

PARK-BAND training program for Parkinson's disease: a feasibility study

Programa de treinamento PARK-BAND para doença de Parkinson: um estudo de viabilidade

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ABSTRACT

Objective: The purpose of this study was to identify primary endpoints related to feasibility of power training in patients with mild-to-moderate Parkinson Disease (PD). **Methods:** This is a pilot study of a randomized controlled trial blinded for data analyzers and outcome evaluators, lasting 12 weeks. We aim to compare power training to a health education program. The pre-planned primary endpoints of the Randomized Clinical Trial are the bradykinesia scores of the Unified Parkinson Disease Rating Scale (UPDRS) and Short Physical Performance Battery (SPPB). Participants were randomized to two groups: power training group (PTG) and health education group (HEG) in 1:1 ratio through a permuted block of 8 patients. **Results:** A total of 34 patients were screened and 8 were enrolled and randomized. Five (62.5%) were female and the median age was 66 (45–77) years. Attendance rate to HEG was 83.3% and to PTG 96.82%, adherence rate to HEG was 80% and to PTG 95.23%, retention rate was 75%. No adverse events were related to the intervention. **Conclusions:** PARK-BAND Training Program for Parkinson's Disease: A Feasibility Study (PARK-BAND) pilot had reasonable acceptance, attendance, adherence, and safety rates to start. (REBEC number: RBR-5w2sq).

Keywords: Resistance training. Elastic Tissue. Feasibility Studies.

RESUMO

Objetivo: Identificar desfechos primários relacionados à viabilidade do treinamento de força em pacientes com Doença de Parkinson (DP) leve a moderada. **Métodos:** Estudo piloto de ensaio clínico randomizado e cego para analisar dados e avaliadores de resultados, durante 12 semanas, objetivando comparar o treinamento de força com um programa de educação em saúde. Os desfechos primários pré-planejados do ensaio clínico são as pontuações de bradicinesia da escala unificada de avaliação da DP e da bateria curta de desempenho físico. Os participantes foram randomizados em dois grupos: treinamento de força (GTF) e educação em saúde (GES) na proporção 1:1, totalizando 8 pacientes. **Resultados:** 34 pacientes foram selecionados e 8 inscritos e randomizados. Cinco (62,5%) do sexo feminino com idade mediana 66 (45–77) anos. A taxa de frequência ao GES foi de 83,3% e ao GTF 96,82%, a adesão ao GES foi de 80% e ao GTF 95,23%, a taxa de retenção foi de 75%. Nenhum evento adverso foi documentado. **Conclusões:** O estudo piloto “Programa de treinamento PARK-BAND para doença de Parkinson: um estudo de viabilidade (PARK-BAND)” apresentou taxas razoáveis de aceitação, assiduidade, adesão e segurança iniciar. (Número REBEC: RBR-5w2sq).

Palavras-chave: Treinamento resistido. Tecido elástico. Estudos de viabilidade.

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INTRODUCTION

Power training has been shown to be effective in improving strength, power, balance, and physical performance in different groups.¹⁻⁴ Emphasis on high-speed movements and low load has improved neuromuscular function in Parkinson Disease (PD) patients in some studies.^{1,2,5} Elastic power training is a type of resistance training (RT) with several possibilities of purposes. They are simple, low-cost, and portable to be used in different locations.⁶ In addition, all major muscle groups are worked upon. However, evidence from meta-analysis on power training for PD compared with other interventions is scarce.²

Considering that power training would focus on the main symptom of PD (bradykinesia), it is important to know the feasibility of this type of rehabilitation since the characteristics of PD patients are potentially troublesome for high-speed exercise due to motor fluctuation, dyskinesia, freezing of gait, postural instability, fatigue, apathy, and daytime somnolence.⁷ The feasibility studies of physical training designs in PD are scarce, therefore more definitive clinical trials progressing from transparent reporting pilots are needed.⁸

A feasibility study of physical intervention is important to guide investigators determining adequate inclusion and exclusion criteria to balance safety, successful recruitment, and adherence. It is also necessary to establish the disease-related profile and their physical capacity to perform the training protocol in rehabilitation studies.⁹

The objective of this study is to describe indicators of feasibility including recruitment, retention, attendance, adherence, and participant experience survey through visual analogic satisfaction scale (VASC) and safety. In addition, we hypothesize that intervention is feasible for mild to moderate PD patients.

MATERIALS AND METHODS

Trial design

This study was performed between December 2019 and March 2020 as a monocentric feasibility intervention study at the Department of Neurology of the Federal University of Ceara. This study was carried out to evaluate the feasibility of an intervention study with elastic devices whose primary objective was to evaluate the effect of power strength training on bradykinesia with UPDRS (Unified Parkinson Disease Rating Scale) and physical performance with SPPB (Short Physical Performance Battery - which is an instrument that evaluates physical performance through the 4-meter gait speed test, balance test (parallel, semi-tandem and tandem feet), lower limb strength through the sit-and-stand test five times) called PARK-BAND. The calculated park-band sample for such outcomes was 50 participants. We performed the feasibility with a block of 8 patients since the park-band intervention was designed to be carried out in blocks of eight.

Eligible participants were randomized into experimental or control groups at 1:1 ratio through a permuted block of eight. The randomization was stratified by sex and motor UPDRS.¹⁰

The first week was dedicated for the outcomes data collection. The intervention was scheduled to last 12 weeks, but it was necessary to stop on March 18 in 10th week because of the covid-19 pandemic, with governmental measures of social isolation. The Broad Ethics Committee of Hospital Universitário Walter Cantídio (HUWC) approved the study (register number 91075318.1.0000.5045). All participants gave their written informed consent.

Participants

Participants were consecutively screened from a list of PD patients with potential eligible criteria from an existing research database at the HUWC's movement disorder outpatient clinic of Neurology Department. The patients were called by telephone to participate in the pilot trial and all who agreed were screened. If eligible, they were invited to a medical consultation until it reached the sample of eight. This evaluation was performed by a medical group to confirm the eligibility. The patients received a government subsidy for transport.

The inclusion criteria were: diagnosis of idiopathic PD, modified Hoehn-Yahr scale (HY) of 1 to 3; literate; age ≥ 40 years; ability to perform basic daily living activities independently with a Schwab and England (SE) score of $\geq 80\%$; on a stable treatment for ≥ 4 weeks; and residence in Fortaleza City. The patient could not have any of the conditions that compromised the ability and safety to perform the standing up exercises and to walk for 10 minutes. The exclusion criteria were: Attendance rate lower than 85%, presence of an adverse event that could have a causal relationship with the intervention, raising concerns about the safety of the participant, and withdrawal of the informed consent form.

Study setting

The HUWC of Universidade Federal do Ceará is a reference center, integrated with the Public Health System.

INTERVENTIONS

The exercise group will meet twice a week, whereas the health education group will meet once a week.

Power Training intervention

The power training program consisted of concentric and eccentric dynamic progressive resistance training. Each workout session lasted up to 60 minutes, including a 5-minute warm-up (comprising dynamic stretching and mobility exercises), and 50 minutes of power training using elastic tubes (Lemgruber®)¹¹ or elastic bands (TheraBand®),¹² and a 5-minute stretching and relaxation exercises. Researchers

spent considerable time repeating instructions. Multiple-joint exercises were performed prior to single-joint. A physical education professional provided individualized training to each participant. Each session consisted of 9 exercises to stimulate different muscle groups, with two sets of 10 submaximal repetitions of each exercise performed up to a predefined maximum time (Table 1). They took breaks of 30 seconds to 1 minute between sets and 1 to 2 minutes between different exercises. Patients were advised to perform the concentric phase of each repetition as quickly as possible and to slow down during the eccentric phase. To maintain the desired speed of movement, physical education professionals provided verbal encouragement such as “faster” and offered tactile feedback to enhance neurosensory awareness, according to European Physiotherapy Guideline for Parkinson's disease.¹³ During the intervention period, the

training load was based on the Rate of Perceived Effort (RPE) classification method using the Borg category ratio scale.¹⁴ It was used RPE scale from 0–10. The numbers relate to how easy or difficult participants classify an activity. For example, 0 (nothing) and 10 (extremely). This is valid for PD scale that assesses perceived exertion, identifying the intensity used at the time of training.¹⁵ In each exercise, each participant sought to reach level 4–5, representing moderate intensity. The protocol for this intervention was inspired by the power training trials of Ni and Signorile in 2016 and 2017 that suggested this type of exercise to improve bradykinesia in parkinsonian patients.² Upper and lower body exercises will be conducted in two stages: six 9 weeks at level 1 followed by the final six weeks at level 2. Level 2 exercises will feature increased complexity in execution and greater muscle activation.

Table 1. Exercise progression.

	Week	1	2	3	4	5	6	7	8	9	10	11	12
TheraBand® color	Yellow or Red	X	X										
	Green			X	X								
	Blue					X	X						
	Black							X	X				
	Silver									X	X	X	X
Lemgruber®	#200	X	X										
	#201			X	X								
	#202					X	X						
	#203							X	X				
	#204									X	X	X	X
Exercise loading	Time of concentric and eccentric movement	10	10	10	9	9	9	8	8	8	7	7	7
	Set	2	2	2	2	2	2	2	2	2	2	2	2
	Repetitions per set (n)	10	10	10	10	10	10	10	10	10	10	10	10
	RPE ^a	4–5	4–5	4–5	4–5	4–5	4–5	4–5	4–5	4–5	4–5	4–5	4–5

^aExercise progression. Ratings of perceived exertion are according to the Borg scale. Time of concentric and eccentric movement in seconds.

The health education intervention

The health education group (HEG) had tutorial meetings to discuss PD educational topics for 10 weeks, held once a week, lasting 50–60 minutes. They received a 12-chapter booklet that tells the story of a patient who received the diagnosis of PD and learned about its clinical features, treatment and complications, being taught about strategies for living well with the disease.

Every session incorporated group dynamics and included tutorial questions for discussion. A psychologist supervised each session. The educational booklet followed the guidelines outlined in “A Guide to Creating and Evaluating Participant

Materials,” ensuring effectiveness through structured content focused on Parkinson's disease clinical features, accessible language devoid of regionalisms to ensure comprehension across all regions, creative layout, and illustrations at the beginning of each chapter to facilitate and motivate learning.¹⁶ During the sessions, the patients discussed their experiences and difficulties. In the end of each meeting, they answered questions about the major topics presented during that day's program. The chapters cover clinical features of PD, pharmacological treatment, physical activity in PD, freezing of gait, fall prevention, constipation, sleep disorders, cognitive symptoms, urinary incontinence, sexual problems, depression, postural hypotension, and coping strategies.

SAMPLE SIZE

Telephone and presential recruitment of 36 patients was carried out during one month, but only eight were eligible. For feasibility and pilot trials, while a sample size justification is important, a formal calculation may not be appropriate.¹⁷ The sample was divided into two groups: power training group (PTG) (n = 4) and health education group (HEG) (n = 4).

OUTCOMES MEASURES

Data were collected and managed through the Research Electronic Data Capture (REDCap) electronic data collection.

Adherence and safety monitoring

A Data and safety monitoring committee (DSMC) was formed to monitor adherence and safety of the intervention. It was composed of a geriatrician, a psychologist, and a psychology student. Each patient was reminded of the session by a telephone call on the day of the meeting to encourage regular participation. Attendance rate was measured by recording individual participation and the reasons for missed sessions.

Primary outcome

The primary outcome was the feasibility indicators: recruitment, attendance, adherence, retention, adverse events, and participant experience through a VASC.

Attendance rate

The attendance rate at the training sessions was quantified by the number of sessions attended divided by the total number of prescribed sessions. It was calculated as follows: first, the expectation of the total number of appearances was raised, based on the multiplication of all four participants per protocol by the total number of sessions. This result was named as patient-session, excluding patients who were discontinued from multiplication. Patients who were discontinued were considered in the calculation until the last session that they participated. Next, we calculated the percentage of participants' total number in all sessions from the expectation of the total number of patient-session.

Adherence rate

Adherence rate was treated as the percentage of intervention sessions fully accomplished without protocol deviations, given the total number of scheduled sessions. It was quantified based on the ratio between the patients who completed the program and the total number of patients who started the training program. Participants who were discontinued due to safety were considered in the calculation until the last session in which they still participated in the study.

Adverse events

All participants were instructed to report adverse events throughout the period of the study. The DSMC recorded

any symptoms or injuries. An adverse event was defined as any complaint related to the intervention that required the participant to get assistance from a professional health provider or to limit their activities. Cell phone contact was available so that participants could contact the research team immediately in case of a serious event.

VASC

A self-administered questionnaire was used to evaluate safety, feasibility, satisfaction, acceptance, clinical symptoms, and future use at each intervention. The questionnaire had 12 questions including VASC, 10 cm horizontal lines, from worst (left) to best (right) and one open-ended question, and patients' personal remarks. Each question contained five faces ranging from 0 to 10 points in satisfaction. For each question, the patient chose one alternative.

The questionnaire is divided into five domains: feasibility; safety during the intervention; appreciation and satisfaction; effectiveness: clinical symptoms during and after the intervention; and acceptance and future use of the intervention.

The lower the score, the more difficulty or the worse-perceived interest, safety, satisfaction, acceptability and positive effects. We also asked an open question: "In what aspect do you think the intervention may be good for individuals with PD?"

RANDOMIZATION

Randomization was conducted by an external research assistant. It was stratified by sex and MDS-UPDRS III (Movement Disorders Society-UPDRS III) and performed in blocks of eight (four participants per block).

ALLOCATION

The number sequence was password protected on a computer operated by the research assistant. The assessors and data analysts were unaware of the allocation until the end of the study.

STATISTICAL ANALYSES

Descriptive statistics were used to profile the study participants and report recruitment, attendance, adherence, retention, safety and exercise participation and survey outcomes. The data were described in absolute and relative values.

RESULTS

Population characteristics

Eight patients were screened for this study, with 4 in each group. Five (62.5%) were female and the median age was 66 (45–77) years. Three (37.5%) were married and five (62.5%) had family history of PD. Table 2 provides demographic and clinical features.

Table 2. Sociodemographic and clinical features of the groups.

	Group	
	HEG	PTG
Gender		
Female	2 (50.0%)	3 (75.0%)
Male	2 (50.0%)	1 (25.0%)
Age	67.5 (54-75)	66 (66-76)
Family history of Parkinson's Disease	2 (50.0%)	3 (75.0%)
Scholarity		
Primary school (incomplete)	1 (25.0%)	0 (0.0%)
High school (incomplete)	1 (25.0%)	3 (75.0%)
High school (incomplete)	1 (25.0%)	0 (0.0%)
College	1 (25.0%)	0 (0.0%)
Postgraduation	0 (0.0%)	1 (25.0%)
Marital status		
Married	2 (50.0%)	1 (25.0%)
Divorced	1 (25.0%)	0 (0.0%)
Single	0 (0.0%)	1 (25.0%)
Consensual marriage	1 (25.0%)	2 (50.0%)
Hypertension	2 (50.0%)	2 (50.0%)
Type 2 Diabetes Mellitus	1 (25.0%)	0 (0.0%)
Dyslipidemia	1 (25.0%)	2 (50.0%)
Coronary artery disease	0 (0.0%)	0 (0.0%)
Peripheral artery disease	0 (0.0%)	0 (0.0%)
Chronic obstructive pulmonar disease	0 (0.0%)	0 (0.0%)
Depression	2 (50.0%)	1 (25.0%)
Levodopa daily dose (mg)	900 (400-2000)	300 (100-600)
Number of medications in use	7 (3-8)	5 (5-6)
Hoehn and Yahr stage		
2	2 (50.0%)	2 (50.0%)
2.5	0 (0.0%)	1 (25.0%)
3	2 (50.0%)	1 (25.0%)
Schwab & England scale	85 (70-100)	85 (60-100)
Depression	1 (25.0%)	3 (75.0%)
Visual hallucinations	0 (0.0%)	1 (25.0%)
Dysautonomia	3 (75.0%)	3 (75.0%)
Dyskinesia	3 (75.0%)	2 (50.0%)
Freezing of gait	4 (100.0%)	2 (50.0%)
Hemoglobin (g/dL)	13.10 (12.90-13.44)	12.10 (11.60-13.50)
Hematocrit (%)	40.10 (37.50-40.72)	37.80 (37.20-39.00)
Creatinine (mg/dl)	.73 (.60-1.23)	1.03 (.73-1.13)
Thyrotropin (ng/dl)	1895 (1600-2440)	2170 (1852-2526)
25-hydroxycholecalciferol (ng/mL)	28.4 (26.4-29.8)	26.4 (23.7-27.6)
Glycemia (mg/dl)	112 (93-163)	92 (90-102)
Glycated hemoglobina (%)	6.1 (5.3-9.4)	5.2 (5.0-5.4)
UPDRS_total	80.5 (61.0-95.0)	71.0 (49.0-119.0)

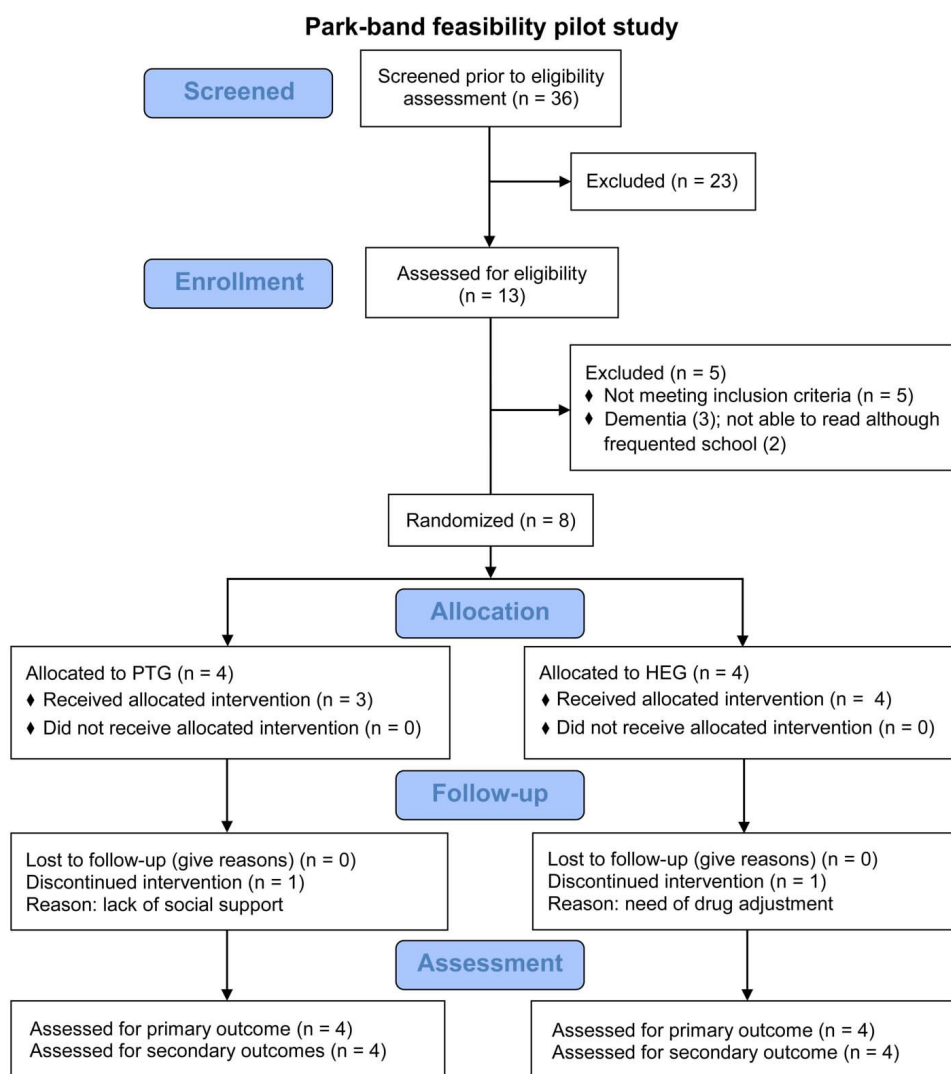
Recruitment rate

We initially screened 36 potential participants from the research database of the hospital's movement disorder outpatient clinic. In the screening telephone calls, we contacted 28 patients because eight telephone numbers were wrong. We excluded 15 patients on phone calls because two patients had a recent cancer diagnosis and would be starting treatment, three had dementia from PD, one was living outside the city, two felt insecure going alone, one didn't have available time, two were illiterate, two were dependent for activities of daily living (ADL), one patient wasn't interested in participating, and one patient didn't accept participate because was feeling a lot of pain related to the disease. The recruitment rate was $8/36 \times 100 = 22\%$ in one month. During recruitment appointment, we evaluated 13 patients. All those who were eligible consented to participate (consenting rate = 100%). Figure 1 shows the study flow diagram.

Attendance rate

The total session's number of interventions was 19 for PTG and nine for HEG, resulting in a total patient-session value of 76 and 36 respectively. In the second week of intervention, one patient placed in HEG discontinued due to lack of social support. In the third, one patient placed in PTG was excluded because of disabling dyskinesia and motor fluctuations that required drug adjustment. We subtracted the absence of patients excluded from the intervention (13 from PTG and six from HEG). We reached the final expected number of 63 appearances in PTG and 30 appearances in HEG. There were two non-replied absences in PTG and five non-replied absences in HEG. Starting from the latter values, represented as 100%, the attendance rate was $61/63 \times 100$ (96.82%) in PTG and $25/30 \times 100$ (83.33%) in HEG. The adherence indicators are in Table 3.

Figure 1. Patient selection process flowchart for Parkinson's disease feasibility study: criteria for patient inclusion.



Adherence rate

Starting from the final expected number of 63 appearances in PTG and 30 appearances in HEG, there were seven non-replied absences and two interrupted sessions (one in PTG and one in HEG). Thus, the adherence rate was $60/63 \times 100$ (95.23%) in PTG and $24/30 \times 100$ (80%) in HEG. Details in Table 3.

Retention rate

There was one discontinuation in each group of four patients, so the retention rate is 75% for both PTG and HEG.

Safety rate

The DSMC did not register any adverse effects associated

with the intervention, no falls in both groups. The safety indicators are in Table 3.

Before and after each training session, the DSMC checked the blood pressure and heart rate of each patient. There was no variation in these vital signs that meant risk. The data are in Table 4.

VASC

The VASC was described in ITT (intention to treat) principle. The answers when they were asked "In what aspect do you think the intervention may be good for individuals with Parkinson's disease?" were: Information to exercise and improve daily life independence, strength, mood, balance, freezing of gait, sleep problems and self-esteem in PTG; strategies to deal with freezing of gait and with disease's coping in HEG.

Table 3. Adherence and safety indicators of the pilot study of PARK-BAND training program.

Participant	Group	Total prescribed sessions	Attended sessions	Replied absences	Reasons for replied absences	Non-replied absences	Reasons of non-replied absences	Interrupted sessions	Reasons of interrupted sessions	Exclusion from trial	Reason of exclusion
A	PTG	19	19	0	—	0	0	0	—	No	—
B	PTG	19	4	0	—	2	Freezing of gait Medical appointment	0	—	Yes	Necessity to change the medication
C	PTG	19	19	1	Work commitment	0	—	0	—	No	—
D	PTG	19	19	1	Viral syndrome	0	—	1	Intestinal problem	No	—
E	HEG	9	8	0	—	1	Lack of social support to accompany the participant	0	—	No	—
F	HEG	9	8	0	—	1	Viral syndrome	0	—	No	—
G	HEG	9	2	0	—	1	Lack of social support to accompany the participant	1	Medical appointment	Yes	Lack of social support to continue the study
H	HEG	9	7	0	—	2	Muscular pain due to parkinsonian symptoms Cellulitis	0	—	No	—

Table 4. Vital signs before and after the PARK-BAND training program.

Patients	A	B	C	D
HR pre	73 (66–82)	78 (63–79)	83 (71–102)	81 (76–92)
HR post	74 (66–82)	70 (64–73)	83.5 (73–102)	77 (69–83)
SBP pre	124 (94–148)	115 (100–143)	117 (100–136)	105 (96–131)
SBP post	119 (99–157)	141 (130–144)	120.5 (110–132)	105 (91–121)
DBP pre	61 (51–71)	71 (60–80)	80 (70–89)	61 (50–76)
DBP post	60 (47–73)	82 (70–83)	80.5 (75–86)	61 (55–69)

Data expressed in median (minimum–maximum); HR: Heart rate in beats per minute; SBP: Systolic blood pressure in mmHg; DBP: Diastolic blood pressure in mmHg.

DISCUSSION

The aim of this study was to evaluate the feasibility of power training in patients with mild-to-moderate PD. Excellent attendance rate (96.82%) and adherence rate (95.23%) in PTG and good attendance rate (83.33%) and adherence rate (80%) in HEG, coupled with no adverse events related to the intervention, good satisfaction and acceptance score were obtained.

Physical activity researchers should use feasibility studies to improve the methods of future trials, considering the challenges of the trials and parkinsonian clinical features (freezing of gait, motor fluctuations, postural instability, comprised motor learning).¹⁸ Since exercise interventions have a potential risk of causing injury, either by the content of the intervention or on the population of interest, the safety of this treatment is fundamental.

The systematic review of 53 trials, involving 1,940 participants with Parkinson's disease, found that adherence and adverse events were rarely reported. However, to support the decision to invest in an intervention, it is essential to have information on retention, adherence, and the occurrence of adverse events, in order to balance its effectiveness with its acceptability and associated risks.⁹

Based on the experience acquired in this feasibility study, we elaborated some recommendations on the protocol to optimize its implementation in a larger definitive study. First, it's necessary to evaluate effectively the social support related to monitoring the most fragile eligible participants. Second, patients with more severe motor fluctuations will need more cautious adjustment in the two months prior to the start of the trial. Third, the high adherence rate we had was facilitated by the phone calls on the day of sessions in both groups and the possibility of replacing the session that couldn't be done on the scheduled day. All participants in both groups received the schedule and were instructed to inform the DSMC in advance regarding when they would not be present. The missed session was offered a day to

replace the absence of each week. Only one patient who needed to be discontinued due to disease complications missed the exercise.¹⁹ Fourth, the HEG was satisfied with the elaboration of a 12-chapter booklet about the challenges faced by PD patients. Each session focused a chapter with group discussion and didactic dynamics. Fifth, we prepared a disease report for the municipal public transport sector, which guaranteed no charge for PD patients less than 60 years of age. Those over or equal to 60 years of age already had a known right. The withdrawal rate was the same between the two groups. Sixth, the interventions were highly supervised which improved their safety and adherence but raised the costs in long term.

To the best of our knowledge, this is the first study to examine systematically the feasibility of power training with elastic devices in PD patients. Important limitations include the small sample size, and the trial had to be interrupted due to COVID–19 pandemic.

This feasibility study suggests the safety, good adherence and attendance rate and participant satisfaction with power training with elastic devices and a health education program using a specific booklet. This preliminary report provides support for future research to determine the efficacy of power training with elastic band in participant with PD HY 1 to 3.

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