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Somatosensory and dynamic balance improvement in older adults with diabetic peripheral neuropathy through sensorimotor exercise: A multisite randomized controlled trial

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A R T I C L E I N F O

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A B S T R A C T

Purpose: To examine the effect of the Feldenkrais method on lower legs and foot somatosensory postural control-related function, dynamic balance, fear of falling and quality of life in adults with diabetic polyneuropathy in the short and mid-term.
Methods: A single-blinded, parallel, multicentric randomized control trial was conducted in two health hospitals. Subjects with diabetic polyneuropathy and older than 55 years with a history of falls or dynamic balance dysfunction were recruited from the hospital databases and randomly allocated to the experimental or control group. The experimental group received 16 sessions of sensorimotor training based on the Feldenkrais method. Both groups received diabetic foot care instructions. The results were measured at the 3 and 6-month follow-up periods.
Results: The mean age was 70 ± 8. A total of 44 participants were enrolled in the study, and 27 completed the process. No adverse events were reported. After the intervention, significant somatosensory results were obtained ($p < 0.001$). The results of the Up and Go and POMA tests were significant after the intervention ($p < 0.001$) and during the 3-month follow-up period for POMA ($p = 0.018$). The fear of falling showed significant results at the 3-month follow-up period ($p = 0.03$), and the quality of life in all measurements.
Conclusions: Significant short-term effects were obtained on somatosensory postural control-related function, dynamic balance, and fear of falling. Significant short and mid-term effects were achieved on quality of life. Older adults with diabetic polyneuropathy, dynamic balance impairment, or a history of falls can improve their abilities through the Feldenkrais method.
Trial registration: Clinicaltrials.gov: NCT05262946.

1. State of the art

Diabetes is behind approximately one-third of the whole cases of peripheral neuropathy (Streckmann et al., 2021). Diabetic polyneuropathy (DPN) is the most common complication of diabetes, affecting the somatosensory function of distal parts of the upper and lower extremities. It frequently leads to balance impairment, gait instability, and a higher risk of falling (Deshpande et al., 2010; Lipsitz et al., 2018).

The somatosensory system is composed of temperature, pain, pressure, vibration, and proprioceptive receptors along the skin, fascia, muscles, tendons and joints (Pasluosta et al., 2018). Specifically, pressure, pressure location changes through graphesthesia (Arnold et al., 2017), vibration and proprioception stimulus in the lower legs and foot are responsable for somatosensory postural control-related function (SPCF). This function is essential for adapting and updating motor patterns in response to changing environment circumstances (Petrofsky

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List of abbreviations

CG	control group
CSII	Cumulative Somatosensory Impairment Index
DB	dynamic balance
DPN	diabetic polyneuropathy
EG	experimental group
FES	Falls Efficacy Scale
FM	Feldenkrais method
LLFDI	Late Life Function and Disability Instrument
QoL:	quality of life
SPCF	somatosensory postural control-related function

et al., 2019; Liu et al., 2023).

Somatosensory postural control-related dysfunction in people with DPN leads to a conservative gait strategy characterized by slower and shorter steps, increased double support time, and a wider base of support that reduce inertial moments and increases gait variability (Jiang et al., 2022). Two major health concerns emerge from this context: one, the potential sedentary behaviors secondary to gait insecurity, lack of self-confidence, and fear of falling, which worsen as people with DPN get older (Hewston and Deshpande 2016); the other, fall-related injuries that lead to a notorious decrease in autonomy and quality of life (QoL) (Kang et al., 2020; Reeves et al., 2021), and result in high medical costs (Florence et al., 2018).

Rehabilitation programs based on different types of therapeutic exercise can significantly improve some clinical manifestations of DPN, including those related to lower legs and foot SPCF (Gu et al., 2019; Streckmann et al., 2021). Among the existing variety of exercise interventions, sensorimotor training focuses on balance improvement and can be easily performed by people with peripheral neuropathy (Streckmann et al., 2021). Despite the risk of diabetic foot ulcers, sensorimotor training can include safe weight-bearing exercises when monitored (Lemaster et al., 2008). Previous randomized controlled trials (Ahmad et al. 2019, 2020; Mao et al., 2023) have successfully applied sensorimotor training to people with DPN, achieving statistically significant proprioceptive responses, and motor control results after the intervention. It is noteworthy that these interventions required some advanced balance control abilities.

A particularly gentle form of sensorimotor training is offered through the Feldenkrais Method (FM), a somatic learning process that uses the attention to perceive sensations associated with movement: range of motion, pressure, weight transference, the base of support, and different strength-intensity possibilities to educate the self-body awareness in a functional context (Vrantsidis et al., 2009; Paolucci et al., 2017; Ahmadi et al., 2020; Berland et al., 2022). It has been shown that a focused observation of self-movement can facilitate somatosensory functional plasticity through peripheral, spinal and supraspinal structure changes (Brach et al., 2013; Mcgregor et al., 2018). Better gait speed and motor skills results have been obtained when attention to self-perception was used during an exercise program compared to resistance treadmill training alone (Brach et al., 2013). Previous studies applying FM have shown significant results in balance abilities (Torres-Unda et al., 2017) and in older adults (Palmer 2017), but it has never been tested in people with DPN.

The justification for the present study arises from the fact that the DPN is the most frequent complication of diabetes, however there is limited literature analyzing samples with a history of falls or at high risk of falling. Additionally, the consequences of focusing on movement and sensory aspects related to exercise practice are not sufficiently explored in this population. Pressure, vibration, proprioception, and graphesthesia were measured for the first time in people with DPN to obtain SPCF results. The total score was the summary of partial results with an independently validated Cumulative Somatosensory Index (CSII) (Deshpande et al., 2010). DB, functionality, QoL, and fear of falling were also measured. Furthermore, this study included measurements at the 3 and 6-month follow-up period to determine the mid-term effect of the training program.

Results are discussed in the context of previous randomized controlled trials applying different types of exercise to people with DPN.

1.1. Hypotheses

Sensorimotor training based on FM can improve SPCF, DB, daily function, fear of falling and QoL in older adults with DPN and balance impairment or history of falls in the short and mid-term.

2. Materials and methods

2.1. Study design

This is a single-blinded, parallel, multicentric randomized controlled trial comparing the effect of a 2-month non-invasive sensorimotor intervention against a standard of care. The recruitment period began in March 2016 and was repeated three times until all the data were collected in December 2019. The study was approved by the Committees on Health Research Ethics of the Hospital Universitario de La Paz and the Hospital Universitario Principe de Asturias (HULP:PI-2438), and was registered at Clinicaltrials.gov: NCT05262946.

2.2. Study sites

Participants were contacted and informed of the study through telephone calls. If interested, a structured interview was conducted by phone to determine eligibility. Eligible participants were received, measured, and underwent intervention in the rehabilitation rooms of two Spanish public health centers. The rooms had chairs, walls, and enough space for participants to explore while walking. Family members frequently transported the participants to the rehabilitation sites.

2.3. Enrollment criteria

As inclusion criteria (Vrantsidis et al., 2009; Deshpande et al., 2010), participants had to be 55 years or older, with type 1 or 2 diabetes, and have been diagnosed with DPN. They had to have suffered a fall during the last 6 months or be unable to complete at least one item of the functionality subscale of the Late Life Function and Disability Instrument (LLFDI). They needed to be able to walk at least 5 m in an inner room or outside without help and to be able to stand up for a minute without help. Adequate cognitive function was required, with a minimum score of 24 on the Spanish version of the Mini Mental Status Examination.

Exclusion criteria (Allet et al., 2010; Dixit, A. Maiya et al., 2014a; Sartor et al., 2014; Paton et al., 2016) included the presence of ulcers at the beginning of the study, a lower leg amputation (admitting those occurred from the second to the fifth toe), Charcot foot, receiving another rehabilitation program simultaneously during the study, or having difficulties in understanding oral or writing forms of the Spanish language.

Elimination criteria were applied when participants missed two or more sessions or developed a diabetic foot ulcer during the study period.

2.4. Sample size

Through the data offered in the reference study (Deshpande et al., 2010), and the statistic program Nquiry Advisor (MTT-1-1) the sample size was calculated using the Mann-Whitney test with a 0.050 two-sided significance level. It was obtained that a sample of at least 13 participants per group has 80% power to detect a probability of 0.173 that an observation in the experimental group is better than in the control group. Given the complex situation of the studied population, a 40% of potential loss was added.

2.5. Randomization, allocation and blinding

Participants were selected through medical history from their own health computerized databases at both study sites. Randomization was possible through computer-generated random number tables created by the Statistical Department. It was applied following confirmation of eligibility criteria and signed consent. Participants randomly took an opaque envelope with a code number. Allocation ratio was 1:1. The training instructor was not blinded. All the examinations and outcome measurements were performed by blinded collaborators. There was no contamination between the experimental group (EG) and the control group (CG) because measurements were conducted in different moments to prevent overlap.

2.6. Intervention procedures

One week after randomization, the intervention commenced. The EG received 60-min sessions conducted by a podiatrist, physical therapist, and Feldenkrais-trained practitioner. The sessions were verbally directed twice a week for 2 months, giving 16 classes at the end of the training. These lessons have been previously applied for research purposes (Vrantsidis et al., 2009).

Each participant performed what was easily achievable, minimizing the risk of adverse events. Far from the usual exercise goals, the main objective of this method is to perceive somatosensory and postural changes while moving, or even imagining movement (Lakshminarayanan et al., 2023), leading to a self-awareness learning process. The authors hypothesize that targeting not only peripheral improvement but supraspinal nervous collaboration can potentially offer more durable benefits.

The lessons were performed in a sitting or standing position and walking with a progressively reduced base of support (for details, see Table 1). After each session, participants received drawings summarizing movements and postural changes explored. The content of the drawings and a short video sequence of lesson 9 are available on Supplementary material (SM). Complete audio sessions are available on the web www.gettinggroundedgracefully.com (Webb 2016).

Both groups, CG and EG, received a dossier with foot care information (available in SM) after signing the consent form and before randomization. All participants continued with their usual healthcare.

Table 1
Intervention details.

SESSION	OBJECTIVES	MATERIAL	DESCRIPTION
1	Turning improvement, axial plane	Standing and chair	Turn differentiation among head, shoulders, rib cage and legs. Legs influence
2	Weight transference, frontal plane	Standing and chair	Weight transference between sitting bones in sitting, between feet in standing position, using spine and pelvis
3	Training flexors, sagittal plane	Standing and chair	In sitting, flexing and extending the spine to feel weight transference. Introduction to postural transference
4	From sitting to standing (one), sagittal plane	Standing and chair	Legs, pelvis, spine and head coordination for weight transference
5	Sensing the feet and ankle	Standing and chair	Foot and ankle movement in sitting, testing sensation in standing later
6	Finding balance options	Standing and chair for resting	Legs and pelvis movements for balance in standing
7	Walking on, three planes	Standing and chair for resting	Weight transference in standing, coordinated with breathing
8	Balance in standing, three planes	Standing and chair for resting	Base of support reduction: crossed legs for weight transference
9	Weight under the feet	Standing, chair and wall	Base of support reduction: crossed legs for weight transference using pelvis and spine next to a wall
10	From sitting to standing (two),	Standing and chair	Trunk and arms movement for position change, increasing the difficulty
11	Walking in tandem	Standing and chair	Standing on one foot, walking in tandem
12	Pelvis and legs coordination	Standing, chair and wall	Feet, ankle, knees, hips, and pelvis coordination in standing, having the head and hands on the wall
13	Middle and lateral arch of the feet	Standing and chair	Pressure sensation in different foot position during walking
14	Pelvis and limbs coordination	Standing, chair and wall	Lateral gait using a wall, alternating arms and legs position
15	Arms in walking	Standing, chair and wall	Contralateral pattern of arms and legs during walking. shoulder blade contribution
16	Summary	Standing, chair and wall	Previous lessons integration. Perceiving acquired mobility

2.7. Outcome measures

The independent outcomes were obtained at baseline. The dependent outcomes were measured at baseline, upon completion of the intervention, and at the 3 and 6-month follow-up periods. The results obtained at the 6-month follow-up were considered as mid-term effects. Two blinded assistants conducted these measurements simultaneously at two health offices of the study sites. At the end of the study, participants received a report about their outcome progression. Additional details about the measurement process, tools, and questionnaires are available in SM.

2.8. Dependent outcomes

The main outcome was SPCF measured with the CSII, which has been validated for people with diabetes with or without DPN (Deshpande et al., 2010) considering pressure, vibration, proprioception and graphesthesia in independent tests. Pressure sensibility was measured with 4.31 g and 4.56 g Baseline® Tactile Semmes-Weinstein Monofilaments (New York, USA); vibration was measured through a 128-Hz tuning fork; proprioception was measured with a digital goniometer (Baseline Digital Absolute Axis Goniometer, New York, USA); for graphesthesia measurement, there weren't necessary instruments, but the assistant's finger had to draw different symbols on the sole of the feet so that the participant could detect differences among them. The four tests were performed bilaterally and with closed eyes. The worst total score was selected, considering both feet. The final score varies between 0 and 8, with 8 being the worst result. In the tool validation process, the measures of the four tests showed a minimal correlation (Spearman p = 0.189-0.212). Therefore, it could be interpreted that each modality is independent and needs to be measured.

CSII was selected because it offers a complete clinical picture of lower legs and foot SPCF, aiding in the assessment of people with DPN at risk of falls. It is inexpensive and easy for routine clinical practice if there is a systematic grading record.

2.9. Dynamic balance test

DB abilities were measured with the Tinetti-Performance-Oriented

Mobility Assessment (POMA) and its balance and gait subscales (POMA-B and POMA-G respectively) (Faber et al., 2006), and the Timed Up-and-Go test (Podsiadlo and Richardson 1991), this one with a specific cut-off score is 10.7 s for people with DPN (Jernigan et al., 2012); changing directions ability in standing was measured with the Four Square Step Test (Dite and Temple 2002).

2.10. Questionnaires

The daily basis was measured through the three subscales (Functionality, Frequence and Limitation) of the validated Spanish version of Short-Form of Late Life Function and Disability Instrument (LLFDI) (Abizanda et al., 2011); Spanish validation of SF-36 Health Survey questionnaire, 1.4 version was used to measure health-related QoL through its 9 subscales (López-García et al., 2003); fear of falling was measured with the Spanish version of Falls Efficacy Scale (FES) (Lomas-Vega et al., 2012).

2.11. Confounding variables

Confounding variables included maximal knee extension strength and ankle flexion and extension strength were measured bilaterally with Saehan Hydraulic Hand Dynamometer, Saehan Corporation, SH5001 (Chungcheongbuk-do, Republic of Korea) using a standard protocol (Bandinelli et al., 1999); cognitive function was evaluated with the Spanish version of Mini Mental Status Examination (Lobo et al., 1999); the above-mentioned Spanish version of the Short Form of LLFDI measured daily basis activities frequency; the number of falls in previous years; the daily use of plantar orthoses; sociodemographic data as age, sex and study level, and anthropometric data as weight, high, body mass index, blood pressure, and waist circumference. Through medical history, the following items were registered: type of diabetes, years from diagnosis, type of treatment (oral or insulin), other neuropathies, presence or absence of ankle reflexes, neuropathic pain, foot ulcer history, and peripheral vascular disease.

2.12. Data monitoring

All data collected during the study are stored securely in locked filing cabinets and password-protected computers and confidentially (using a unique identification code) on paper and electronically and will only be accessible to the investigators. Following the study, data will be stored for at least 10 years.

2.13. Statistical analysis

The statistical analysis was performed on an intention-to-treat basis. Qualitative data were presented as absolute frequencies and percentages, and quantitative data as means $\pm$ standard deviation (SD), minimum and maximum if they followed normality, and by means of median and interquartile range if they did not. Normality for the quantitative data was analyzed using the Shapiro-Wilk test. The median of change was analyzed in two measurement points. The association between qualitative variables is analyzed using the chi-square test or Fisher's exact test. For the comparison between qualitative and quantitative data, the T-Student test, or the Mann-Whitney test for independent samples and the Wilcoxon test as non-parametric tests were used. The effect size of the results that were close to 0.05, but not inferior, was measured from the operation absolute value of Z divided by the square root of the sample size. For non-parametric calculations, the criterion described by Cohen could be used to assess the size of the effects obtained: between 0 and 0.1 no effect, between 0.1 and 0.3 low effect, between 0.3 and 0.5 medium effect, between 0.5 and 0.7 large effect, and from 0.7 onwards a very large effect. Differences were considered statistically significant at $p \leq 0.05$. Confidence intervals (CIs) were made using a 95% confidence level, and a power of 80% was used. Statistical analysis is conducted using the statistical program SAS 9.3 (SAS Institute, Cary, NC, USA).

3. Results

No adverse or side events were reported from the intervention sessions, and the study was completed as scheduled.

The initial sample comprised 44 participants, and the final sample included 27 participants. A flow diagram of participants is presented in Fig. 1. The general adherence just after the intervention was 93%: EG adherence to FM intervention was 95%, being 91% for CG; at the 3-month of follow-up, adherence decreased to 68% (EG 71%, CG 65%) and further declined to 61% at the 6-month follow-up measurement (EG 62%, CG 61%).

The mean age of participants was 70 $\pm$ 8 years, with 59.1% being men. Participants had a mean duration of diabetes of 20 years. Additionally, 61.6% of participants had experienced previous falls (56.5% CG, 66.7% EG), and all participants exhibited balance control impairments. The baseline comparison between groups did not reveal any significant differences, as detailed in Table 2. Notably, the 82.2% of the participants had more than two comorbidities (69.6% CG, 95.2% EG), as shown in Table 3.

The total results of the dependent outcomes are summarized in Table 4. The total scores of the CSII demonstrated significant improvement following the intervention ($p < 0.001$) with a large effect size. Figs. 2 and 3 illustrate the differences in total CSII scores between groups at each measurement point. Postural control showed improvement after intervention through the global POMA results (Fig. 4) and the Timed Up and Go test (Fig. 5), both showing significant changes ($p < 0.001$) and a large effect size. These improvements were maintained at the 3-month follow-up measurement for the POMA ($p = 0.018$). The Four Square Step test and the global scores from the LLFDI questionnaire did not obtain significant changes (Figs. 6 and 7 respectively). Global results obtained through the SF-36 questionnaire showed significant improvements across all measurements ($p < 0.002$, $p < 0.001$, $p < 0.001$), as shown in Figs. 8 and 9. A significant reduction of the fear of falling measured through FES was observed at the 3-month follow-up measurement ($p < 0.003$), with additional details available in Fig. 10.

Partial results of the CSII are shown in Table 5. No significant differences were found between left and right foot results; therefore, the total scores were used. Significant improvements were observed for pressure ($p < 0.05$), proprioception ($p < 0.002$) and graphesthesia ($p < 0.004$), with significant results for graphesthesia at the 3-month follow-up ($p < 0.004$). Medium effect sizes were found for pressure, proprioception and graphesthesia when comparing baseline and 6-month follow-up results.

The results for the POMA subscales are detailed in Table 6. The Balance POMA subscale showed significant improvement post-intervention ($p < 0.001$) and at the 3-month follow-up ($p < 0.006$) with large and medium effect sizes, respectively (Fig. 11).

Table 7 shows the results for the LLFDI subscales. Significant improvement was observed in the Limitation subscale at the 6-month follow-up ($p < 0.0015$), with a medium effect size (Fig. 12).

Table 8 details the results for the SF36 subscales. The Emotional Role subscale exhibited significant improvement for the EG across all measurements points ($p < 0.001$, $p < 0.006$, $p < 0.002$). Significant differences were noted for the Transition and Physical Role subscales post-intervention ($p < 0.004$, $p < 0.001$, respectively), and for for Physical Role at the 3-month follow-up ($p < 0.001$). Significant differences in Social Function and Vitality were observed at the 6-month follow-up ($p < 0.0045$, and $p < 0.039$, respectively).

4. Discussion

The significant results obtained for the EG in the short-term demonstrate that global somatosensory postural control-related

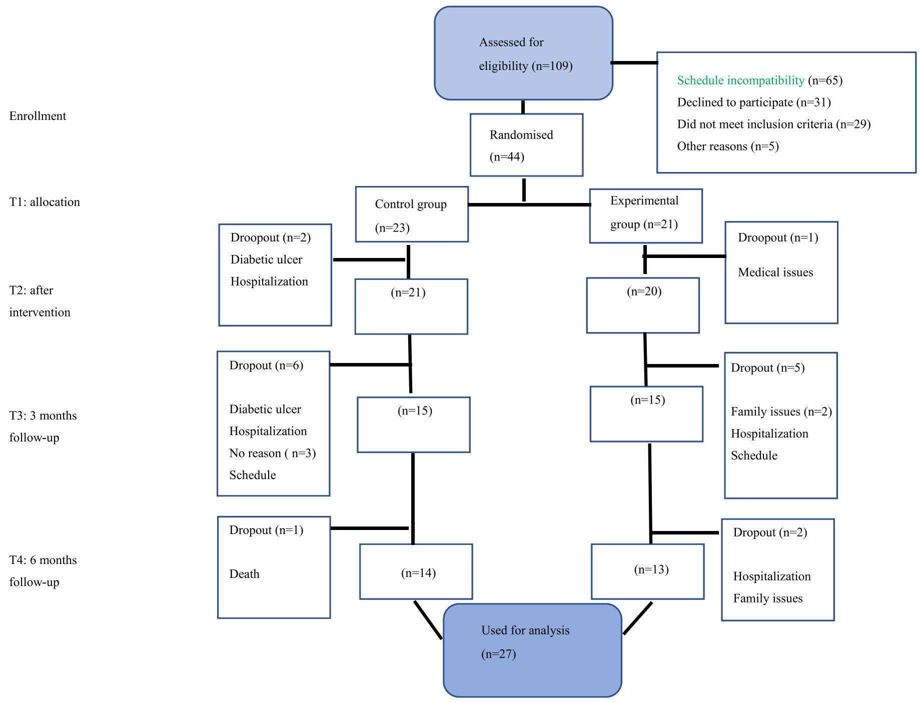

Fig. 1. Participants Flow chart.

Table 2
Groups characteristics homogeneity at baseline N: Sample; NC: control group sample; NE: experimental group sample; IR: Interquartile Range.

Variable	N	NC	NE		p-value
Sex					0.541
Men	26	15 (57.7%)	11 (42.3%)		
Female	18	8 (44.4%)	10 (55.6%)		
Type diabetes					–
Type 1	7	3 (42.9%)	4 (57.1%)		
Type 2	37	20 (54.1%)	17 (45.9%)		
Diabetes treatment					–
Oral	5	3 (60.0%)	2 (40.0%)		
Insulin	39	20 (51.3%)	19 (48.7%)		
Neuropathic pain					0.227
No	22	14 (63.6%)	8 (36.4%)		
Yes	22	9 (40.9%)	13 (59.1%)		
Dyslipemia					–
No	10	5 (50.0%)	5(50.0%)		
Yes	34	18 (52.9%)	16 (47.1%)		
Ankle reflex					0.764
No	20	10 (50.0%)	10 (50.0%)		
Yes	23	13 (56.5%)	10 (43.5%)		
Orthesis					1.000
No	27	14 (51.9%)	13 (48.1%)		
Yes	17	9 (52.9%)	8 (47.1%)		
Variable	NC	Control median (IR)	NE	Experimental median (IR)	p-value
Age	23	70 (62, 75)	21	70 (65, 76)	0.403
Body mass index	23	27.4 (25.1, 32.9)	21	28.2 (24.7, 31.2)	0.925
Years from diabetes diagnosis	23	19 (11, 28)	21	21 (11.5, 32.5)	0.630
Mini mental test	23	34 (31, 35)	21	33 (31, 34)	0.231
A1c	23	7.9 (6.6, 8.6)	21	7.5 (6.85, 8.25)	0.878

Table 3
Comorbidities NC: control group sample; NE: experimental group sample.

Variable	NC	Control	NE	Experimental
Previous ulcer (yes)	23	10 (43.5%)	20	9 (45.0%)
Parkinson (yes)	23	0 (0.0%)	21	0 (0.0%)
Brain injury (yes)	23	1 (4.3%)	21	5 (23.8%)
Cardiopathy (yes)	23	5 (21.7%)	21	12 (57.1%)
Respiratory disease (yes)	23	2 (8.7%)	21	2 (9.5%)
Psychopharmacotherapy (yes)	22	3 (13.6%)	21	3 (14.3%)
Falls (yes)	23	13 (56.5%)	21	14 (66.7%)
Other neuropathies (yes)	22	9 (40.9%)	21	11 (52.4%)
Peripheral arterial disease (yes)	23	8 (34.8%)	21	12 (57.1%)
Number of comorbidities	23		21	
0		4 (17.4%)		1 (4.8%)
1		3 (13%)		0 (0%)
2 or more		16 (69.6%)		20 (95.2%)

function and postural control itself can be improved in people with DPN, with a large effect size. A significant improvement was found in the total QoL scores across all measurements using the SF-36 questionnaire, and in five of its nine subscales at various measurement points, with medium to large effect sizes. The perceived functional limitation and the fear of falling also showed significant improvement during the follow-up period.

To our knowledge, neither graphesthesia, nor proprioceptive detection in the lower legs, nor the total CSII has been specifically measured in an experimental study involving people with DPN before. However, previous research has investigated some somatosensory modalities in this population: consistent with our findings, pressure detection significantly improved through aerobic intervention (Dixit, A.G. Maiya et al., 2014). In contrast, vibration detection has shown significant improvement through aerobic exercise (Dixit et al., 2019) but remained unchanged following our sensorimotor intervention based on the FM, home-based ankle and foot exercises (Win et al., 2020) or combined exercises (Stubbs et al., 2019). These inconsistencies may be attributed to the characteristics of the Pacinian and Meissner corpuscles, which are specialized in detecting vibratory stimulus and are sensitive to frequency-dependent responses to ramp and hold stimulus (Pasluosta

Table 4
Total results of the dependent outcomes Changes between groups and each measurement point: between baseline (0) and postintervention (1) results, between baseline and 3-month follow-up measurement (2), and between baseline and 6-month follow-up period (3). ***Significant differences; **Large effect size; *Medium effect size; N C: control group sample; N E: experimental group sample; Total CSII total: global score of the Cumulative Somatosensory Impairment Index; Total POMA: global score of the *Tinetti- Performance-Oriented Mobility Assessment*; Total LLFDI: global score of the *Late Life Function and Disability Instrument*; FES: *Falls Efficacy Scale; IR:* Interquartile Range.

Variable	Measurements comparison	N C	Control median (IR)	N E	Experimental median (IR)	p-value	Effect size
Total CSII	0 and 1	21	0.0 (−1.0, 1.0)	20	2.0 (1.0, 3.0)	<0.001***	0.6**
	0 and 2	15	1.0 (0.0, 2.0)	15	1.5 (0.2, 3.7)	0.123	0.3
	0 and 3	14	1.0 (1.0, 2.0)	13	1.0 (0.0, 2.0)	0.743	0.1
Four Square Step Test	0 and 1	21	−0.80 (−3.83, 0.69)	20	0.00 (−2.41, 1.45)	0.465	0.1
	0 and 2	15	−0.22 (−4.42, 1.19)	15	−0.77 (−5.17, 1.67)	0.943	0.01
	0 and 3	14	−1.05 (−4.42, 1.67)	13	−0.14 (−2.68, 2.22)	0.225	0.2
Timed Up and Go	0 and 1	21	−0.25 (−1.15, 0.75)	20	1.99 (0.86, 3.99)	<0.001***	0.6**
	0 and 2	15	0.39 (−0.23, 2.22)	15	0.91 (−0.12, 3.59)	0.331	0.2
	0 and 3	14	0.46 (−0.66, 2.29)	13	1.19 (0.38, 5.27)	0.058	0.4*
Total POMA	0 and 1	21	1.0 (−0.5, 2.0)	20	−2.5 (−5.5, −1.0)	<0.001***	0.6**
	0 and 2	15	0.0 (−1.0, 1.0)	15	−3.5 (−6.7, 0.0)	0.018***	0.4*
	0 and 3	14	0.0 (−1.0, 1.0)	13	−1.0 (−4.5, 0.0)	0.082	0.3
Total SF-36	0 and 1	21	2.00 (−3.61, 12.86)	20	−8.71 (−22.44, −2.09)	0.002***	0.49*
	0 and 2	15	3.41 (−1.72, 9.89)	15	−10.53 (−21.16, −0.69)	0.001***	0.6**
	0 and 3	14	1.99 (−6.34, 16.47)	13	−12.24 (−17.88, −4.23)	0.001***	0.6**
Total LLFDI	0 and 1	21	−4.0 (−6.0, 5.5)	20	−8.0 (−10.7, 2)	0.147	0.2
	0 and 2	15	−1.0 (−3.0, 1.5)	15	−6.0 (−15.5, 3.7)	0.330	0.2
	0 and 3	14	−1.0 (−5.5, 4.5)	13	−9.0 (−13.5, −0.5)	0.382	0.2
FES	0 and 1	21	−1.0 (−3.0, 1.5)	20	2.5 (−2.0, 4.0)	0.055	0.3
	0 and 2	15	−1.0 (−5.5, 4.5)	15	3.5 (2.0, 5.7)	0.030***	0.4*
	0 and 3	14	−1.0 (−3.5, 6.0)	13	2.0 (−1.5, 4.0)	0.593	0.1

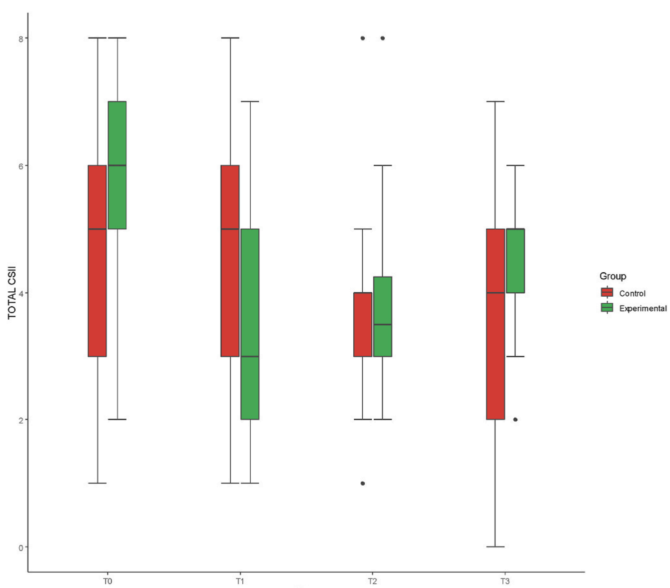

Fig. 2. Box plot showing the global CSII results.

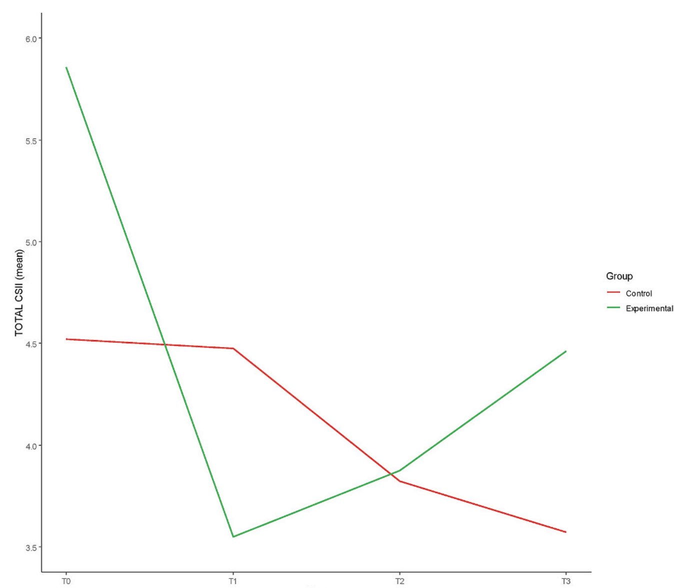

Fig. 3. Linear graph showing the global CSII results.

et al., 2018). We hypothesize that incorporating more varied interventions, possibly including additional therapeutic options such as electrical techniques (Najafi et al., 2023), with changes in stimulus frequency over time, could better stimulate this type of somatosensory receptors.

Functionality measured through LLFDI did not achieve significant results. Although some evidence supports its validity and sensitivity to change, further research is needed to stablish LLFDI values for clinically important changes (Beauchamp et al., 2014). No randomized controlled trials using this questionnaire specifically for DPN were found, leading to an impossible comparison.

Although several studies reveal a higher risk of falls in people with diabetes (Reeves et al., 2021), this is the first time that fear of falling in older adults with DPN has been measured before and after sensorimotor training. Fear of falls increases the risk of falling, and falls are associated with multiple health complications, such as poor glycemic control secondary to the acquisition of sedentary habits (Pop-Busui et al., 2017; Llavero-Valero et al., 2020). More research in this domain should be considered. Additionally, the SF-36 questionnaire revealed a significant and sustained improvement in EG over time when compared to the CG. Undoubtedly, exercise can improve general health and QoL through mood changes, well-being enhancement, better resting time, abilities acquisition over postural control, and consequent autonomy recovery (Colberg et al., 2016). Our findings are coincident with previous studies about the effect of exercise on people with diabetes (Dixit, A. Maiya et al., 2014b).

Consistent with our results, the available evidence shows that postural control abilities can be improved in people with DPN (Colberg et al., 2016; Streckmann et al., 2021). However, it is important to note that there are scarce randomized controlled trials including samples

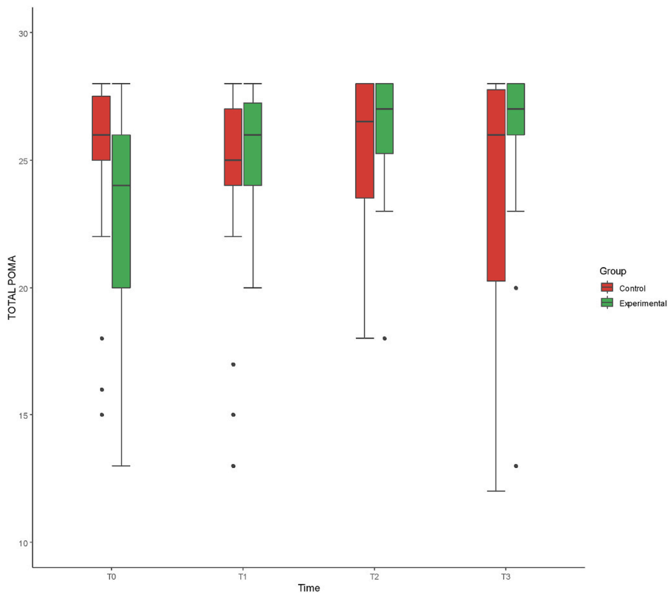

Fig. 4. Box plot showing the global POMA results.

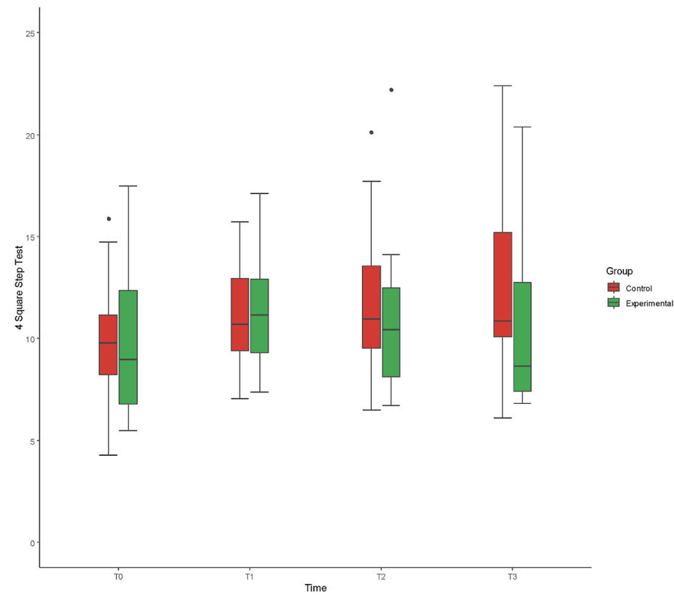

Fig. 6. Box plot showing the 4 Square Step Test results.

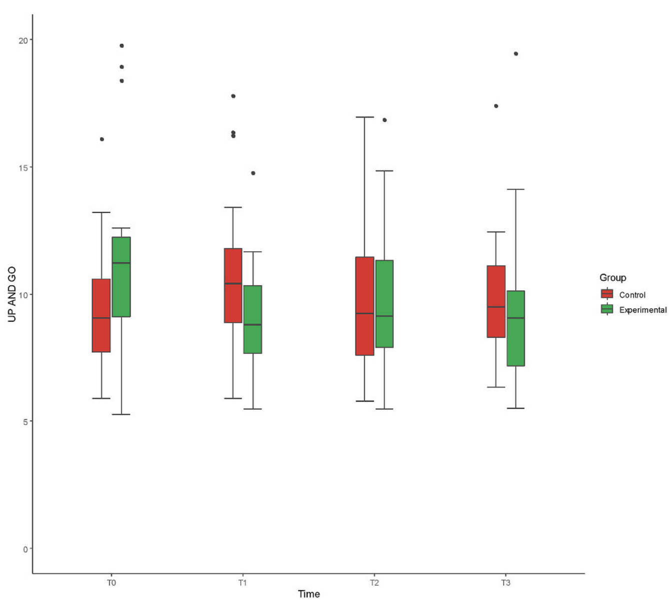

Fig. 5. Box plot showing the Up and Go test results.

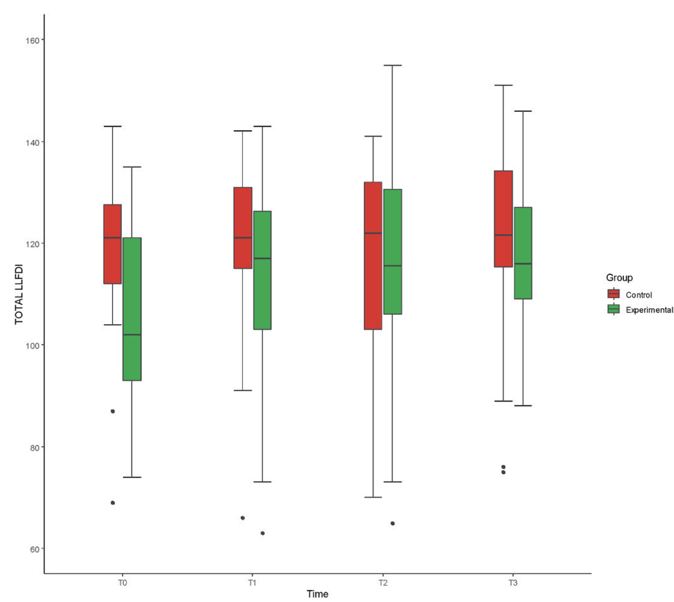

Fig. 7. Box plot showing the global LLFDI results.

with proven postural control dysfunction or having suffered previous falls. The Up and Go test and the POMA test offered significant results for the EG, however, the quick change of direction required for the Four Square Step test likely needs more specialized and demanding intervention strategies, which were not provided in the present study. Previous studies applying sensorimotor training in people with DPN (Ahmad et al. 2019, 2020) differ in the design: their samples are younger (from 45 to 75 years), they do not include any necessary balance impairment among inclusion criteria, and they do not include follow-up period. Their interventions consist of exercises requiring advanced DB abilities, such as managing the body on unstable surfaces, assuming a prone position on the floor, and performing some aerobic tasks. The authors consider that most of them could be unattainable for older adults with DPN and a proven postural control dysfunction. Despite the differences, these works report interesting significant effects in motor behavior and proprioception, though they focus on the whole-body proprioception rather than specifically on the feet and lower legs.

A noteworthy aspect of our study is the high dropout rate, with only 27 out of 44 participants completing the 6 months of follow-up, representing a 39% loss. The substantial sample loss impacts data interpretation. However, it is necessary to consider that the sample has a history of falls or postural control dysfunction at baseline, frequent comorbidities, and a deteriorated autonomy. It has been previously evidenced that people older than 60 and with chronic diseases, often interrupt intervention, particularly in longitudinal studies measuring functional aspects (Provencher et al., 2014; Bullard et al., 2019). Despite these challenges, the follow-up period demonstrated that the EG maintained the significant improvement in graphesthesia, fear of falling and postural control abilities (measured through the POMA and Balance POMA test) at the 3-month follow-up measurement; additionally, the SF-36 questionnaire indicated significant improvements in social function and vitality, and the perceived functional limitation obtained significant improvement at the 6-month follow-up. These sustained improvements are crucial for encouraging more active lifestyles. Despite

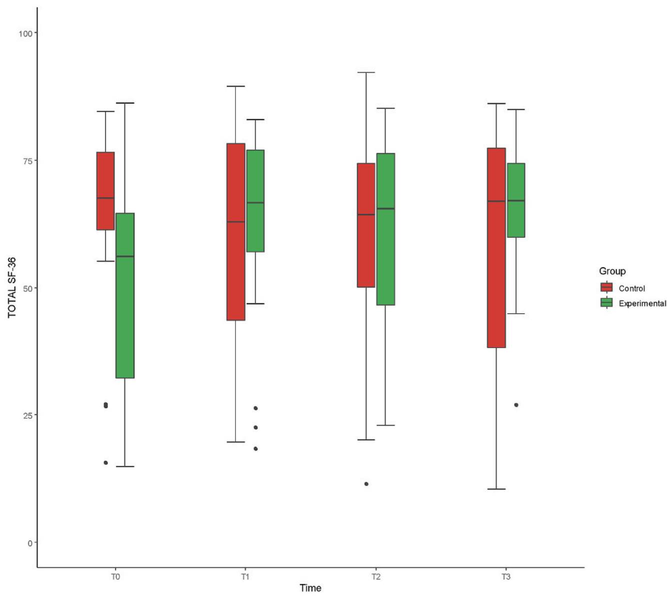

Fig. 8. Box plot showing the global SF-36 results.

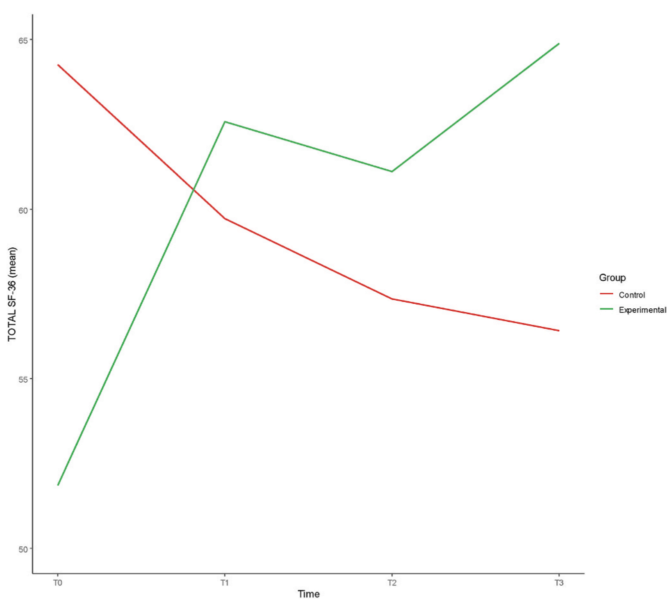

Fig. 9. Linear graph showing the global SF-36 results.

the difficulties encountered, further research efforts focusing on older adults with chronic diseases are essential (Goodwin et al., 2023). It is necessary to persist in creating therapeutic strategies to extent the autonomy of older adults with DPN (Stevens and Lee 2018).

Among different types of exercise applied to people with DPN, sensorimotor training is probably the most feasible, realistic and effective therapeutic option to balance control and self-confidence recovery when a high risk of falling can be found. The learning process pursued through Feldenkrais method is specially indicated for the older adults because the central nervous system can compensate for peripheral deficits (Dideriksen and Negro 2021). This approach was included in the present study to enhance gait pattern coordination, which has been previously evidenced to benefit balance control abilities (Mikula et al., 2018). The intervention and the measurement processes are straightforward and generalizable. The improvement in SPCF, DB strategies, fear of falling reduction, and a better QoL could facilitate the inclusion of older adults with DPN in other exercise interventions.

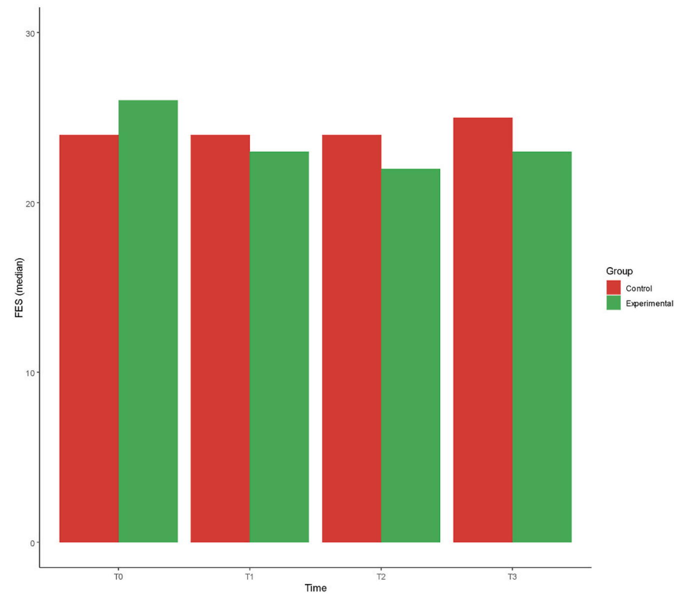

Fig. 10. Histogram showing the FES results.

4.1. *Unanswered questions and future research*

In future studies, the sample should be stratified by age and DPN severity to achieve a deeper knowledge of this major health concern.

Aspects related to training periodicity also merit mentioning: general recommendations about training duration in peripheral neuropathy defend it should be 12 weeks or longer (Streckmann et al., 2021). Further research will be required to determine the optimal dosage of exercise training.

Differences in intervention procedures, principally in aspects related to isolated or combined types of exercise and training periodicity, make it difficult to compare cause-effect interactions. Tailored training programs for older adults with DPN are needed to reduce falls and fall-related injuries. The authors hypothesize that complementing our intervention with electric therapy, adding strength exercises, changing directions activities, ramps, and steps could have been more effective, leading to significant vibration threshold improvement.

There is evidence about the effect of exercise on diabetic foot prevention (Silva et al., 2021). The recovery of pressure sensibility in people with DPN could benefit this major health concern and should merit specific research.

Significant improvement in sural nerve conduction has been observed in people with DPN after an exercise intervention, probably due to remyelination or accelerated axonal regeneration (Dixit, A.G. Maiya et al., 2014). The above-mentioned somatosensory results should be measured with neurophysiological changes.

Previous studies have proposed home-based exercise to recover participants' autonomy (Win et al., 2020; Silva et al., 2021). It could be especially appropriate in older adults with DPN and a high risk of falls because they tend to be dependent. The relation between participants' autonomy and potential sample loss is recommended to be analyzed in future works design.

In the present study, pain and falls measurements were only measured at baseline and not after treatment or during the follow-up period. Given the importance of fall prevention, and the fact that pain could interfere with SPCF and DB control (Karmakar et al., 2014), further research should include them as dependent variables.

Table 5
Partial results of the CSII. Group and measurement point comparison. DIF: difference; Proprio: proprioception; Graphes: graphesthesia; N: sample size; ***significant differences; *medium effect size.

	N	U- Mann-Whitney	W-Wilcoxon	Z	Sig.asymptotic (bilateral)	Effect size
DifPressure T0-T1	41	125.500	365.500	−2.833	0.005***	0.4*
DifPressure T0-T2	30	135.500	288.500	−0.19	0.985	0.003
DifPressure T0-T3	27	90.500	181.500	−0.389	0.697	0.1
DifVibration T0-T1	41	175.000	406.000	−0.994	0.320	0.2
DifVibration T0-T2	30	136.000	272.000	0	1.000	0
DifVibration T0-T3	27	89.000	194.000	−0.123	0.902	0
DifProprio T0-T1	41	106.000	337.000	−2.895	0.004***	0.45*
DifProprio T0-T2	30	118.000	271.000	−0.698	0.485	0.1
DifProprio T0-T3	27	58.500	149.500	−1.785	0.074	0.34*
DifGraphes T0-T1	41	100.500	331.500	−3.139	0.002***	0.49*
DifGraphes T0-T2	30	70.500	223.500	−2.649	0.008***	0.46*
DifGraphes T0-T3	27	56.500	161.500	−1.835	0.067	0.35*

Table 6
POMA subscales results POMA B: POMA balance; POMA G: POMA gait; NC: control group sample; NE: experimental group sample; ***significant differences; **large effect size; *medium effect size.

Variable	Measurements comparison	N C	Control median (IR)	N E	Experimental median (IR)	p-value	Effect size
POMA B	0 and 1	21	1.0 (0.0, 1.5)	20	−1.5 (−4.0, −0.25)	<0.001***	0.6**
	0 and 2	15	0.0 (−0.5, 2.0)	15	−2.0 (−4.0, 0.0)	0.006***	0.48*
	0 and 3	14	0.0 (−1.0, 1.0)	13	−1.0 (−4.0, 0.0)	0.050	0.4*
POMA G	0 and 1	21	0.0 (−1.0, 0.0)	20	0.0 (−1.0, 1.0)	0.766	0.1
	0 and 2	15	0.0 (−1.0, 0.0)	15	0.0 (−2.25, 0.0)	0.610	0.1
	0 and 3	14	0.0 (0.0, 1.0)	13	0.0 (−2.0, 0.0)	0.104	0.3

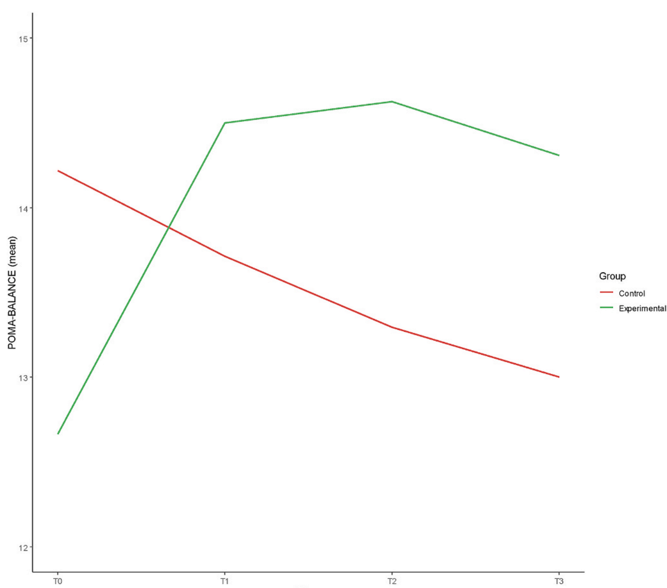

Fig. 11. Linear graph showing Balance POMA subscale results.

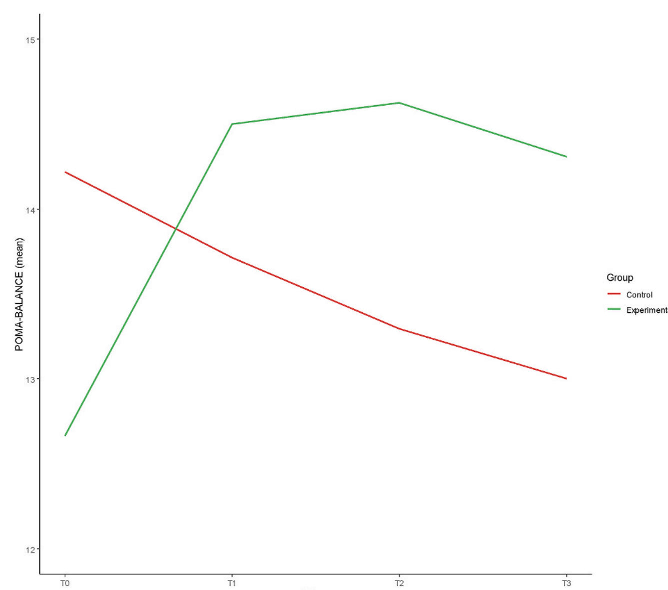

Fig. 12. Linear graph showing LLFDI Limitation subscale results.

Table 7
Partial results of the LLFDI questionnaire LLFD": Late Life Function and Disability Index; NC: control group sample; NE: experimental group sample; ***Significant differences; *Medium effect size.

Variable	Measurements comparison	N C	Control median (IR)	N E	Experimental median (IR)	p-value	Effect size
LLFDI function	0 and 1	21	−2.0 (−4.0, 1.5)	20	−4.0 (−6.75, −0.25)	0.278	0.2
	0 and 2	15	−2.0 (−9.0, 2.5)	15	−3.0 (−8.5, 3.5)	0.928	0.2
	0 and 3	14	−4.0 (−8.25, 0.25)	13	−2.0 (−7.5, 3.5)	0.284	0.2
LLFDI frequence	0 and 1	21	0.0 (−2.0, 3.0)	20	−2.0 (−4.0, 1.0)	0.116	0.3
	0 and 2	15	−1.5 (−4.0, 2.25)	15	−2.0 (−6.5, 1.75)	0.489	0.3
	0 and 3	14	−2.0 (−6.0, 3.0)	13	−1.0 (−6.0, −0.5)	0.694	0.3
LLFDI limitation	0 and 1	21	0.0 (−2.0, 3.0)	20	−3.0 (−5.75, 1.75)	0.050	0.3
	0 and 2	15	0.5 (−1.25, 2.25)	15	−3.0 (−8.25, 1.0)	0.080	0.3
	0 and 3	14	−1.0 (−1.0, 2.0)	13	−4.0 (−5.5, −1.5)	0.015***	0.46*

Table 8
Partial results of the SF-36 questionnaire. NC: control group sample; NE: experimental group sample; ***Significant differences; **Large effect size *Medium effect size.

Variable	Time measurement	N C	Control median (IR)	N E	Experimental media (IR)	p-value	Effect size
SF-36 Body Function	0 and 1	21	0.0 (−7.5, 10.0)	20	−2.5 (−20.0, 12.5)	0.325	0.2
	0 and 2	15	−5.0 (−15.0, 10.0)	15	−5.0 (−20.0, 5.0)	0.394	0.1
	0 and 3	14	−5.0 (−15.0, 5.0)	13	−10.0 (−20.0, 0.0)	0.303	0.2
SF-36 Physical Role	0 and 1	21	0.0 (0.0, 37.5)	20	−25.0 (−50.0, 0.0)	0.001***	0.53**
	0 and 2	15	0.0 (0.0, 25.0)	15	−25.0 (−43.75, 0.0)	0.001***	0.6**
	0 and 3	14	0.0 (0.0, 18.75)	13	−25.0 (−50.0, 0.0)	0.060	0.4
SF-36 Body Pain	0 and 1	21	0.0 (−20.0, 28.75)	20	0.0 (−21.87, 19.37)	0.905	0.0
	0 and 2	15	10.0 (−15.0, 23.75)	15	0.0 (−23.75, 12.50)	0.416	0.1
	0 and 3	14	0.0 (−20.62, 48.12)	13	10.0 (−16.25, 20.0)	0.789	0.1
SF-36 General Health	0 and 1	21	0.0 (−12.5, 10.0)	20	−10.0 (−15.0, 0.0)	0.304	0.2
	0 and 2	15	0.0 (−10.0, 7.5)	15	−5.0 (−5.0, 5.0)	0.971	0.0
	0 and 3	14	−2.5 (−10.0, 1.25)	13	−5.0 (−17.5, 0.0)	0.418	0.2
SF-36 Vitality	0 and 1	21	10.0 (−2.5, 20.0)	20	−5.0 (−10.0, 13.75)	0.232	0.2
	0 and 2	15	5.0 (−2.5, 15.0)	15	−2.5 (−13.75, 5.0)	0.078	0.3
	0 and 3	14	5.0 (0.0, 22.5)	13	0.0 (−22.5, 7.5)	0.039***	0.4*
SF-36 Functionality Role	0 and 1	21	0.0 (0.0, 23.75)	20	0.0 (−10.0, 12.5)	0.300	0.2
	0 and 2	15	0.0 (0.0, 27.5)	15	0.0 (−11.87, 0.0)	0.120	0.3
	0 and 3	14	0.0 (0.0, 35.62)	13	0.0 (−16.25, 0.0)	0.045***	0.4*
SF-36 Emotional Role	0 and 1	21	0.0 (0.0, 16.67)	20	−33.34 (−66.67, 0.0)	<0.001***	0.55**
	0 and 2	15	0.0 (0.0, 33.33)	15	−24.0 (−66.67, 0.0)	0.006***	0.48*
	0 and 3	14	0.0 (−8.33, 8.33)	13	−66.66 (−66.67, 0.0)	0.002***	0.6**
SF-36 Mental Health	0 and 1	21	−4.0 (−14.0, 3.5)	20	−2.0 (−23.0, 6.0)	0.446	0.1
	0 and 2	15	0.0 (−6.0, 10.0)	15	−2.0 (−15.0, 7.0)	0.447	0.1
	0 and 3	14	0.0 (−9.0, 20.0)	13	0.0 (−12.0, 4.0)	0.607	0.1
SF-36 Transition	0 and 1	21	0.0 (0.0, 0.0)	20	−25.0 (−25.0, 0.0)	0.004***	0.48*
	0 and 2	15	0.0 (−25.0, 0.0)	15	−25.0 (−25.0, 0.0)	0.080	0.3
	0 and 3	14	0.0 (−25.0, 25.0)	13	−25.0 (−25.0, 0.0)	0.100	0.3

4.2. Strengths and limitations

4.2.1. Strengths

This study targeted a population frequently neglected in terms of functionality, despite the fact that physical activity is one of the main pillars of its treatment. The safe sensorimotor training based on the FM is affordable for a vulnerable sample, something that is also difficult to find in the current scientific literature. The FM emphasizes attention, something unusual to find in traditional exercise interventions.

The study's novelty includes the assessment of the different somatosensory modalities related to postural control for the first time. It is also important the fear of falling measurement and reduction since it is itself a risk factor for falling. The selection of the tests for this study is characterized by their simplicity, agility in handling clinical activity and low cost.

4.2.2. Limitations

Several limitations were identified, including the small sample size, which limits the generability of the results. Placebo and learning effects in both groups could have influenced the outcomes in both groups. Moreover, the subjective nature of the test and questionnaires can interfere with the results obtained. Regarding the CSII, while the reliability of individual somatosensory modality test has been proved (Deshpande et al., 2010), the reliability of the total score has not been tested. In the case of LLFDI, the sensibility to important clinical changes has not been adequately, potentially explaining the lack of significant results. Additionally, the use of the drawings to facilitate lesson adherence may have been ineffective, as they were scarcely used by participants.

5. Conclusions

Significant short-term effects were observed in somatosensory postural control-related function, dynamic balance, and fear of falling. Significant short and mid-term effects were achieved on quality of life. Older adults with diabetic polyneuropathy, dynamic balance impairment, or a history of falls can benefit from the Feldenkrais method. This method has been evidenced as a useful and safe exercise modality for older people with DPN at risk of falling. The learning process through the attention paid to the movement and its consequences, engages the central nervous system to compensate for peripheral damage. The recovery of somatosensory and postural control functionality can increase autonomy and may facilitate participation in more intense exercise programs targeting metabolic changes.

CRediT authorship contribution statement

M.J. Jimenez-Mazuelas: Writing – original draft, Investigation, Conceptualization. **N. Gonzalez-Perez de Villar:** Methodology, Data curation. **S. De Casas-Albendea:** Methodology. **L. Martinez-Gimeno:** Methodology. **S. Jimenez-Gonzalez:** Methodology, Conceptualization. **M.T. Angulo-Carrere:** Writing – review & editing, Supervision.

Data deposition

Supplementary material (SM) is available on: this information is not offered to obey the confidentiality rules.

Data availability

The data used in the analysis reported in this paper will be made available upon request to the corresponding author.

Ethical approval

This study was conducted in accordance with the Declaration of Helsinki. The experimental procedures were approved by the Hospital Universitario de La Paz and the Hospital Universitario Principe de Asturias Ethics committee.

Declaration of competing interest

This research did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors. The authors

declare that they have not known competing for financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jbmt.2024.10.041.

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