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Effects of a gait training program with the Fisior® sequential square mat on balance and gait in patients with Parkinson's disease: a randomized clinical trial

José Alegre-Tamariz[1,6], Carlos Ramirez[2], Fernando M. Runzer-Colmenares[3], José F. Parodi[4], Asier Arrizabalaga-Otaegui[5] and Alberto Bermejo-Franco[6,7*]

Abstract

Background Parkinson's disease (PD) is a neurodegenerative disorder that affects mobility, balance, and gait, increasing fall risk.

Objectives This study aims to evaluate the efficacy of a gait training program using the Fisior® sequential square mat to improve gait speed and physical performance in PD patients.

Methods A randomized, multicenter clinical trial was conducted with individuals over 50 years old diagnosed with Parkinson's disease from two centers in Spain ($n=52$). Participants were assigned to a control group receiving conventional physiotherapy or an intervention group using the Fisior® sequential square mat. The 12-week intervention included progressive balance and resistance training sessions (30–40 min, three times per week). Multiple linear regression models were used to analyze variations in physical performance, gait speed, and fall risk.

Results Results showed significant functional improvements in the intervention group. Participants exhibited better performance in the Sit & Stand test (β = -15.61; $p=0.029$), Short Physical Performance Battery (SPPB) global score (β = 1.35; $p=0.011$), balance test (β = 0.54; $p=0.041$), chair test (β = 0.67; $p=0.042$), and Timed Up and Go (TUG) test (β = 0.10; $p=0.006$). Additionally, FallSkip time was significantly associated with TUG performance (β = -0.01; $p=0.035$), suggesting improved reaction times and a potential reduction in fall risk.

Conclusions The Fisior® training program improves balance, mobility, and functional performance in individuals with PD, suggesting it may be a useful adjunct within physiotherapy to reduce gait impairments and fall risk.

Clinical trial registration number NCT05131880 (Registered on August 11, 2021).

Keywords Frailty, Aged, Mobility, Physical performance, Healthy aging, Physical therapy

*Correspondence:
Alberto Bermejo-Franco
alberto.bermejo@universidadeuropea.es; a.bermejofranco@gmail.com

Full list of author information is available at the end of the article

Introduction

Parkinson's disease (PD) is a progressive neurodegenerative disorder characterized by motor symptoms such as bradykinesia, rigidity, tremor, and postural instability, as well as non-motor impairments that affect quality of life. Within three years after diagnosis, more than 85% of individuals with PD develop gait impairments, which tend to worsen as the disease progresses [1]. Although dopaminergic therapies help manage gait disturbances, their long-term efficacy diminishes and some motor symptoms become refractory. Neurodegenerative alterations in the basal ganglia, cortex, and cerebellum contribute to significant gait and balance deficits [2, 3].

Postural instability is a key predictor of disability in PD, strongly correlating with gait dysfunction and mobility limitations [4, 5], resulting in an increased risk of falls, loss of autonomy, and greater morbidity and mortality [6, 7]. Falls are associated with fractures, post-fall anxiety, reduced mobility, loss of independence, and lower quality of life [8].

Physical therapy is a fundamental non-pharmacological approach for managing PD motor impairments, particularly through targeted gait training [9, 10]. The European Physiotherapy Guidelines highlight gait rehabilitation and recommend multicomponent exercise programs [1]. Repetitive, task-oriented, and sufficiently intensive training promotes neuroplasticity and motor relearning, helping mitigate disease-related deficits [11, 12]. Structured physical exercise has been associated with reduced mortality, improved mobility, and enhanced performance in activities of daily living (ADLs) in PD, especially when following FITT principles (frequency, intensity, type, and time) [13]. Additionally, visual cueing strategies further improve gait initiation, spatiotemporal parameters, turning ability, and freezing episodes, reducing fall risk [14].

Accumulating evidence suggests that regular, prolonged, and high-intensity physical exercise can attenuate PD progression by enhancing neural plasticity, increasing synaptic connectivity, modulating corticomotor excitability, and preserving gray matter volume [15–17]. Among gait rehabilitation strategies, treadmill-based training has been widely implemented in PD physiotherapy [18]. Evidence shows it improves gait speed, stride length, balance, and overall gait dynamics [19, 20]. Combining treadmill therapy with visual cueing yields superior outcomes; for example, Schlick et al. (2016) reported significant improvements in gait performance in moderate-stage PD patients receiving visually augmented treadmill training [21].

Alternative approaches such as the Square Stepping Exercise (SSE) have also been explored. SSE involves multidirectional step patterns performed on a 40-square mat to enhance dynamic balance and coordination [22]. This method has shown efficacy in fall prevention among older adults, with improvements in balance and postural control [23]. Pilot studies using the Fisior® sequential square mat in PD patients and older adults have shown promising results in gait kinematics and physical performance [24, 25].

Given these findings, further research is needed to determine the effectiveness of the Fisior® sequential square mat in individuals with PD. This study aims to evaluate the impact of a 12-week gait training program using the Fisior® mat as a complement to conventional physiotherapy, assessing improvements in balance, gait performance, and fall risk.

Methods

Study design, population, and sample

A multicenter randomized clinical trial was conducted in individuals aged over 50 years with Parkinson's disease (PD) from two patient associations located in Gran Canaria (Center 1) and Madrid (Center 2). Both centers provide regular physiotherapy as part of standard care. The study adhered to CONSORT guidelines and the principles of the Declaration of Helsinki. Ethical approval was granted by the Research Ethics Committees of the European University of Madrid (CIPI/12/032) and the Dr. Negrín University Hospital of Gran Canaria (2021-350-1). The trial was registered at ClinicalTrials.gov (NCT05131880). All participants provided written informed consent and consent for publication.

Recruitment was carried out through an official announcement sent by the associations to their members, informing them of study objectives, procedures, and eligibility criteria. Interested individuals registered voluntarily and were assessed for eligibility by the association physician. Of 98 contacted individuals, 63 expressed interest and 52 met the inclusion criteria.

The inclusion criteria were: age 50 years or older, confirmed diagnosis of PD, not institutionalized, no diagnosis of cognitive impairment (Mini-Mental State Examination [MMSE] score ≥ 24) [26, 27], ability to communicate, ability to stand up and walk at least 10 m without assistance, and a Barthel Index score of ≥ 60 points [28, 29].

The exclusion criteria included medical conditions preventing participation in a gait training program and severe cognitive or behavioral impairments that could hinder engagement in the training.

After eligibility screening, participants were randomly allocated (1:1) to Group A or Group B using a computer-generated randomization sequence created by an independent researcher. Allocation concealment was ensured through sequentially numbered, opaque, sealed envelopes. Although recruitment was based on an open call distributed by patient associations, the randomization

process followed standard RCT procedures in accordance with CONSORT guidelines.

Group A received only conventional physiotherapy (treadmill walking, stationary cycling, exercise, and general physical activity), while Group B received this same program plus gait training with the Fisior® sequential square mat. Each condition lasted 12 weeks, with assessments performed before (T1) and after (T2) the intervention. All measurements and interventions were conducted on-site at the respective centers. The participant flow throughout the study, from initial assessment to final analysis, is illustrated in the flow diagram, which follows the CONSORT guidelines (Fig. 1).

The intervention period took place between October 2021 and April 2024, with Center 1 conducting the intervention from October to December 2021, and Center 2 from February to April 2024. Participant recruitment at each center began approximately one month prior to the start of the respective intervention period. The intervention concluded once all participants had completed the program assigned to their intervention group.

Procedure

An initial informational meeting was held with users from Centers 1 and 2 (Spain), and a brochure outlining the study objectives was distributed, inviting them to participate. First, the research team collected sociodemographic data, medical history (e.g., number of diseases, polypharmacy, use of eyeglasses, history of falls), and functional dependency (Barthel Index) through surveys and measurements.

Participants were randomly assigned to two groups: a control group and an intervention group. Both groups followed a conventional physiotherapy program for Parkinson's disease, designed to address key therapeutic objectives such as improving postural control, increasing gait stability, reducing freezing episodes, enhancing coordination, and minimizing fall risk. The program included gait training to promote step initiation and continuity, balance exercises to improve weight shifting and reactive postural adjustments, stretching to maintain joint mobility and reduce rigidity, and psychomotor activities to enhance proprioception and movement planning. The therapy was conducted by two physiotherapists per center, with sessions lasting 30 min, three times per week, over 12 weeks. The pharmacological treatment that participants regularly received was not modified during the intervention to avoid altering the natural progression of the disease.

To clarify distinctions between groups, the intensity, frequency, and content of the Fisior® program were precisely defined. Conventional physiotherapy included treadmill walking, stationary cycling, general gait exercises, balance training, stretching, and psychomotor activities. In contrast, the Fisior® program added a structured neuromotor training protocol using the sequential

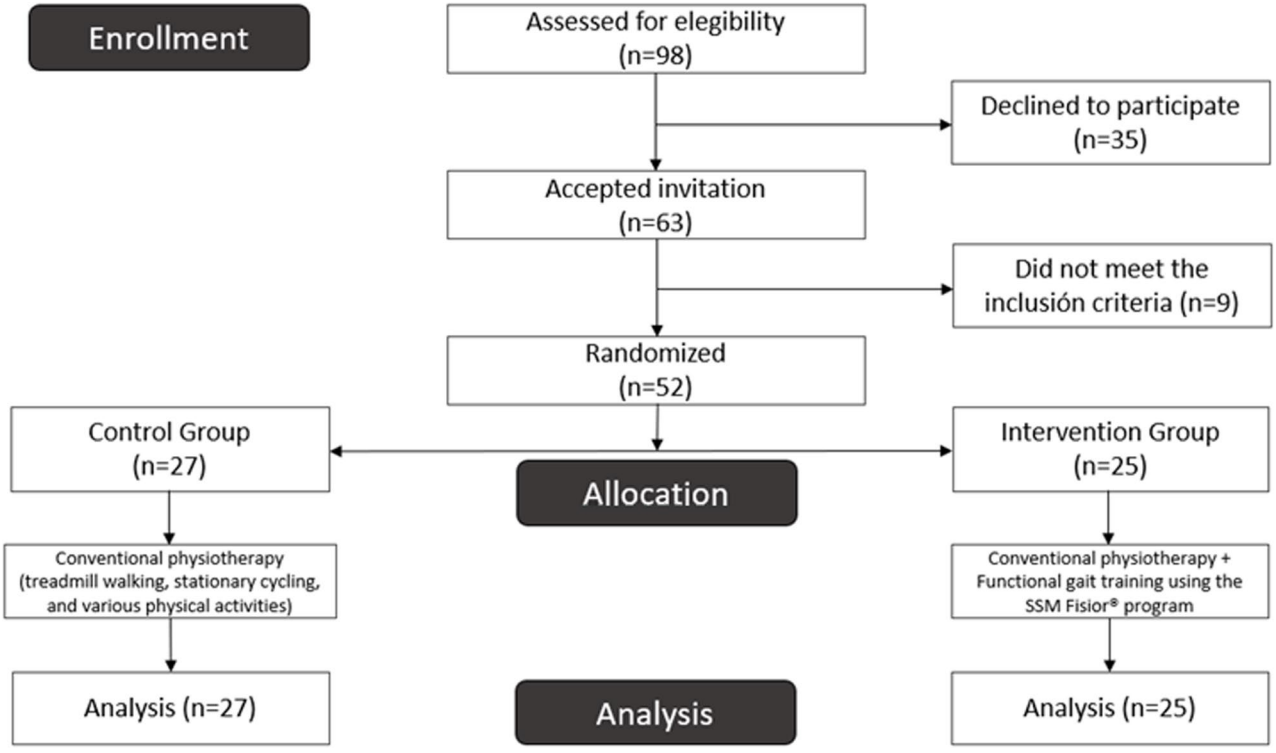

Fig. 1 CONSORT flow diagram of the clinical trial

square mat, with progressive intensity (increased load, repetitions, reduced rest, and multidirectional movement). This additional protocol provided specific postural control challenges and multidirectional stepping tasks not present in conventional physiotherapy.

In addition to conventional therapy, the intervention group followed a treatment protocol using the Fisior® sequential square mat, supervised by a trained physiotherapist from each center. This therapy, described in Annex 1 (Annex 1), focused on postural control and gait exercises with progressive intensity: low for the first four weeks, moderate until week eight, and high from weeks nine to twelve. Load progression followed a structured protocol, incorporating increased ankle weights, higher repetitions, reduced rest time, and expanded movement directions from anterior to lateral. This program has shown preliminary effectiveness in improving gait and postural control in older adults and individuals with Parkinson's disease. These additional sessions lasted 30 min and were conducted three times per week over the 12-week intervention. Table 1 summarizes the key differences between the two programs.

Variables

Outcome variables

Physical Performance The Short Physical Performance Battery (SPPB) is a validated tool for assessing mobility in Parkinson's disease [30]. It includes balance tests, four-meter walking speed, and a sit-to-stand test, generating a total score from 0 (worst) to 12 (best) [31]. The SPPB helps evaluate lower limb function, detect motor disability, and identify frailty in PD patients [32–34]. The SPPB has also been proposed for evaluating the mobility subdomain of intrinsic capacity, which comprises the functional ability required for healthy aging [35].

Walking Speed was assessed using the Timed Up & Go (TUG) test. The TUG test assesses basic mobility by measuring the time taken to stand up, walk three meters, return, and sit down [36, 37]. It correlates with functional mobility scales (Berg Balance Scale, gait speed, and Barthel Index) [38, 39]. and helps identify fall risk: under 10 s is normal, 10–20 s indicates frailty, and over 20 s signals a high fall risk [38, 40]. The TUG test is a valid, time-efficient tool for evaluating gait, balance, motor control, and muscle strength in older adults [37, 39–41].

Instrumental Gait Analysis Assessment FallSkip is a sensor-based system that quickly evaluates balance, gait, sit-to-stand performance, reaction time, and fall risk in older adults, including PD where this evaluation is essential [7, 42]. It analyzes biomechanical variables through a device on the lumbar region, providing an objective fall

Table 1 Comparison of conventional physiotherapy and Fisior® intervention components

Component	Control Group: Conventional Physiotherapy	Intervention Group: Fisior® + Conventional Physiotherapy
Session duration	30 min	30 min conventional + 30 min Fisior® (total 60 min/session)
Frequency	3×/week	3×/week (for both components)
Total duration	12 weeks	12 weeks
Therapists	Physiotherapists (2 per center)	Same + additional physiotherapist trained in Fisior® protocol
General objectives	Global mobility, postural control, flexibility, gait continuity, fall prevention	Same global objectives + device-based motor learning and precision stepping
Gait training	Step initiation, continuity, treadmill, cycling	Sequential stepping on mat with predefined activation patterns and directional cues; increased complexity over time
Balance training	Weight shifting, static/dynamic balance, reactive responses	Multidirectional dynamic weight-shifting on square mat with timed sequences and unstable foot placement demands
Stretching & mobility	Flexibility, reduction of rigidity	Not part of Fisior®, addressed only in conventional therapy
Task-specific exercises	General coordination and proprioception tasks	Highly specific reactive postural control tasks linked to mat sequence patterns
Progression criteria	Therapist-adjusted; non-standardized progression	Structured progression: • Weeks 1–4: low intensity • Weeks 5–8: moderate intensity • Weeks 9–12: high intensity • Increased ankle loads • Reduced rest intervals • Movement expansion: anterior → lateral → multidirectional
Motor-cognitive demand	Low–moderate; conventional dual-task work	High; visual–motor sequencing, anticipatory stepping, timing response to mat cues
Unique elements	—	Device-specific protocol based on activation sequences, volume progression, and task complexity

Variable assessments were performed before and after the intervention period

risk score. Validated in multiple studies, including in PD patients, it is a reliable tool for assessing functional status and mobility impairments [43–46].

Functional Capacity Barthel Index. The Barthel Index (BI) assesses a patient's independence in performing basic activities of daily living (ADLs) and is widely used in physical rehabilitation. It measures independence in ten daily activities, such as mobility, personal care, and toileting [28]. Scores range from 0 (completely dependent) to 100 (completely independent), classifying levels of dependency [29]. The BI helps assess limitations affecting quality of life and track patient progress being considered the most effective tool for identifying limitations in daily life that impact quality of life [47].

Exposure variables

Fisior® sequential squares mat program: The Fisior® sequential squares mat program combines step-length (60 cm) and stride-length (120 cm) sequences, incorporating strength elements like ankle weights and obstacle navigation in multiple directions. It focuses on postural control and gait exercises, following the principle of goal-directed movement [48] and load adequacy [49] to match patients' abilities.

The program includes four difficulty levels with progressive strength, balance, and endurance training. Intensity increases over 12 weeks: low (weeks 1–4), moderate (weeks 5–8), and high (weeks 9–12) (Annex 1).

The TCS Fisior® mat is 2.45 mm thick, 60 cm wide, and 300 cm long, non-slip, rollable, and weighs 2 kg. Developed in Spain by physiotherapist José Alegre Tamariz (2019), it features 30 cm x 30 cm squares, numbered 1–10, with alternating white and orange colors, a bidirectional red arrow, and a green lateral line on squares 1, 4, 7, and 10.

The TCS Fisior® is used as a physiotherapy tool to generate movement strategies within a stable environment, i.e., under specific environmental constraints and consistent conditions, as proposed by Fitts and Posner in the associative stage of their motor learning model [48].

Other considered variables

The other variables considered were age (treated as a continuous variable), sex (obtained from participants' identification documents), body mass index (treated as a continuous variable), use of hearing aids and glasses (treated as a dichotomous variable; it did not specify whether the glasses were for near or distance vision, nor the type of lenses), and polypharmacy (defined as the use of two or more medications and treated as a continuous variable). Additionally, the study included a history of falls (self-reported, based on the number of falls in the past year) and use of prosthetics.

Statistical analysis

Frequencies and percentages were calculated for categorical variables, while means and standard deviations were computed for numerical variables, given their normal distribution according to the histogram.

For the bivariate analysis, the Student's t-test and Exact Fisher´s test were used to analyze numerical and cathegoric variables respectively. Finally, linear regression models with robust variance were constructed to quantify the association between covariates according to the intervention group, considering changes in variable values before and after the intervention. Adjusted linear regression models with robust variance were constructed to quantify the association between the intervention and changes in outcome variables. Six primary outcome models were constructed (Sit & Stand test, Reaction time, SPPB global score, Balance test, Chair Stand test, and TUG test). All predictor variables were included in each adjusted model based on a priori specification following reviewed literature on confounding factors. Given the exploratory nature of this study with a limited sample size and the hypothesis-driven selection of primary outcomes aligned with the intervention's theoretical framework, no formal correction for multiple comparisons was applied. However, we acknowledge that the p-values should be interpreted with caution in the context of the number of statistical tests performed. Statistical significance was set at $p < 0.05$ (two-tailed). Beta coefficients (β) are reported with 95% confidence intervals and represent the magnitude of change in outcome measures associated with the intervention group compared to the control group, with positive values indicating improvement in functional performance and negative values indicating reduction in test duration (indicating faster performance or better reaction time). All variables were included in the adjusted model because they were considered confounders according to the reviewed literature. The absence of collinearity was verified using the VIF command. In an exploratory analysis, statistical power was estimated based on the β coefficients, mean differences, and standard deviations for three functional performance measures: the Timed Up and Go test, the Short Physical Performance Battery (SPPB), and the Sit-to-Stand test. The estimated statistical power values were 100%, 100%, and 88.39%, respectively. All computations were performed using OpenEpi version 3.0. Further details are available in the Supplementary Material.

All analyses were performed using Stata v.18.0 for Windows.

Results

In Table 2, we can see the descriptive analysis of the study variables, where we observe that the majority of participants, 57.69%, were male ($n = 30$), the average age was

Table 2 Descriptive analysis of study variables ($n = 52$)

Variables	*n*	%	Control Group *n* (%)	Intervention Group *n* (%)	*P*-value
Sex					0.483
Female	22	42.31	12 (44.44)	10 (40.00)	
Male	30	57.69	15 (55.56)	15 (60.00)	
Age (years)*	71.35	7.96	71.37 (7.70)	71.32 (8.38)	0.982
Body Mass Index (BMI)*	26.28	3.83	25.36 (3.98)	27.27 (3.46)	0.072
Hearing Aid Use					0.276
No	48	92.31	26 (96.30)	22 (88.00)	
Yes	4	7.69	1 (3.70)	3 (12.00)	
Glasses Use					0.508
No	28	53.85	15 (55.56)	13 (52.00)	
Yes	24	46.15	12 (44.44)	12 (48.00)	
Prosthesis Use					-
No	45	86.54	20 (74.07)	25 (100.00)	
Yes	7	13.46	7 (25.93)	0 (0.00)	
Polypharmacy					0.237
No	16	30.77	10 (37.04)	6 (24.00)	
Yes	36	69.23	17 (62.96)	19 (76.00)	
Falls					0.526
No	32	61.54	17 (62.96)	15 (60.00)	
Yes	20	38.46	10 (37.04)	10 (40.00)	
Barthel Index Score*	89.62	13.17			
Group					
Control	27	51.92	87.59 (12.11)	91.80 (14.13)	0.254
Intervention	25	48.08			

P-values for cathegoric variables were calculated with Fisher Exact test, for numeric variables, with T-test

*Data expressed as mean and standard deviation

71.35 years with a standard deviation of 7.96, and 48.08% of the participants were in the intervention group ($n = 25$) and 51.92% in the control group ($n = 27$). Additionally, we performed a bivariate analysis considering control and intervention group, with no significant differences between groups.

Additionally, in Table 3, we can observe the descriptive analysis of the pre- and post-intervention assessments, respectively, where we describe the findings obtained from the instrumental gait assessment (FallSkip), the SPPB, and the TUG test.

Following the descriptive results shown in Tables 3 and 4 presents the bivariate comparisons between the control and intervention groups to identify statistically significant changes in the pre–post assessments. Table 4 reports mean changes (SD) and p-values for each outcome. Significant differences were observed in favor of the intervention group for reaction time in the instrumental gait assessment (FallSkip), Sit-to-Stand performance, overall SPPB score, balance tests, Chair Stand Test, and TUG test. No statistically significant differences were found for the remaining variables.

Building on the bivariate findings shown in Tables 4 and 5 presents the adjusted linear regression analyses conducted to quantify the association between pre–post changes and the intervention group. Six models were constructed, one for each outcome variable. In Model 1 (Sit & Stand test), an improvement (decrease in percentual score) was observed in the intervention group after adjusting the model for sex, age, BMI, hearing aid use, glasses use, polypharmacy, falls, prosthesis use, and Barthel index score, with statistically significant results (β Coefficient: 0.15.61; 95% CI: [-29.52, -1.70]; $P = 0.029$). In Model 2 (Reaction time), an improvement (increase in percentual score) was observed in the intervention group after adjusting the model for sex, age, BMI, hearing aid use, glasses use, polypharmacy, falls, prosthesis use, and Barthel index score, but without statistically significant results by a narrow margin (β Coefficient: 10.01; 95% CI: [-0.54, 20.56]; $P = 0.062$). In Model 3 (Overall SPPB score), an improvement was observed in the intervention group after adjusting the model for FallSkip in seconds, sex, age, BMI, hearing aid use, glasses use, polypharmacy, falls, prosthesis use, and Barthel index score, with statistically significant results (β Coefficient: 1.35; 95% CI: [0.33, 2.37]; $P = 0.011$). On the other hand, in Model 4 (Balance test), improvement was observed in the intervention group after adjusting the model for FallSkip in seconds, sex, age, BMI, hearing aid use, glasses use, polypharmacy, falls, prosthesis use, and Barthel index score, with statistically significant results (β Coefficient: 0.54; 95% CI: [0.02, 1.07]; $P = 0.041$). Additionally, in Model

Table 3 Descriptive analysis of Pre/Post-Intervention assessment ($n=52$)

Variables	Pre-Intervention		Post-Intervention	
FallsSkip				
Risk of Falls *				
Low	7	13.46	11	21.15
Mild	11	21.15	10	19.23
Moderate	17	32.69	14	26.92
High	10	19.23	12	23.08
Very high	7	13.46	5	9.62
Balance (%) **	76.08	21.06	75.77	18.31
Gait (%) **	78.08	16.45	82.27	17.07
Reaction Time (%) **	71.50	10.75	69.87	17.23
Sit & Stand test (%) **	71.77	17.28	72.08	18.42
FallSkip Score (%) **	72.71	24.68	73.88	21.26
FallSkip (seconds) **	14.65	4.54	14.28	3.55
SPPB Global Score ***	9.17	2.63	9.77	2.63
Balance Test **	3.38	0.99	3.46	0.96
Gait Test **	3.37	1.03	3.50	0.80
Chair Stand Test **	2.42	1.11	2.81	1.24
Up & Go Test (seconds) **	0.57	0.15	0.60	0.18

*Data expressed as frequency (n) and percentages

**Data expressed as mean and standard deviation

***Short Physical Performance Battery (SPPB)

Table 4 Bivariate analysis between pre-post assessment and intervention group (*n=52*)

Variables	Pre-post variation: Control Group Mean (SD)	Pre-post variation: Intervention Group Mean (SD)	P-Value	Global Post-Intervention Variation Mean and Standard Deviation	
FallsSkip					
Balance (%)	2.07 (22.39)	-2.88 (18.28)	0.389	-0.31	20.47
Gait (%)	3.52 (14.92)	4.92 (13.26)	0.723	4.19	14.02
Reaction Time (%)	-5.89 (15.25)	2.96 (14.68)	**0.038**	-1.63	15.49
Sit & Stand Test (%)	7.22 (17.29)	-7.16 (21.43)	**0.010**	0.31	20.52
FallSkip Score (%)	-1.00 (16.86)	3.52 (11.82)	0.272	1.17	14.69
FallSkip (seconds)	0.04 (2.99)	-0.80 (2.27)	0.259	-0.37	2.68
SPPB Global Score*	0.11 (1.37)	1.12 (1.39)	**0.011**	0.60	1.46
Balance Test	-0.15 (0.66)	0.32 (0.63)	**0.012**	0.08	0.68
Gait Test	0.11 (0.70)	0.16 (0.55)	0.782	0.13	0.63
Chair Test	0.15 (0.82)	0.64 (0.91)	**0.045**	0.38	0.89
Up & Go Test (seconds)	-0.02 (0.11)	0.08 (0.08)	**0.001**	0.03	0.11

P-values were calculated using the Student`s t-test. The highlighted text in bold corresponds to P values ≤ 0.05 (statistically significant difference)

*Short Physical Performance Battery (SPPB)

5 (Chair Stand Test), improvement was observed in the intervention group after adjusting the model for FallSkip in seconds, sex, age, BMI, hearing aid use, glasses use, polypharmacy, falls, prosthesis use, and Barthel index score, with statistically significant results (β Coefficient: 0.67; 95% CI: [0.02, 1.32]; $P=0.042$). Finally, in Model 6 (TUG test in seconds), improvement was observed in the intervention group after adjusting the model for FallSkip in seconds, sex, age, BMI, hearing aid use, glasses use, polypharmacy, falls, prosthesis use, and Barthel index score, with statistically significant results (β Coefficient: 0.10; 95% CI: [0.03, 0.17]; $P=0.006$).

No important harms or unintended effects were observed in any of the intervention groups throughout the study period.

Discussion

The adjusted linear regression analysis showed significant associations between the intervention and functional performance tests. The intervention group had a significant reduction in Sit & Stand test time (β = -15.61; $p=0.029$) and improvements in the SPPB global score (β = 1.35; $p=0.011$), balance test (β = 0.54; $p=0.041$), chair test (β = 0.67; $p=0.042$), and TUG test (β = 0.10;

Table 5 Adjusted linear regression analysis to quantify the association between pre-post assessment and intervention groups (*n=52*)

Variables	β Coefficient (Standard Error)*	P-Value	95% CI
Model 1: Sit & Stand Test (%)			
Intervention group	-15.61 (6.89)	**0.029**	[-29.52, -1.70]
Male sex	2.85 (6.31)	0.654	[-9.88, 15.59]
Age (years)	0.32 (0.39)	0.414	[-0.46, 1.10]
Body Mass Index (BMI)	0.73 (0.79)	0.360	[-0.86, 2.32]
Hearing Aid Use (yes)	18.22 (10.30)	0.085	[-2.59, 39.03]
Glasses Use (yes)	0.76 (5.82)	0.897	[-11.00, 12.52]
Polypharmacy (yes)	-4.57 (6.99)	0.516	[-18.68, 9.54]
Falls (yes)	-2.12 (5.54)	0.704	[-13.30, 9.06]
Prothesis Use (yes)	2.61 (8.07)	0.748	[-13.68, 18.90]
Barthel Index Score	-0.11 (0.20)	0.572	[-0.51, 0.29]
Model 2: Reaction Time (%)			
Intervention group	10.01 (5.22)	0.062	(-0.54, 20.56)
Male sex	3.63 (4.35)	0.409	(-5.15, 12.41)
Age (years)	-0.27 (0.36)	0.469	(-1.00, 0.47)
Body Mass Index (BMI)	-0.20 (0.64)	0.759	(-1.49, 1.09)
Hearing Aid Use (yes)	-12.22 (7.48)	0.110	(-27.33, 2.89)
Glasses Use (yes)	-4.65 (4.63)	0.321	(-13.99, 4.69)
Polypharmacy (yes)	5.08 (5.58)	0.368	(-6.18, 16.34)
Falls (yes)	-2.44 (5.63)	0.668	(-13.81, 8.94)
Prothesis Use (yes)	7.16 (6.53)	0.280	(-6.03, 20.34)
Barthel Index Score	0.35 (0.18)	0.059	(-0.01, 0.72)
Model 3: SPPB Global Score**			
Intervention group	1.35 (0.51)	**0.011**	[0.33, 2.37]
Male sex	-0.08 (0.09)	0.399	[-0.26, 0.11]
Age (years)	-0.48 (0.41)	0.243	[-1.31, 0.34]
Body Mass Index (BMI)	0.02 (0.02)	0.373	[-0.02, 0.06]
Hearing Aid Use (yes)	-0.06 (0.05)	0.201	[-0.17, 0.04]
Glasses Use (yes)	-1.31 (0.58)	**0.030**	[-2.49, -0.13]
Polypharmacy (yes)	0.42 (0.41)	0.311	[-0.41, 1.25]
Falls (yes)	0.41 (0.44)	0.359	[-0.48, 1.29]
Prothesis Use (yes)	-0.87 (0.47)	0.073	[-1.83, 0.08]
Barthel Index Score	0.35 (0.57)	0.536	[-0.79, 1.50]
Intervention group	-0.02 (0.02)	0.185	[-0.06, 0.01]
Model 4: Balance Test			
Intervention group	0.54 (0.26)	**0.041**	[0.02, 1.07]
Male sex	-0.01 (0.05)	0.887	[-0.11, 0.09]
Age (years)	0.09 (0.19)	0.651	[-0.30, 0.48]
Body Mass Index (BMI)	0.02 (0.02)	0.281	[-0.01, 0.05]
Hearing Aid Use (yes)	-0.00 (0.02)	0.858	[-0.05, 0.04]
Glasses Use (yes)	-0.39 (0.28)	0.174	[-0.96, 0.18]
Polypharmacy (yes)	-0.06 (0.20)	0.755	[-0.46, 0.34]
Falls (yes)	0.05 (0.27)	0.864	[-0.50, 0.59]
Prothesis Use (yes)	-0.35 (0.23)	0.127	[-0.81, 0.11]
Barthel Index Score	0.10 (0.33)	0.769	[-0.57, 0.76]
Intervention group	-0.00 (0.01)	0.698	[-0.02, 0.01]
Model 5: Chair Stand Test			
Intervention group	0.67 (0.32)	**0.042**	[0.02, 1.32]
Male sex	-0.01 (0.06)	0.930	[-0.12, 0.11]
Age (years)	0.11 (0.27)	0.682	[-0.44, 0.66]
Body Mass Index (BMI)	0.00 (0.01)	0.758	[-0.02, 0.02]
Hearing Aid Use (yes)	-0.05 (0.04)	0.258	[-0.13, 0.04]
Glasses Use (yes)	-0.72 (0.32)	**0.029**	[-1.36, -0.08]

Table 5 (continued)

Variables	β Coefficient (Standard Error)*	P-Value	95% CI
Polypharmacy (yes)	0.20 (0.27)	0.461	[-0.34, 0.75]
Falls (yes)	0.43 (0.27)	0.115	[-0.11, 0.96]
Prothesis Use (yes)	-0.47 (0.32)	0.152	[-1.12, 0.18]
Barthel Index Score	0.26 (0.38)	0.492	[-0.50, 1.03]
Intervention group	-0.01 (0.01)	0.645	[-0.03, 0.02]
Model 6: Up & Go Test (seconds)			
Intervention group	0.10 (0.03)	**0.006**	[0.03, 0.17]
Male sex	-0.01 (0.01)	**0.035**	[-0.03, -0.00]
Age (years)	-0.03 (0.03)	0.376	[-0.08, 0.03]
Body Mass Index (BMI)	-0.00 (0.00)	0.146	[-0.01, 0.00]
Hearing Aid Use (yes)	-0.01 (0.00)	**0.037**	[-0.02, -0.00]
Glasses Use (yes)	-0.01 (0.06)	0.862	[-0.13, 0.11]
Polypharmacy (yes)	0.04 (0.03)	0.193	[-0.02, 0.09]
Falls (yes)	0.05 (0.04)	0.205	[-0.03, 0.12]
Prothesis Use (yes)	-0.02 (0.03)	0.548	[-0.08, 0.04]
Barthel Index Score	0.03 (0.04)	0.470	[-0.05, 0.12]
Intervention group	0.00 (0.00)	0.300	[-0.00, 0.00]

*Linear regression models adjusted with robust variance. The highlighted text in bold corresponds to P values ≤ 0.05 (statistically significant difference).

**Short Physical Performance Battery (SPPB)

$p = 0.006$), indicating enhanced balance, strength, and mobility. FallSkip time was also significantly associated with TUG performance (β = -0.01; $p = 0.035$). Regarding sociodemographic and clinical factors, hearing aid use correlated negatively with the SPPB global score (β = -1.31; $p = 0.030$) and chair test (β = -0.72; $p = 0.029$), while no significant associations were found with other variables. These findings underscore the intervention's positive impact on mobility, independent of participant characteristics.

Postural control deficits in PD, often unresponsive to dopaminergic therapy, impair gait and balance, supporting Massion's concept of independent mobility domains in PD [50, 51]. Our results suggest that complementing physiotherapy with the Fisior® sequential square mat could be an effective therapeutic tool for improving balance, gait, reaction time, overall functional mobility, and fall risk.

Differences in fall prevention and balance rehabilitation between PD and non-PD populations are due to distinct neurobiological mechanisms. In PD, motor and postural control impairments arise from basal ganglia dysfunction and cognitive decline, which reduce automaticity and increase reliance on attentional control [52]. Gait abnormalities like festination and freezing, along with non-motor symptoms such as orthostatic hypotension and visuospatial deficits, further increase fall risk. In contrast, balance issues in non-PD individuals are typically due to peripheral causes, such as sarcopenia or vestibular dysfunction, which respond well to conventional training. Therefore, PD-specific rehabilitation must combine pharmacological management with targeted strategies like external cueing and compensatory network engagement to improve outcomes effectively [53, 54].

The improvements observed in participants following the Fisior® sequential square mat intervention were reflected in the significant gains in the SPPB global score, balance test, chair test, and TUG test, indicating enhanced balance, muscle strength, and overall mobility. Additionally, the significant association between FallSkip time and TUG performance highlights the intervention's positive impact on reaction time and fall risk reduction [55]. These functional improvements align with the objectives of the Fisior® program, which targets multidimensional motor skills, and further support its efficacy in addressing key mobility challenges in individuals with Parkinson's disease.

These findings reinforce that targeted interventions may help address the intricate relationship between balance and gait in Parkinson's disease. However, it remains uncertain whether dynamic balance training alone can improve both postural control and locomotion [50].

Authors as Sacheli et al. (2019) [56] suggests that exercise enhances corticostriatal plasticity and dopamine release, which may explain the functional improvements observed in this study. The Fisior® program, focusing on dynamic balance and cognitive-motor integration, likely stimulates neural circuits involved in motor control, enhancing neuroplasticity, especially given the dopaminergic deficits and altered connectivity in Parkinson's disease [57].

Moreover, considering that the Fisior® program requires sustained attention, motor planning, and the execution of complex movement patterns, it is plausible

that such cognitive-motor engagement contributes to modulating mesolimbic dopaminergic activity, as suggested by Sacheli et al. (2019) [56]. This dual impact—on both motor function and neural plasticity—could explain the improvements in reaction time and overall functional mobility observed in our participants [58].

One limitation of this study is its multicenter design, which may have introduced variability, although efforts were made to ensure consistency by selecting similar centers and standardizing therapist training. The sample size was limited ($n = 52$), partly due to post-COVID-19 restrictions, and no a priori power calculation was performed; nevertheless, post-hoc analyses showed adequate statistical power for the main outcomes (100% for TUG and SPPB; 88.39% for the Sit-to-Stand test). The lack of stratification for comorbidities and the absence of Minimal Clinically Important Difference (MCID) measurements may affect the interpretation and generalizability of the results. Although assessor blinding was not implemented in this trial, the predominantly objective nature of our primary outcomes mitigates the risk of detection bias. The Short Physical Performance Battery (SPPB), Timed Up and Go (TUG) test, and FallSkip system all provide quantitative measurements based on standardized, predefined criteria that are less susceptible to assessor knowledge of group allocation. All evaluation protocols were standardized and uniformly applied to both groups at baseline and post-intervention. The literature demonstrates that lack of assessor blinding has limited impact on objective, instrument-based outcomes compared to subjective measures. Nonetheless, this represents a limitation of the study design that should be considered when interpreting results. In addition, the sample size was determined by feasibility constraints rather than a priori power calculation, although post-hoc analysis revealed adequate statistical power (100% for TUG and SPPB; 88.39% for Sit-to-Stand test), limiting generalizability to larger populations. On the other hand, pharmacological treatment was maintained constant during the intervention but not systematically modified, potentially masking drug-intervention interactions. Furthermore, the study was limited to two multicenter sites in Spain, potentially limiting generalizability to other geographic regions and healthcare settings, considering a 12-week intervention period with immediate post-assessment that provides no information regarding sustainability of effects or long-term outcomes. Finally, while the change-score regression analytical approach is appropriate for pre-post RCT designs, it does not formally test time-by-group interactions or account for temporal dynamics beyond baseline-to-endpoint change. Future studies should incorporate longer follow-up periods, stratified randomization for key comorbidities, and explicit time-by-outcome interaction modeling to address these limitations.

Future studies should incorporate larger and more diverse samples, stratified randomization for key comorbidities, longer follow-up periods, and explicit time-by-outcome interaction modeling. In addition, integrating neuroimaging or neurophysiological assessments may clarify the mechanisms underlying functional improvements, and exploring differential responses across patient profiles (e.g., those with greater dopaminergic deficits or cognitive impairment) could support more personalized rehabilitation strategies.

Conclusion

In conclusion, this study highlights the beneficial effects of the Fisior® sequential square mat intervention as a complement to conventional physiotherapy in individuals with Parkinson's disease. Participants in the intervention group demonstrated significant improvements in balance, muscle strength, mobility, and reaction time, as reflected in the SPPB global score, balance test, chair test, and TUG test. These results indicate that the program effectively enhances key aspects of functional performance, particularly balance and gait. The observed association between FallSkip time and TUG performance suggests improvements in reaction time, which may be related to a lower fall risk; however, this relationship cannot be confirmed without longitudinal follow-up.

Supplementary Information

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Supplementary Material 1.

Supplementary Material 2.

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Authors' contributions

José Alegre-Tamariz: Conceptualization & Study Design, Ethical Approval & Patient Recruitment, Validation, Resources, Methodology, Writing - review & editing. Carlos Ramírez-Moreno: Writing - review & editing , Validation, Funding acquisition. Fernando M.Runzer-Colmenares: Data Analysis & Interpretation, Writing - original draft. José F. Parodi: Data curation, Conceptualization & Study Design. Asier Arrizabalaga Otaegui: Writing - review & editing, Visualization. Alberto Bermejo-Franco: Conceptualization & Study Design, Ethical Approval & Patient Recruitment, Writing - review & editing, Visualization, Project administration, Investigation.

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Data availability
All data is presented in the study. For any additional information needed, please contact the corresponding author at alberto.bermejo@universidadeuropea.es.

Declarations

Ethics approval and consent to participate
The study was conducted in accordance with the guidelines of the Helsinki Declaration, and the study protocol was approved by the Research Ethics Committee of the European University of Madrid in September 2021 with code CIPI/12/032, as well as by the Research Ethics Committee of the Dr. Negrín University Hospital of Gran Canaria with code 2021-350-1.
The study is registered at ClinicalTrials.gov under the registration number NCT05131880 (registration date: August 11, 2021).

Consent for publication
Informed consent was obtained from all subjects involved in the study or their legal guardians. Written informed consent was obtained to publish this article. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this work is consistent with those guidelines.

Competing interests
The authors declare no competing interests.

Author details
[1]Universidad Europea de Madrid, Faculty of Medicine, Health and Sports, Department of Physiotherapy, School for Doctoral Studies and Research, Madrid 28670, Spain
[2]Universidad Europea de Madrid, Faculty of Medicine, Health and Sports, Department of Medicine, Madrid, Spain
[3]Universidad Científica del Sur, Facultad de Ciencias de la Salud, Carrera de Medicina Humana, CHANGE Research Working Group, Lima, Perú
[4]Universidad de San Martin de Porres, Facultad de Medicina Humana, Centro de investigación del Envejecimiento (CIEN), Lima, Perú
[5]Deusto Physical Therapiker Research Group, Physical Therapy Departament, Faculty of Health Science, University of Deusto, Bilbao, Spain
[6]Universidad Europea de Madrid, Faculty of Medicine, Health and Sports, Department of Physiotherapy, Madrid, Spain
[7]Neurosciences & Physical Therapy Research Group, Department of Physiotherapy, Faculty of Medicine, Health and Sports, Universidad Europea de Madrid, Madrid, Spain

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