in muscle strength, 6-minute walk test distance, motor function, quality of life, anxiety and depression in individuals with PD. The 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 [17].

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 [33]. 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 [34]. Therefore, the importance of combining medication and concomitant physical exercise [35]. 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 in 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.
Thus, it is considered that the implementation of a functional training protocol, as well as the Mat Pilates for individuals with PD may contribute to form 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 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.

**Trial Status**

This trial protocol is version 1.0, dated 02 October 2019. The trial recruitment will be on 01 January 2021, and recruitment will be completed about on 01 March 2021.

**List Of Abbreviations**

BAI: Beck Anxiety Inventory  
BDI: Beck Depression Inventory  
BRUMS: Brunel's Mood Scale  
HY: Hoehn and Yahr Degree of Disability Scale  
MMSE: Mini Mental State Examination  
PD: Parkinson's disease  
PDQ-39: Quality of life scale in Parkinson's disease  
TUG: Timed Up and Go  
UPDRS: Movement disorders society force on rating scales for Parkinson's disease

**Declarations**

**Availability of data and materials**

The results derived from this project will be published in international scientific journals. The data can be made available with the corresponding author upon request.

**Acknowledgements**

Not applicable

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Jéssica Moratelli; Kettlyn Hames Alexandre; Leonessa Boing; Melissa de Carvalho Souza Vieira; Adriana Coutinho de Azevedo Guimarães.

Author Contributions

JM conceived of the study, initiated the study design, developed the methodology, and commented on initial drafts of the manuscript. KH conceived of the study, initiated the study design, developed the methodology, and commented on initial drafts of the manuscript. MdCSV initiated the study design and developed the methodology. LB initiated the study design, developed the methodology, and commented on initial drafts of the manuscript. ACdAG initiated the study design and commented on initial drafts of the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Ethical approval was granted through the Ethics Committee on Research in Human Beings (CEPSH) of UDESC -protocol 3.613.483. All subjects that will participate of the study will give written informed consent in accordance with the Declaration of Helsinki.

Consent for publication

Published data will not contain any personal identification numbers. Thus, no individual can be identified by published results.

Competing interests

The authors have no conflicts of interest to declare.

Funding Sources

This research did not receive funding for its development.

References


Figures
Figure 1
Flowchart of the participant selection process and protocol steps, Consolidated Standards of Reporting Trials (CONSORT).
### Figure 2

Study evaluation schedule (SPIRIT).

### Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SPIRITchecklist.doc