



Recruitment rate, feasibility and safety of power training in individuals with Parkinson's disease: a proof-of-concept study

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ABSTRACT | Background: It has been suggested that power training should be implemented in interventions in Parkinson's disease (PD). However, it is necessary to determine the feasibility and safety of training rapid movements in such individuals. Objectives: To determine the rate of recruitment of potential participants, the rate of attendance at training sessions, the levels of adherence to the intervention, and the rate of adverse events. Method: Patients with PD, users of the national public health system underwent power training of the lower limb muscles three times a week for 10 weeks. The number of people who were screened and recruited was recorded, as well as the rate of attendance at the training sessions and adherence to the intervention protocol. Safety was assessed by the presence of adverse events, pain, number of falls, and risk of injury associated with the intervention. Results: Over the course of eight months, 62 individuals were screened and only 13 completed the program. The rates of attendance and adherence were 88% and 97%, respectively. There were no adverse events during training. Two participants reported joint pain and one reported falls during the training period. Conclusions: The recruitment rate was low due to the subjects' difficulties with transportation and lack of interest. The high rates of adherence and attendance and the absence of adverse events suggest that power training is feasible and safe in PD.

Keywords: Parkinson's disease; safety; rehabilitation; physical therapy.

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Introduction

Dopaminergic loss in subjects with Parkinson's Disease (PD) results in reduction in corticospinal activaction with deficit in the recruitment of motor units, contributing to muscle weakness and bradykinesia¹. Moreover, tissue changes such as the selective loss of type II muscle fibers in subjects with PD can contribute to the inability to generate strength during the performance of fast movements². Muscle power is the measure of the capacity to generate strength quickly³ and this is reduced in PD⁴. Such reduction has been attributed to a decline in muscle strength³ and to bradykinesia^{3,4}, and it seems to be associated with slow gait speed and the occurrence of falls in subjects with PD⁵.

Some authors suggest that intervention strategies created to increase muscle power through fast movements should be implemented in exercise programs for PD⁵. Power training programs with low load improve strength, muscle power, balance,

contraction speed, and time of movement in older adults⁶⁻⁸. In these subjects, loads equal to 40% of one maximal resistance (1MR) were able to increase muscle power because of the gains in movement speed^{8,9}.

Power training has been shown to be safe and well tolerated in older adults¹⁰, however there is a need to determine possible adverse events associated with the training of fast movements in frail, sedentary older adults with functional deficits^{10,11}. There is still no evidence that this kind of exercise can be safe and tolerated by subjects with PD, although safety is the main concern for these subjects when deciding to participate in a clinical trial¹².

Proof-of-concept clinical trials generate the first evidence that a treatment might be effective, provide information about tolerance and adverse events associated with this treatment¹³, and contribute to the planning of controlled randomized trials^{13,14}. In addition, information about attendance and

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adherence is important because it reflects the treatment's adequacy for a targeted population and should be considered during the development of training protocols for patients with PD^{15,16}. Finally, it is necessary to understand the factors that could potentially interfere in the process of selection and recruitment of research subjects with PD users of the national public health system.

Therefore, the overall aim of the present study was to investigate the feasibility and safety of lower limb power training in subjects with PD. Specifically, the intent was to determine the rate of recruitment, the rate of attendance at the training sessions, the level of adherence to the proposed intervention protocols, and the rate of adverse events related to training.

Method

The current study was developed with subjects with PD recruited according to the following inclusion criteria: diagnosis of idiopathic PD, age of 50 years and over, classification on the Hoehn & Yahr Scale (HY)¹⁷ as stage 1 to 3, regular use of anti-parkinsonian medication, score of more than 24 on the Mini Mental State Exam (MMEE)¹⁸, ability to walk 14 meters independently and sign the informed consent form. Subjects were excluded if they had adverse clinical conditions that prevented their participation in the proposed protocol, such as uncontrolled arterial hypertension and other neurological, orthopedic or rheumatologic disorders. Subjects were also excluded if they had undergone surgical intervention for PD, received physical therapy treatment or exercised regularly for at least two months before the start of this study. The present research had the approval of the Research Ethics Committee (ETIC 000/10) of Universidade Federal de Minas Gerais (UFMG), Belo Horizonte, MG, Brazil, and free informed consent was obtained from all of the participants.

Subjects with PD received training three times a week for ten weeks, with sessions lasting 60 minutes. The power training sessions were conducted by a trained physical therapist in groups of up to four participants. The lower limb muscle groups trained were the hip flexors, extensors, adductors, abductors; knee flexors and extensors; ankle dorsiflexors; and plantar flexors. Subjects were instructed to perform each movement 'as fast as possible' in the concentric phase of the exercise.

Free weights and elastic bands (Thera-bands®) were used for training. For the free weights, the load was set at 40% of 1MR^{8,9} across all exercises and

readjusted every two weeks. MR was defined as the maximal load that can be raised once throughout the whole range of motion without compensation⁵. With the elastic bands, progression was made when subjects were able to perform three sets of ten repetitions with slight fatigue in the last set⁷. Three sets of ten repetitions were performed for each exercise with 1-2 minutes of rest between them, according to the protocol proposed by the American College of Sports Medicine (AMCS)¹⁹. A vest with four front pockets and four back pockets was designed to hold the free weights during the exercises for the plantar flexors. Blood pressure and heart rate were measured before, during, and after each training session.

Recruitment assessment

Recruitment was done at the Movement Disorders Clinic of the University. This clinic is a center of reference in the southeastern part of the country in research and assistance to subjects with various movement disorders, such as parkinsonisms²⁰. The clinic's patients use the national public health system (Sistema Único de Saúde-SUS).

Subject recruitment was conducted by physical therapy students capable of evaluating the eligibility criteria while patients waited to be seen by the neurologist. Data were recorded for the number of eligible subjects and for the reasons for ineligibility. Similarly, data were recorded for the reason given by eligible subjects for declining to participate in the study.

Assessment of attendance and adherence

Data on attendance and adherence to training protocol were collected by the physical therapist during the period of intervention. At each training session, the subjects' presence or absence was recorded, as well as the reason for the absence. The total number of training sessions available varied slightly among the subjects due to the public holidays during the period of intervention.

Treatment adherence was determined by the number of sessions completed in full (60 minutes). The number of incomplete sessions and the reasons for not completing the session were recorded. The reason for the absence was identified on the same day during a phone call from the researchers.

Safety evaluation

The safety of the power training program was assessed on the basis of adverse events, pain during and after the activity, number of falls, and risk of injury associated with the treatment. Adverse events were monitored and recorded at each session and defined as injury or complaint related to the treatment if they required that the subject seek professional help or limited his/her activities²¹. Throughout each session, the supervising physical therapist asked each subject about the presence of any discomfort and pain related to the activity. In the presence of pain, the Visual Analogue Scale was used. Risk of injury was defined as the ratio of number of subjects with complaints of adverse events to the total number of subjects²².

The Borg Scale of Perceived Exertion²³ was used after each training session in order to investigate the subject's tolerance to the exercise. The minimal score (6) refers to the perception of no effort during exercise, and the highest score (20) reflects maximal effort.

Statistical analysis

Descriptive statistics such as mean (standard deviation) and percentage were performed for the proposed variables.

Results

A total of 13 subjects with PD (eight men and five women), with a mean age of 63.8±12.3 years (50-87), participated in the training program. In 8%, the HY classification was equal to 1.5; in 38%, HY=2.5; and 16%, HY=3. The mean length of evolution of the disease was of 7.9±4.6 years (2-16).

Table 1 shows the socio-economic and cultural profile of the subjects. Most of them were married, lived with their relatives, and had an income of less than 2.5 times the minimum wage. All subjects made use of levodopa-based medication combined with other anti-parkinsonian medications, such as dopaminergic agonists, anticolinergics, and amantadine. The most frequent health condition was arterial hypertension, present in five participants (38%), followed by osteoarthritis in four (31%), and depression in three (23%).

Recruitment

A total of 62 subjects with PD were selected for the verification of eligibility between March and October/2011. Of these, 19 (31%) were excluded because they did not fulfill the inclusion criteria (Table 2). The major reasons for the exclusion were: uncontrolled arterial hypertension, recent orthopedic surgery, and early onset PD. Of the 43 eligible subjects, 36 (84%) refused to participate in the study, and the reasons are shown in Table 3. The most significant reason was the lack of financial resources for transportation and access to the training location.

In short, seven (11%) subjects were eligible and consented to participate in the study. The nine subjects who reported lack of money for transportation had their expenses covered by the researchers, reaching a total of 16 subjects. Of these, three had to interrupt their training on the third, fifth, and sixth week of the protocol, despite attendance above 89% until the date they left the study. The reasons for withdrawing

Table 1. Socio-economical and cultural characteristics of the subjects (n=13).

| Variable | (%) |
|------------------------------------|----------|
| Marital status | |
| Married | 8 (62) |
| Single, widowed or divorced | 5 (38) |
| Living arrangements | |
| With family | 12 (92) |
| Alone | 1 (8) |
| Educational Level (years of study) | |
| <9 years | 10 (77) |
| 9 years | 1 (8) |
| 12 years | 2 (15) |
| Family income | |
| 1 - 3 x minimum wage | 12 (92) |
| 4 - 6 x minimum wage | 1(8) |
| Occupation | |
| Retirees and pensioners | 13 (100) |

Table 2. Number (%) of individuals with PD who were screened but excluded (n=19).

| Reason | Excluded (%) |
|---|--------------|
| Patients with adverse health conditions | 4 (21) |
| Early onset PD (<50 years) | 4 (21) |
| Current physical therapy treatment | 3 (16) |
| Patients on waiting list or submitted to surgery for PD | 3 (16) |
| MMSE (<24) | 3 (16) |
| Dementia/Psychiatric symptoms | 2 (10) |

MMSE: Mini-Mental State Examination.

Table 3. Number (%) of individuals with PD who declined to participate (n=36).

| Reason | (%) |
|------------------------------------|--------|
| Lack of money for transportation | 9 (25) |
| Lack of interest (motivation) | 8 (22) |
| Lack of caregiver/partner support | 7 (19) |
| Living in other cities | 7 (19) |
| Disliked exercise/physical therapy | 5 (15) |

were personal problems, such as a relative diagnosed with a serious illness or involved in an accident and the need to take care of grandchildren.

Attendance

The rate of attendance was of 88±7.3%, thus 328 of the 373 available sessions were attended by the subjects. The main reasons for the absence were: health problems, such as feeling unwell and having influenza (35%); difficulties with public transportation (overcrowding, lack and bad conditions of the vehicles) (32%); family problems (28%), and travel for religious purposes (5%). Eight subjects (61%) attended 89% or more of the available sessions.

Adherence

Of the 328 sessions attended by the subjects, 318 were completed, and ten were not completed due to health reasons. Four subjects did not complete the total time of the training session due to motor fluctuations (70%) and physical feeling of indisposition.

Safety

Adverse events did not happen during training. Two subjects reported knee and back pain related to preexisting osteoarthritis. The average intensity of pain was four (3-5) according to the Visual Analogue Scale, therefore it was not necessary to exclude the subjects from the program. In one of them, the pain persisted in the following session, and it was necessary to reduce the intensity of the exercises, however there was no pain in the subsequent sessions. One participant reported two falls that occurred at home during the ten-week training period but without consequences or need for medical attention. The risk of injury was null, considering the absence of occurrence of adverse events. Although arterial hypertension was the most frequent health condition,

no cardiovascular problems were reported during the intervention period. The average perceived exertion was 12.8±1.1 (11-14), which corresponds to 'somewhat hard' on the Borg Scale.

Discussion

To our knowledge, this is the first study to investigate the feasibility and safety of a power training program in subjects with mild to moderate PD. The data concerning the recruitment rates, attendance, adherence, and safety of the subjects will be discussed next.

Recruitment

It has been pointed out that the main obstacle to the implementation of clinical experiments in PD is patient recruitment^{12,24}. The present study showed a low recruitment rate of 11% during the period of eight months. Considering the characteristics of the recruitment environment and of the direct access of the researchers to the subjects with PD, a higher success rate was expected. Several reasons have been cited for the low rates of recruitment in feasibility studies in PD. Ashburn et al.24 cited the inclusion of subjects with PD who were physically and cognitively capable of participating in an exercise program for balance improvement as an obstacle to recruitment, which had a success rate of 13% in a period of one year of study. In the study by Keus et al.25, the effectiveness of a physical therapy program based on exercises for posture, balance, and gait was evaluated, and the recruitment rate was 14%, although the period had not been defined. According to the authors, the greatest difficulty was the refusal of subjects with PD to participate because of the possibility of being allocated to the control group, with no treatment²⁵.

In the present study, the main obstacles to recruitment were the lack of financial resources for transportation to the training location, the lack of interest, and the lack of a caregiver/partner. The lack of interest was the second most frequent reason for not joining the study. The fact that the recruitment was performed before the doctor's appointment may have been a limitation of the study, since there was no referral from the neurologist. Some studies suggested that the recommendation of a neurologist plays a major role in a PD subject's decision to participate in an exercise program^{12,26}. Valadas et al.¹² showed that the neurologist's recommendation of a clinical trial had a more determining role in that decision

than the severity of symptoms and free medication and treatment. It is possible that the emphasis given by the clinical neurologist to the importance of the participation in exercise programs can maximize the recruitment rate of these programs.

In addition to having a low income, the participants came from the suburbs and had to use one or more means of public transportation to get to the city center, where the training was conducted. The distance between their homes and the training location in addition to mobility impairments (e.g. freezing, bradykinesia, fear of falling) meant that the subject required a caregiver/partner for the trip. Recently, another study developed in Brazil²⁷ also cited lack of money for transport as the main barrier to participation and attendance by subjects after stroke. Studies that investigated the sociodemographic profile of SUS users in different regions in Brazil reported that such users have low income, low educational levels, and greater need for health support^{28,29}. Therefore, to conduct future studies, it is crucial that researchers secure sufficient funding for transportation so that subjects with PD who use SUS can take part in the research, thus improving recruitment rates.

Attendance

This study showed high attendance at the intervention sessions, close to the rate reported by studies on strength training in PD, which ranged from 89% to 92% A qualitative analysis of progressive resistance programs for individuals with PD indicated that socialization with people at the same stage of the disease was the most important motivating factor for attendance by these subjects It is possible that the group power training in the present study fostered integration among the participants, motivating them to continue with the program. Researchers and clinicians should consider the group approach in PD interventions in order to generate greater social interaction and, consequently, better attendance.

Three participants had the flu during the training period, which coincided with the winter, and the season's typically low temperatures may have contributed to the symptoms. Moreover, the difficulties with public transport (e.g. overcrowding, poor maintenance, and limited number of vehicles) were also cited as justification for absences. A recent systematic review showed that the lack of transportation was the most common reason given by subjects with PD for discontinuing their participation in different training program¹⁶. Most participants lived far from the training location and

relied solely on public transportation. According to Ribeiro et al.²⁸, SUS users seek less preventive intervention and rehabilitation treatment than nonusers. It is possible that the lack or precariousness of public transportation options available to these individuals is one of the aspects that influences the decision to participate in treatments that require more frequent weekly attendance, as in the case of physical therapy.

Adherence

One of the subjects did not complete five of the sessions because of an 'off period' characterized by the early end of the effect of medication. According to Ahlskog and Muenter³², after four to six years of levodopa, 40% of users exhibit motor fluctuations. Considering the prevalence of this drug complication over the course of the disease, studies should report its occurrence during any type of intervention. In addition, more flexible scheduling of training sessions can increase adherence of individuals with PD to exercise programs.

Safety

A recent study suggested that power training can be implemented in physically active older adults, but may not be adequate to those considered fragile and sedentary¹¹. The reason given for this was the vigorous nature of power training, which requires physical fitness in order to allow adequate adaptation of the tissues¹¹. However, in this study, no adverse events related to power training in subjects with PD were reported. Although the subjects were sedentary and some had balance deficits, there was no serious discomfort or injury. The absence of adverse events might be attributed to the load used. Exercises with light load have been shown to be effective, better tolerated, and less likely to cause injury during training in older adults¹⁰. The study by de Vos et al.¹⁰ on power training in older adults showed that low loads (20% of 1RM) increased peak power just as moderate (50% 1RM) and high (80% 1RM) loads, with a lower occurrence of injury than in others.

Some participants with a history of osteoarthritis reported pain during exercise. It has been suggested that strength exercises with low loads are less likely to aggravate the symptoms of illnesses such as osteoarthritis [OA] in older adults³³. However, it is necessary to consider the possibility that training exacerbates pain and the fact that OA has been singled out as one of the most frequent causes of chronic

pain in patients with PD and may be exacerbated by • References the disease³⁴. Therefore, a careful joint assessment is recommended prior to the start of the exercise program as well as greater care during its execution, specifically with range of motion exercises, in order to avoid the worsening of pain.

The participant who reported falls early in the treatment had already fallen in the previous year and did not suffer more falls in the last five weeks of intervention. Freezing is a common disorder in the gait of subjects with PD and contributes to the occurrence of falls as much as postural instability³⁵. Power training can improve the ability to react quickly to unexpected disturbances and contribute to greater agility, minimizing the effects of freezing and the occurrence of falls in PD. However, this aspect needs to be investigated further.

Given the need for fast and explosive performance of the exercises, individuals can report a significant effort due to bradykinesia. In the present study, however, the subjects' average score on the Borg Perceived Exertion Scale indicated that the perceived exertion was close to 'somewhat heavy'. Sayers⁹ showed similar results after a power training with 40% of load in older adults. The findings of this study suggest that fast, intense, and explosive movements were perceived as tolerable by individuals with mild to moderate PD, contributing to greater adherence to the program. Future studies are needed to investigate perceived exertion in power training in individuals at more advanced stages of the disease, whose motor impairment due to more pronounced rigidity and bradykinesia may require greater effort during the exercises.

The results showed a low recruitment rate due to difficulties with transportation and lack of interest of individuals with PD in participating in the study. The high rates of attendance and adherence combined with the absence of adverse events indicate that power training is feasible and safe in PD.

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