Additional file 2

Template for Intervention Description and Replication (TIDieR)

1. Title: Effects of a power strength training by elastic resistance exercise on the motor and nonmotor symptoms in patients with Parkinson's disease HY 1 to 3: Study protocol for a randomized controlled trial. PARK-BAND Study.

2. Why: Describe any rationale, theory, or goal of the elements essential to the intervention

Resistance training (RT) is relatively a new intervention for Parkinson's disease (PD). RT is well tolerated and appears to be effective in improving motor symptoms and strength in PD (1)(2)(3). Reduced muscle strength coincides with an increased risk for falls in patients with PD, causing postural impairment and loss of mobility (4)(5). In a study, Corcos et al. (2013) (1), at the Clinical Motor Control Laboratory of the University of Illinois, investigated the effects of progressive RT (PRT) on off-medication Unified Parkinson's Disease Rating Scale (UPDRS)-III score. The sample comprised 38 participants who underwent a 24-month intervention. The authors demonstrated that PRT promoted statistically and clinically significant reduction in the UPDRS-III scores from baseline to 24 months of intervention. The results corroborate with a recent systematic review investigating the effects of exercise on patients with PD. The review reported that clinical improvement was demonstrated by most studies regardless of the exercise type. In that review, 13 of the 28 included studies had PRT as treatment intervention. Training was conducted twice a week, of which 4 studies reported a duration of 40–60 min per session. Although the exercise

protocols were heterogeneous, the main muscle groups in the body or the muscles of the lower limbs were addressed in the studies. Therefore, we require a meta-analysis of PT studies with correction for the protocol heterogeneity (6).

Muscle power is the product of force and contraction velocity, factors that lead to a reduction in either of these parameters, or both, will contribute to reduced muscle power output. PT is based in high speed movement with low loads of resistance (7). Power training (PT) as a specific method of RT that has been emphasized to be effective in improving strength, power, and physical performance in different populations (8)(9)(10)(11). Bradykinesia is the main characteristic of PD causing functional impairment in these patients. Studies have also shown high prevalence of sarcopenia and dynapenia in patients with PD compared to patients without PD (12). High-speed strength training has been reported to improve functional outcomes in PD (8)(13) . However, the literature on the advantages of PT compared to other interventions on PD is limited (6).

Because PT focuses on rapid movement speed by low resistance training, it would be beneficial to examine its role on functional outcomes in patients with PD. Indeed, further studies are required in the PD population to support the beneficial effects of different types of RT and to investigate the superiority of PT to other treatment strategies.

Webber and Porter (2015) (14) concluded that ankle movements performed as quickly as possible with elastic bands improved the foot movement time in 50 women with impaired mobility (age, 70–88 years) compared to weight exercise, and stretching and education program as controls. Improvement in foot movement time is necessary to generate torque at the ankle to avoid falls.

Training with elastic bands represents a simple and affordable form of exercise suitable for elderly individuals, including those with mobility limitations. The ability to perform movements with speed has relevant clinical implications for the functional performance of elderly people with low mobility and risk of falls. Similar to conventional RT and use of different exercise regimes (15), exercises performed with elastic bands are effective in promoting strength increase. Exercise with elastic bands will be performed following instructions to achieve concentric contraction as fast as possible. Elastic band allows for greater mobility to execute movements, and its use therefore prevents the limitations of range of motion restricted by machines. Elastic bands are a simple-to-use tool for multipurpose physical training, allowing for all the major muscle groups to be worked on. In elastic RT, TheraBand® elastic bands and elastic tubing are the preferred options. TheraBand® comes in different colors, with each color representing a different resistance level. The elastic tubing is available in different diameters and resistance. Thus, this range, which provides varied resistances, allows for greater mobility and increased exercise intensity without excessive weight load. These tools are portable, inexpensive, reliable, and highly practical (13)(16). Recently, RT using elastic bands has been applied safely and effectively to older people (12)(14)(17)(18)(19) and people younger than 60 years (16)(20)(21)(22) (23)(24), regardless of various exercise protocols.

Power training using elastic bands and tubing is expected to promote the production of high levels of muscle strength in the early stages of muscle contraction, ensuring rapid movement execution while minimizing bradykinesia.

We hypothesize that the structured park-band program will be superior to health education program in improving motor and nonmotor symptoms of PD and physical functional performance in individuals with mild-to-moderate PD.

3. What (materials): Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g., online appendix, URL)

A specific teacher training workshop will be performed before the start of the study. The objective is to train the professionals involved in all the committees.

3.1 Exercise Intervention Committee:

3.1.1 Five different sizes of elastic tubing (Lemgruber®; Brazil) will be used. The inside diameter (ID) and outside diameter (OD) of each tubing are described according to the manufacturer's specifications: # 200 (ID: 3.0 mm, OD: 5.5 mm); # 201 (ID: 4.0 mm, OD: 5.5 mm), # 202 (ID: 4.0 mm, OD: 8.0 mm), # 203 (ID: 6.0 mm, OD: 9, 0 mm), and # 204 (ID: 6.0 mm, OD: 11.5 mm) (25).

3.1.2 Six resistances levels (yellow, red, green, blue, black, and silver) of TheraBand® (Hygenic Co., Akron, OH, USA) will be used (26).

3.1.3 A notebook containing spreadsheet for frequency, adverse events, and vital signs will be used.

3.1.4 An ONROM upper arm blood pressure monitor will be used to measure blood pressure and cardiac frequency before and after exercise.

3.2 Data Collection of Outcome Committee:

For data collection, the REDCap® electronic data collection software will be used. The coordinators of the committees will check the data and make necessary corrections.

3.2.1 Biodex System 4 Pro® (Biodex Medical Systems, Inc., New York, USA) (27) will be used to measure peak torque (Nm), work (Joule), and average power (Watt) and rate of torque development (Nm/s) of isokinetic variables.

3.2.2 Handgrip dynamometer Saehan (28) for upper limbs strength.

3.2.3 A stopwatch to measure time of gait speed.

3.2.4 A firm chair of 45 cm to measure Five Times Sit-to-Stand Test time (29).

3.2.5 Actigraph ActTrust (Condor (30) Instruments) to measure sleep patterns, physical activity, physical activity intensity, and sedentary behavior.

3.2.6 Tempur®/T-foam™: 10-cm high foam, medium density T41 (firmness rating), to evaluate balance in Mini-BESTest (31).

3.2.7 A 10-degree inclination ramp to evaluate balance in Mini-BESTest.

3.2.8 A 22.9-cm high box (e.g., two shoe boxes stacked and fastened together) to evaluate gait and balance in Mini-BESTest.

3.2.8 A tape to measure and mark the floor: 3 m away from the chair to evaluate “Timed get up ang go of Mini-BESTest.

3.3 Health Education Group:

3.3.1 A data show for slides presentations.

3.3.2 A notebook containing spreadsheet for recording frequency and adverse events.

3.3.3 A booklet of 12 chapters to be discussed.

3.3.4 Cards, colored pens, markers for the group dynamics.

The chapter titles of the booklet are:	
1.	Clinical features of Parkinson's disease.
2.	Pharmacological treatment.
3.	Physical activity in Parkinson's disease.
4.	Freezing of gate.
5.	Prevention of falls.
6.	Intestinal constipation.
7.	Sleep disorders in Parkinson's disease.
8.	Cognitive symptoms in Parkinson's disease.
9.	Urinary incontinence and sexual problems.
10.	Depression.
11.	Postural hypotension.
12.	Coping with Parkinson's disease.

4. What (procedures): Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.

4.1 Recruitment

A list of people with PD meeting the eligible criteria for participation in the clinical trial will be compiled from an existing research database at the hospital's movement disorder outpatient clinic. Patients will be contacted by telephone to participate in the clinical trial. All patients who agree to participate in the trial will be screened telephonically. They will be invited to a medical consultation. This evaluation will be performed by a medical group to confirm the inclusion and exclusion criteria of the recruitment. In this appointment, we will apply the informed consent. Subsidy will be offered for transportation payment.

The recruitment method prior to the medical consultation will be performed according to a computer-generated random number table. This table will reveal the numbers representing each patient in the list. When a patient does not exist (e.g., death), their inclusion will be ignored, and we will select the next number. If the summoned patient does not want to participate in the research, another patient in the table sequence will be summoned.

4.2 Outcomes collection pre-intervention

The collection of pre-intervention outcomes will be conducted in the week following the medical consultation. Two patients will be evaluated per day. The outcomes are explained in item 12 of the SPIRIT study protocol. Data Collection of Outcome Committee (DCOC) will be trained, and they will use the handling of

a standard operating procedure short version during each data collection. They will have a meeting before the trial onset to consolidate data collection procedures. Periodic meetings and written communication are established to promote internal transparency and consistency.

4.3 Randomization

After pre-intervention outcome collection, stratified randomization for sex and motor UPDRS will be performed in blocks of eight for both groups (health education and training with bands and tubes). The randomization will be conducted by an external research assistant, who will not participate in any other clinical trial function. According to the intention-to-treat (ITT) principle, all randomized patients, including the dropouts, will be included for final evaluation. The number sequence will be password protected on a computer operated by the external research assistant. The hardcopy of the allocation list will be kept in a sealed opaque envelope inside a locked safe. Therefore, randomization will be conducted without any influence of the principal investigators, raters, or therapists.

4.4 Intervention

4.4.1 Control group (health education)

The control group will have tutorial meetings to discuss PD educational topics for 12 weeks. The meetings will be held once a week, each lasting 50–60 min. The group will receive a 12-chapter booklet that will tell the story of a patient who received the diagnosis of PD and learned about its clinical features, treatment

and complications. In each chapter, the reader will be provided with strategies for quality living with the disease.

During the sessions, the patients will discuss their experiences and difficulties. In the final section of each meeting, they will answer a few questions about the major topics presented during the day's program.

4.4.2 Exercise group (elastic band and tubing exercise)

The PT program will consist of concentric and eccentric dynamic progressive resistance training. Each exercise session will last a maximum of 60 minutes with a 5-minute warm-up (dynamic stretching and mobility exercises), 50 minutes of PT using elastic tubing (Lemgruber ®) or elastic bands (Theraband ®), a 5-minute cool-down (stretching and relaxation exercises). During the familiarization period of two weeks before the 12-week PT, researchers will also spend considerable time repeating instructions to ensure proper exercise performance by the participants. Multiple-joint exercises will be performed prior to single-joint exercises.

4.5 Outcome collection post-intervention

The DCOC will meet before the trial onset to consolidate data collection procedures. Periodic meetings and written communication are established to promote internal transparency and consistency.

The PARK-BAND program will consist of concentric and eccentric dynamic progressive power elastic training (for more details, see Table 1). Each exercise

session will take a maximum of 60 min, with a 5-min warm up (dynamic stretching and mobility exercises), a 50-min strength training using elastic tubes or elastic bands, and a 5-min cool down (stretching and relaxation exercises). During the familiarization period of two weeks, researchers will spend considerable time repeating instructions to ensure proper performance by the participants.

5. Who provided: For each category of intervention provider (e.g., psychologist, nursing assistant), describe their expertise, background and any specific training given:

The study will be conducted by a multidisciplinary team of health professionals, including nutritionists, physical therapists, nurses, psychologists, physical education professionals, neurologists, geriatricians, and statistical professionals. The health professionals have prior experience in dealing with patients with PD. They will be invited to participate in a training program for the Park-Band study. The training will last 6 months, with meetings held twice a week at the Hospital Universitário Walter Cantidio/Universidade Federal do Ceará. Both the professional and participant will each receive a user manual that provides the program and protocol details.

6. How: Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group:

The health education group will meet once a week for 12 weeks, with each meeting lasting for 60 min. The exercise group will have training sessions twice a week, each session of 50–60 min duration.

7. Where: Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.

The exercise training will take place at the neurofunctional physiotherapy outpatient clinic of Universidade Federal do Ceará. The physiotherapy room is spacious and has equipment and materials required for neurological rehabilitation. For this project, the space will be adapted with a locking of 3 support bars arranged horizontally and vertically for better fixation of elastic and tubing bands.

The health education program will take place at the Department of Physiotherapy classrooms of the Universidade Federal do Ceará.

8. When and how much: Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.

The exercise group will have 4 participants as in the control group. The participants will be instructed to move as fast as possible during the concentric phase of each repetition and to move slower during the eccentric phase. Each exercise session will take a maximum of 60 minutes with 5 minutes warming up (dynamic stretching and mobility exercises), 50 minutes PT by elastic tubing (Lemgruber ®) or elastic bands Theraband®, and 5 minutes cooling down

(stretching and relaxation exercises) (32)(33)(34). For each participant, a trained physical education professional or student will provide individualized training with supervision of the PT intervention coordinator. The prescription of the exercise intervention was elaborated by a specialized Physiotherapist with expertise in PT. Each session consists of 9 exercises designed to stimulate different muscle groups, with 10 submaximal repetitions performed up to a predefined maximum time. They will rest for 30 sec to 1 minute between sets and 1 to 2 minutes between different exercises. To ensure the required movement speed of the exercises, the physical education professionals will say phrases to encourage like “faster, faster”, “go faster” and touch the patient to make a neurosensorial feedback (35)(36)(37)(10).

Before the start of the PT regimen we will perform the familiarization period of two weeks to teach the participants to exert force as fast as possible during the concentric phase and move slower in eccentric phase. During the familiarization period, researchers will also spend more time repeating instructions for the proper performance of participants and teaching the participants to use the Rating of Perceived Exertion (RPE) method using the Borg category ratio scale. This scale is known as a valid, simple rating instrument that assesses perceived exertion, identifying the intensity used at the time of training. During the intervention period, the training load will be based on the RPE method using the Borg category ratio scale (39). The Borg scale may be used in individuals with PD in whom formal exercise testing may not be available (40).

Upper and lower body exercises will be executed in two phases. Six weeks in level 1 and the last 6 six weeks in level 2. Level 2 exercises will have greater complexity of execution and greater muscle demand. Exercises of upper body

level 1 will be as follows: seated bilateral row with elastic tubing, seated bilateral chest press with elastic band, seated bilateral elbow flexion with elastic band, and seated unilateral elbow extension with elastic band. Exercises of upper body level 2 will be as follows: standing bilateral row with elastic tubing, standing bilateral chest press with elastic band, standing unilateral shoulder flexion with elastic band, and standing unilateral shoulder extension with elastic band. Exercises of lower body level 1 will be as follows: seated unilateral knee extension with elastic tubing, seated unilateral hamstring pull with elastic tubing, lying unilateral leg press with elastic band, lying unilateral hip flexion with elastic tubing, and lying unilateral ankle plantar flexion with elastic band. Exercises of lower body level 2 will be as follows: sit and get up from the chair with elastic band, standing unilateral knee flexion with elastic tubing, seated unilateral leg press with elastic band, lying bilateral hip abduction with elevation with elastic band, and seated unilateral ankle. The exercises will be divided into two levels of progression with different start positions (Table 2). Please see Additional file 5 for pictures describing the exercises performed in the PARK-BAND intervention program.

Individuals will gradually increase the dimension and color of elastic tubing or bands, respectively, enabling sufficient adaptation of the connective tissue. The resistance will be increased at each pre-established period, as is described in Table 3.

In the first two weeks of familiarization prior to the PT program, the participants will be familiarized with the exercises and the use of the Borg scale for establishing appropriate rating of the perceived exertion using the yellow or red TheraBandand® and #200 Lemgruber® tube. To ensure adequate systematization and progression of the resistance of each tube dimension, as

was obtained in the study of Lima et al. (2019) (23), each muscle group will be exercised in a predetermined range of motion respecting the equivalence of the length of the limb and the tubing in pre-stretching.

During PT program, the exercises will be performed to achieve a score of 4–5 on Borg scale (31)(41). The resistance will be increased as tolerated using this scale and following the progression schedule detailed in table 3 of the main manuscript. We will use the progression scale by the colors of Thera-band® and diameters of elastic tubing Lemgrumber® as shown in Table 3. The progression will be individualized according to RPE scale. When the RPE scale is lower than 4, the researcher will increase the resistance of the elastic devices according to Table 3 in the next session. Thus, to increase the intensity of the exercise in order to adjust the RPE values, the color that was being used will be replaced by the next color and the next diameter on the resistance scale, for example changing from red to green elastic band Theraband® and from # 200 to # 201 elastic tubing Lemgruber®. For individuals who achieve the highest resistance (silver color in Theraband® and # 204 in tubing Lemgrumber®), another elastic band and tubing will be added, always following the order of progression (eg: gray + yellow; #204 + #200).

Blood pressure and heart rate will be assessed before and after each exercise session. For safety reasons, when a participant's blood pressure is >170 mmHg systolic or >100 mmHg diastolic, the participant will be prohibited from that exercise session.

Item 9. Tailoring: If the intervention was planned to be personalized, titrated or adapted, then describe what, why, when, and how

After the first week of familiarization, we will assess if the participant requires larger tubes or more resistant elastic bands to achieve greater resistance quickly. In such cases, the participant will reach the last dimension of the tube and the band color, but he or she must follow progressive execution of movements with higher speed until the end of the 12 weeks.

In addition, the change in the elastic band color or the tube dimension will be per the subjective perception of the effort, regardless of the period of change of the pre-established resistance (see Table 2).

Item 10. Modifications: If the intervention was modified during the course of the study, describe the changes (what, why, when, and how): NA

Item 11. How well (planned): If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them:

Each patient will be reminded of the session by a telephone call on the day of the meeting. In case of any absence, the Intervention Monitoring Committee will contact the patient to clarify the reason for the absence and to reschedule the session.

Item 12: How well (actual): If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned: NA

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