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Treadmill training and kinesiotherapy versus conventional physiotherapy in Parkinson's disease: a pragmatic study

Esteira e cinesioterapia versus fisioterapia convencional na doença de Parkinson: estudo pragmático

Entrenamiento en la cinta de correr y la cinesioterapia versus fisioterapia convencional en la enfermedad de Parkinson: estudio pragmático

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Abstract

Introduction: Physiotherapy has been identified in the literature as an important treatment for individuals with Parkinson's disease (PD) to improve functional capacity. Little is discussed about the physiotherapy practice environment for this population. **Objective**: To assess pragmatically the effects of two physiotherapy protocols: Conventional Physiotherapy (CP) and Treadmill Training and Kinesiotherapy (TTK) in PD patients. **Method**: Twenty-four PD patients classified from 1 to 3 on the Hoehn and Yahr scale were randomly distributed into two groups. In CP group (12 patients), exercises aimed to improve range of motion, bradykinesia, postural adjustments and gait. In TTK group (12 patients), exercises aimed to improve physical fitness, mobility and

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functional independence. The treatments were performed for 50 minutes, twice a week for 14 weeks. The following evaluations were performed before and after the interventions: Unified Parkinson's Disease Rating Scale (UPDRS); gait speed (GS); up stairs (US) and down stairs (DS) tests; timed get-up-and-go test (TUG) and 6-Minute Walk Distance Test (6-MWDT). Sociodemographic and clinical data were presented as descriptive analysis. Variables with normal and non-normal distributions were analyzed by specific statistical tests. **Results**: Intragroup analysis showed significant results for the TTK group (TUG, US, DS, GS, UPDRS total and UPDRS II) and for the CP group only UPDRS total. Intergroup analysis was favorable for the TTK group (TUG, US, DS, 6-MWDT). **Conclusion**: CP group improved the patients' general clinical status, while treadmill and kinesiotherapy improved the physical-functional and clinical aspects.

Keywords: Parkinson's Disease. Physiotherapy (modalities). Motor Activity. Physical Fitness. Rehabilitation.

Resumo

Introdução: *A fisioterapia tem sido apontada na literatura como um importante tratamento para indivíduos com doença de Parkinson (DP) para melhorar a capacidade funcional. Pouco se discute sobre o ambiente da prática fisioterapêutica para essa população.* ***Objetivo:*** *Avaliar pragmaticamente os efeitos de dois protocolos fisioterapêuticos: Fisioterapia Convencional (FC) e Treinamento em Esteira e Cinesioterapia (TEC) em pacientes com DP.* ***Método:*** *Vinte e quatro pacientes com DP entre 1 e 3 da escala Hoehn e Yahr foram alocados aleatoriamente em dois grupos. No grupo FC (12 pacientes) foram aplicados exercícios visando melhorar a amplitude de movimento, bradicinesia, ajustes posturais e marcha. No grupo TEC (12 pacientes) foram aplicados exercícios visando melhorar a aptidão física, mobilidade e independência funcional. Os tratamentos foram conduzidos por 50 minutos, duas vezes por semana durante 14 semanas. Avaliações realizadas antes e após a intervenção: Unified Parkinson's Disease Rating Scale (UPDRS); velocidade da marcha (VM); subir escadas (SE) e descer escadas (DE); timed get up and go test (TUG) e Teste de Caminhada de 6 Minutos (TC6'). Dados sociodemográficos e clínicos apresentados como análise descritiva. Variáveis com distribuição normal e não-normal foram analisadas por testes estatísticos específicos.* ***Resultados:*** *Análise intragrupo mostrou resultado significativo para o grupo TEC (TUG, SE, DE, VM, UPDRS total e UPDRS II) e para o grupo FC apenas UPDRS total. Análise intergrupo foi favorável para o grupo TEC (TUG, SE, DE, TC6').* ***Conclusão:*** *A FC melhorou o estado clínico geral dos pacientes, enquanto a esteira ergométrica e cinesioterapia melhoraram aspectos físico-funcionais e clínicos.*

Palavras-chave: *Doença de Parkinson. Fisioterapia (modalidades). Atividade Motora. Aptidão Física. Reabilitação.*

Resumen

Introducción: *La fisioterapia se ha señalado en la literatura como un importante tratamiento para las personas con enfermedad de Parkinson (EP) para mejorar la capacidad funcional. Poco se discute sobre el ambiente de la práctica fisioterapéutica para esa población.* ***Objetivo:*** *Evaluar pragmáticamente los efectos de dos programas de tratamiento fisioterapéutico: Fisioterapia Convencional (FC); Entrenamiento en la cinta de correr y la Cinesioterapia (ECCC) en pacientes con EP.* ***Método:*** *Veinticuatro pacientes con EP entre 1 y 3 de la escala Hoehn y Yahr, se asignaron al azar en dos grupos. En el grupo FC (12 pacientes) se aplicaron ejercicios para mejorar la amplitud de movimiento, bradicinesia, ajustes posturales y marcha. En el grupo ECCC (12 pacientes) se aplicaron ejercicios para mejorar la aptitud física, movilidad e independencia funcional. Los tratamientos se realizaron durante 50 minutos, dos veces por semana durante 14 semanas. Evaluaciones realizadas antes y después de la intervención: Unified Parkinson's Disease Rating Scale (UPDRS); velocidad de marcha (VM); subir escaleras (SE) y bajar escaleras (BE); timed get up and go test (TUG) y Prueba de Caminata de 6 Minutos (TC6'). Datos sociodemográficos y clínicos presentados como análisis descriptivo. Las variables con distribución normal y no normal se analizaron mediante pruebas estadísticas específicas.* ***Resultados****:*

*El análisis intragrupo mostró un resultado significativo para el grupo ECCC (TUG, SE, BE, VM, UPDRS total y UPDRS II) y para el grupo FC sólo UPDRS total. El análisis intergrupo fue favorable para el grupo ECCC (TUG, SE, BE, TC6'). **Conclusión**: La FC mejoró el estado clínico general de los pacientes, mientras que la cinta de correr y la cinesioterapia mejoraron aspectos físico-funcionales y clínicos.*

Palabras clave: *Enfermedad de Parkinson. Fisioterapia (modalidades). Actividad Motora. Aptitud Física. Rehabilitación.*

Introduction

Parkinson's disease (PD) is a progressive neurodegenerative disease affecting the central nervous system. The primary impairment is the depletion of dopamine neurons in the substantia nigra pars compacta in the midbrain [1].

Currently, PD affects around 0.3% of the world's population. When considering people above their 60's, the percentage increases to 1% [2]. Due to the elderly population growth in the world, the number of people affected by this disease is going to increase over the next decades [2].

The negative effects of PD on daily activities (ADL's) are evident and worsen with the progression of the disease. One of the non-pharmacological strategies for PD is physical exercise. Some of the variables directly related to the regular practice of physical activity are: muscle strength, muscle endurance and cardiorespiratory capacity [3-5].

According to Morris [6], in patients in stages from 1 to 3 on the Hoehn and Yahr scale [7], the physiotherapy treatment aims to promote health, maintain regular physical activity, train movement strategies, promote muscle strengthening, maintain the range of motion and prevent falls [8].

The practice of physical exercise is important for individuals with PD. Although physical exercise does not cure the disease, it can positively influence functional capacity and consequently improve patients' health. Dance, yoga, muscle strengthening, and aerobic exercises are different types of physical exercise that can be used in PD. These physical exercises are directly associated with improvement in different ADL's, mobility and social activity [9-11].

Physical exercise is a neuroprotective modality in PD and cannot be considered less important than therapeutic strategies, but should be adequately exploited [12]. Shulman et al. [13] identified important differences regarding the physical improvement associated with the motor stimulus given to the individual. Low-intensity treadmill training (40% to 50% of heart rate reserve) was noticed more beneficial in improving gait speed compared with high-speed treadmill (70% to 80% of heart rate reserve), resistance and stretching training [13]. Carvalho et al. [14] proved that a 12-week treadmill intervention training at 70% of maximum heart rate improved 35% of UPDRS III. Another intensity proposed was a 7-week treadmill training at 50% to 60% of heart rate reserve. Studies indicate that treadmill is effective in cardiovascular conditioning (improving oxygen consumption (VO2) and heart rate and decreasing double product peak) and gait variables, though muscle resistance training is effective in improving muscle strength in PD [11, 13-17].

Many studies have demonstrated the benefits of physical exercise to motor deficits and functional capacity, represented by the improvement in the UPDRS total score, and sections II (ADL's) and III (motor examination), quality of life, muscle strength, balance, posture and gait [8, 13-15, 17-19].

Therefore, physical exercise undoubtedly benefits the rehabilitation of PD patients. The question is whether physiotherapy practice replicates the improvements observed in well-defined and controlled settings. In this way, pragmatic studies seek to identify the effectiveness of an intervention within less controlled environments. Also, pragmatic studies are designed to test the effectiveness of the intervention in a broad routine clinical practice to maximize applicability and generalizability [20]. Thus, this study aimed to evaluate the effects of two physiotherapy programs: Conventional Physiotherapy (CP) and Treadmill Training and

Kinesiotherapy (TTK), on functional outcomes of outpatients with PD, using a pragmatic design.

Methods

This study consists of a pragmatic analysis initially including 27 patients of both genders, aged between 55 and 75 years old, diagnosed with PD according to the Brain Bank of the United Kingdom standards, and classified in stages from 1 to 3 on Hoehn and Yahr scale. The following exclusion criteria were adopted: patients without an adequate drug regimen for at least three months; patients who had undergone physiotherapy within three months before the protocol; inability to perform physical exercises; presence of other neurological disorders and/or severe impairment of the cardiorespiratory and/or musculoskeletal system. In cases in which patients had changes in the drug regimen during the study or missed sessions, they were disregarded.

The patients were randomly divided into two groups – CP and TTK using the fixed allocation randomization method. Allocation to the CP and TTK groups was undertaken using a ratio of 1:1. A detailed evaluation was carried out based on specific protocols that included: clinical, motor and functional status (Unified Parkinson's Disease Rating Scale – UPDRS). The scores of Sections II (daily activities) and III (motor exam) were used as well as the total score [21]; gait speed (GS), and upstairs (US) and downstairs (DS) tests [22]; Dynamic balance and mobility (Timed get-up-and-go test – TUG) [23] and functional capacity (6-Minute Walk Distance Test – 6MWDT) [24, 25] were assessed. Both physiotherapy programs were performed with 50-minute sessions, twice a week for 14 weeks. In both groups, patients were treated by two different physical therapists. The treatments were performed individually for both groups. The outcome variables were assessed at baseline and after the 14th week.

The CP group protocol aimed to improve the range of motion, bradykinesia, postural adjustments and gait impairments. This protocol emphasized trunk, and upper and lower limbs. Patients underwent the following phases in each session: 1st phase: relaxation and active stretching exercises; 2nd phase: mobility and dynamic balance training; 3rd phase: strengthening training; 4th phase: functional activity training; 5th phase: relaxation and active stretching exercises.

In the TTK group protocol, the session was divided into two phases, namely: 1st phase: 5 minutes walking on the treadmill to warm up (slow speed), followed by 15 minutes training on the treadmill with moderate to high intensity (Borg Scale 3 to 7); 2nd phase: training on a circuit using dumbbells and over balls (20 minutes); 3rd phase: training on stationary bike as well as step workout (10 minutes).

To analyze clinical and demographic data, Student's t-test or Mann-Whitney Rank Sum test was adopted for comparison between CP and TTK groups. Mean and standard deviation (SD) were used for obtaining the descriptive statistics. According to data distribution (Shapiro-Wilk test), Paired t-test and Wilcoxon Signed Rank Test were used for the intra-group analysis for pre and posttreatments data. The differences were considered significant when $p < 0.05$, and all analyses were performed in the SIGMA PLOT 11.0 software.

The Ethics Research Committee approved the study by the number protocol CAAE 15050713.6.2001.5257, and all participants signed a Free and Informed Consent Term.

Results

Twenty-seven patients were included in the study and divided into two groups, namely: CP or TTK. Each group consisted of 12 PD patients, totalling 24 patients. Three patients were excluded because they missed the sessions and, consequently, they did not complete the physiotherapy treatment programs (Figure 1). The values of the pretreatment intergroup did not present statistically significant differences, showing the homogeneity of the samples selected considering the following variables: age, H&Y, PD onset, UPDRS total, UPDRS II, UPDRS III, TUG, 6MWDT, DS, US and GS.

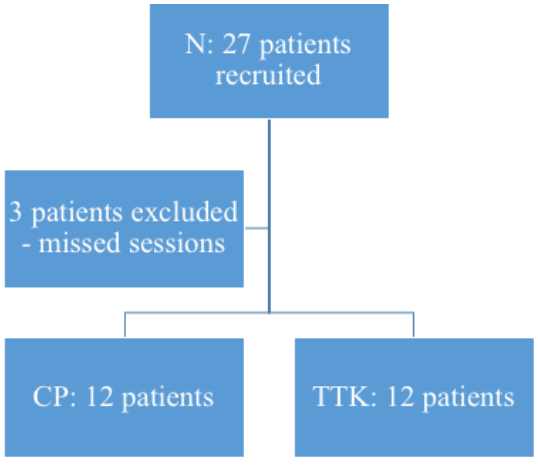

Figure 1 – Flow chart of patient inclusion. CP: Conventional Physiotherapy; TTK: Treadmill Training and Kinesiotherapy.

Both groups did not present statistically significant differences related to the variables analyzed, except for gender. CP group presented a similar number between male and female (7/5), while TTK group had a discrepancy between male and female (11/1) (Table 1).

Table 1 – Clinical and demographic data of CP and TTK groups at baseline

Variables	CP (mean±SD)	TTK (mean±SD)	p-value
Age (years)	67.42 ± 10.85	61.83 ± 11.09	0.226#
Gender (M/F)	7 M / 5 F	11 M / 1 F	-
H&Y (1-5)	2 ± 0.67	1.87 ± 0.86	0.695+
PD onset (years)	6.42 ± 6.93	4.92 ± 3.94	0.839+
UPDRS total (0-199)	46.17 ± 12.54	44.08 ± 20.06	0.763#
UPDRS II (0-52)	14.50 ± 7.42	14.33 ± 5.53	0.951#
UPDRS III (0-108)	24.17 ± 8.99	23.50 ± 12.54	0.882#
TUG (s)	11.06 ± 3.37	10.36 ± 4.11	0.341+
6MWDT (m)	420.58 ± 124.42	500.66 ± 109.96	0.109#
DS (s)	5.26 ± 2.56	4.78 ± 2.49	0.341+
US (s)	5.16 ± 2.05	4.77 ± 1.60	0.564+
GS (m/s)	1.13 ± 0.31	1.16 ± 0.26	0.827#

Note: Clinical and demographic data. UPDRS (Unified Parkinson's Disease Rating Scale); H&Y (Hoehn&Yahr Staging Scale); TUG (Timed get-up-and-go); 6MWDT (6-Minute Walk Distance Test); DS (Downstairs); US (Upstairs); GS (gait speed); PD (Parkinson's disease); CP (Conventional Physiotherapy); Treadmill Training and Kinesiotherapy (TTK); SD: standard deviation; s: second; m: meters; m/s: meters per second; #: Student's t-test; +: Mann-Whitney Rank Sum Test.

Analyses for motor outcomes, namely: TUG, 6MWDT, DS, US, GS, UPDRS total, UPDRS II and UPDRS III for intra/intergroup were performed considering pre/posttreatments. Intragroup analysis for CP group showed statistically significant difference only UPDRS total (Paired t-test). Intragroup analysis for TTK showed statistically significant differences based on Paired t-test for TUG, US, GS, UPDRS total, UPDRS II and based on Wilcoxon Signed Rank Test for DS (Table 2).

Intergroup analysis showed statistically significant differences based on Student's t-test for 6MWDT, US, GS, UPDRS II in favour of the TTK group, and TUG, DS (based on Mann-Whitney Rank Sum Test), supporting the TTK group (Table 2).

Table 2 – Clinical and motor outcomes of cp and ttk groups

Variables	CP			TTK			CP/TTK post
	Pre (mean ± SD)	Post (mean ± SD)	p value	Pre (mean ± SD)	Post (mean ± SD)	p value	p value
TUG (s)	11.06 ± 3,37	11.48 ± 3.68	0.451_1	10.36 ± 4.11	7.77 ± 1.44	$*0.023_1$	*0.002+
6MWDT (m)	420.58 ± 124.42	417.00 ± 106.84	0.275_2	500.66 ± 109.96	554.50 ± 97.55	0.065_1	*0.003#
DS (s)	5.26 ± 2.56	5.41 ± 2.40	0.707_1	4.78 ± 2.49	3.73 ± 1.43	$*0.034_2$	*0.040+
US (s)	5.16 ± 2.05	5.29 ± 1.31	0.775_1	4.77 ± 1.60	3.73 ± 1.02	$*0.025_1$	*0.004#
GS (m/s)	1.13 ± 0.31	1.11 ± 0.25	0.586_1	1.16 ± 0.26	1.38 ± 0.27	$*0.016_1$	*0,020#
UPDRS total (0-199)	46.17 ± 12.54	37.83 ± 12.16	$*0.014_1$	44.08 ± 20.06	33.50 ± 10.32	$*0.024_1$	0.259#
UPDRS III (0-108)	24.17 ± 8.99	19.17 ± 9.34	0.093_1	23.50 ± 12.54	19.33 ± 7.61	0.155_1	0.962#
UPDRS II (0-52)	14.50 ± 7.42	12.25 ± 4.24	0.248_1	14.33 ± 5.53	8.75 ± 3.25	$*0.007_1$	*0.034#

Note: Variables of the CP (Conventional Physiotherapy) and TTK (Treadmill Training and Kinesiotherapy) groups. TUG (Timed get up and go); 6MWDT (6-Minute Walk Distance Test); DS (Downstairs); US (Upstairs); GS (gait speed); UPDRS (Unified Parkinson's Disease Rating Scale); SD: standard deviation; s: second; m: meters; m/s: meters per second; CP/TTK post: intergroup analysis; *: $p < 0.05$; #: Student's t-test; +: Mann-Whitney Rank Sum Test; $_1$: Paired t-test; $_2$: Wilcoxon Signed Rank Test.

Discussion

This study proposed to analyze in a pragmatic way two different types of physiotherapy interventions (CP and TTK) in PD patients.

According to the European Physiotherapy Guidelines for PD [26], the physiotherapy intervention in patients with stage 2 of H&Y has some objectives: to improve or maintain activities such as gait, balance, transfers and manual activities. Concerning UPDRS II, there are aspects related to walking, transfers and ADL's. Thus, it evaluates outcomes that can be explored in the different physiotherapy interventions, corroborating the recommendations by the European Physiotherapy Guidelines for PD [26]. Clarke et al. [27] combined Physiotherapy and Occupational Therapy in a pragmatic study including individuals (n = 746) with PD and showed, in the early stages of the disease, patients did not have gains in relation to ADL's compared with the control group, which did not perform any intervention. Thus, the authors pointed out a difficulty in the clinical practice of the Physiotherapy and Occupational Therapy, which demands an appropriate dosimetry for each patient. Besides, Coutinho et al. [20] defend the practice of pragmatic clinical research to confirm controlled clinical trials, thus achieving results that can be replicated.

Intragroup analysis showed an improvement in the CP group only for UPDRS total. According to the American College of Sports Medicine [28], when the protocol aims to gain strength or physical conditioning, working at the limit of every individual's capacity is necessary. A problem observed in the treatment offered to patients was that they did not perform at their maximum individual capacity. What we observed in this Physiotherapy Service may represent what happens in the Brazilian scenario. Recognizing the different realities of Physiotherapy Services that assist PD patients would be a need. Although physiotherapy treatments were based on the European Physiotherapy Guidelines for PD [26], the dosimetry was not prescribed for each participant.

The TTK group showed an improvement in almost all variables (TUG, DS, US, GS, UPDRS total, UPDRS II), except UPDRS III and 6MWDT, that showed a tendency to improve, but we believe that if the speed had been controlled, the results could have been better. These results pointed that this intervention was efficient for most of the variables analyzed, despite the poor control of the dosimetry. The intergroup improvement in TUG, DS, US, GS, 6MWDT and UPDRS II in favor of the TTK group shows it was a better protocol than CP group, pointing to a multimodal approach, including an aerobic training that could bring better results for PD patients, also pointed out by Shulman et al. [13]. Perhaps the improvement observed in the TTK group is because it was composed mainly of men (11M/1F) compared with the CP group (7M/5F). Men and women could have different physical responses when exposed to the same exercise protocol [28].

Shulman et al. [13] evaluated three different protocols of physical intervention: high-speed treadmill training, low-speed treadmill training, and stretching and strengthening in subjects with PD. The intensity was monitored for each patient, showing patients improved the outcomes analyzed. That is, muscle strength training increased their strength. Patients who performed treadmill aerobic training with different intensities improved gait speed and cardiovascular conditioning. Our study demonstrated a statistically significant improvement in the 6MWDT in the TTK group. The study carried out by Carvalho et al. [14] showed tendency to decrease symptoms of the disease for aerobic training and muscular strengthening groups compared with the conventional physiotherapy group, corroborating the results of our study. Regarding muscle strengthening, determining the loads implemented is necessary, so that better results can be obtained. To obtain the expected motor results, load prescription has to follow the overload principle, which is one of the principles of the Exercise Physiology.

This study aimed to verify whether the clinical practice of physiotherapy care reproduces what randomized clinical trials have presented. That is, to verify the improvement in motor outcomes in PD patients after different protocols of physiotherapy approach [29]. Another important point in this study is the selection of the variables analyzed, preferably seeking measures that involve the "Activities" domain of the ICF in individuals with PD.

Corcos et al. [17] showed improvement in the UPDRS III (motor examination). This result was observed because strength training with progressive resistance was adopted. Corcos' control group and our CP and TTK groups did not work with progressive resistance. Thus, this could be a reason to explain the small improvement observed in the UPDRS III, which did not obtain statistically significant results.

According to the literature, physical activity is prescribed for PD. Exercises such as treadmill training, strength and balance are recommended for these patients [30]. In our study, we observed a protocol based on combined stimulus is a good strategy for treatment in PD. Although the physiotherapy service setting investigated in our study used specific and appropriate evaluation instruments for analysis of motor outcomes, control of dosimetry prescription (load, frequency, speed and duration) was not observed. In the clinical setting, the physiotherapist should be able to prescribe dosimetry for each patient to positively influence motor outcomes and, consequently, bring benefits related to physical-functional aspects.

The small sample size and the fact that the treatment frequency was low, i.e., twice a week, are the limitations of this study. Also, this study evaluated only one physiotherapy service that assists PD patients. Knowing other national realities would be very interesting, including instruments used in different services to verify clinical coherence between the variables adopted for evaluation and the motor outcomes exploited.

As conclusion, the results showed the effects of the two Physiotherapy programs were effective; however, when comparing the groups, the CP group improved the patients' general clinical status (UPDRS total), while exercise treadmill and kinesiotherapy improved both physical-functional (TUG, 6MWDT, DS, US, GS) and clinical aspects (UPDRS II).

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