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Article

Assessment of Postural Control and Gait in Chronic Stroke Patients After Treadmill Perturbation-based Training: A Randomized Clinical Trial

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Abstract

Background. After ischemic heart disease, stroke is globally the second leading cause of death and the second most common cause of disability. The rehabilitation of chronic stroke patients increasingly uses advanced technologies, such as treadmill perturbation-based training (TPBT). While the results of studies with TPBT are promising, they are inconclusive due to the limited number of works and inconsistent research methodologies. Therefore, more randomized clinical trials (RCTs) are needed to evaluate TPBT's efficacy and applicability in post-stroke rehabilitation. This prospective RCT was designed to assess whether and to what extent TPBT can improve postural balance and gait quality and reduce fear of falling in chronic stroke patients. **Methods.** Fifty individuals at least six months post-stroke were enrolled in the trial and randomly assigned to the experimental group (EG; n = 25) to receive the TPBT or the control group (CG; n = 25) to receive overground gait and balance training. Both groups exercised six times per day for three weeks. **Results.** The Berg Balance Scale showed post-intervention that postural balance improved significantly in both groups (EG, p=0.001 and CG, p=0.009) but the change did not statistically significantly differentiate the EG from the CG (p=0.256). Significant improvements in walking speed over the distance of 10 meters (p=0.015) and fear of falling (p=0.002) in the CG were not significantly different from those in the EG (p=0.543). **Conclusions.** TPBT applied to chronic stroke patients improves their postural control comparably to conventional gait and balance training but does not enhance their gait quality.

Keywords: stroke; physical therapy; treadmill; balance perturbations; perturbation-based training; postural control; gait quality

1. Introduction

Stroke is the second most common cause of death after ischemic heart disease and the second leading cause of disability globally [1]. The Global Burden of Disease Study [1] estimated that in 2016, 80.1 million people were living with stroke worldwide (95% uncertainty interval [UI] 74.1–86.3), of whom 13.7 million (95% UI 12.7–14.7) suffered a first-ever stroke. Stroke, mostly of ischemic type

(84%; 95% UI 82.1–86.4), was diagnosed in 41.1 million women (95% UI 38.0–44.3) and 39.0 million men (95% UI 36.1–42.1). According to the Study's stroke mortality statistics, 5.5 million people (95% UI 5.3–5.7) died of a stroke in 2016, and 116.4 million (95% UI 111.4–121.4) became disabled as a result of acute or chronic stroke [1]. Between 1990 and 2013, the global number of strokes and stroke-related deaths and disabilities among individuals aged 20–64 years increased significantly by 1.4–1.8 times for ischemic strokes and 1.2–1.9 times for hemorrhagic strokes [2].

After a systematic review of clinical trials, Steward et al.[3] pointed to physical activity as a vital element of stroke prevention and treatment. Physical exercise reduces the effects of neurological damage and stimulates brain plasticity in stroke survivors, with the greatest improvement in motor function occurring in the early post-stroke phase. In the chronic phase (six months after a stroke and later), many patients reach a plateau or experience slower motor recovery, which dispirits them and causes that they withdraw from physiotherapy [4,5]. Studies show, however, that regular physical exercise can offer significant health improvements even months after stroke [6–12], also in patients who have reached a recovery plateau [6]. This means that patients in the late post-stroke period should not be excluded from training programs based on physical exercises that require learning new tasks, engage conscious attention, and stimulate cognitive functions [13].

The most common consequences of stroke are postural balance, control, and gait impairments. France by De Peretti et al. [14] reported balance disorders in 50% of post-stroke patients. Three months after stroke, gait disorders still affect 60% of patients, with 20% of whom need wheelchairs to move around [15–17]. The distance that an adult who suffered an acute or subacute stroke can cover is 40–50% shorter than that a healthy adult can walk [18]. De Haart et al. [19] found abnormal postural control to be one of the main causes of post-stroke mobility impairment. Pohl et al. [18] concluded that balance improvement was the strongest predictor of gait distance that patients could walk three months after stroke.

Post-stroke patients show many changes in motor strategies for postural control, among which body weight asymmetry, delayed and reduced anticipatory postural adjustments, synergistic muscle coactivation, and abnormal postural tilt are the most common. The majority of the changes are related to the impaired central nervous system, but some appear to be adaptive compartments [20]. Lamb et al. [21] concluded that postural and balance impairments are the strongest predictors of falls in stroke survivors, and Belgen et al. [22] reported that individuals who had experienced falls were more fearful of falling in the chronic post-stroke phase (relative risk [RR]=2.4; 95% confidence interval [CI] 1.1–4.9) and show lower falls-related self-efficacy ($p=0.04$) and more depressive symptoms ($p=0.02$) than those who had not fallen. Evidence has also been presented that individuals with a history of multiple falls have poorer balance ($p=0.02$), greater fear of falling ($RR=5.6$; 95% CI, 1.3–23), and use more medications ($p=0.04$) than non- or one-time fallers [22]. Falls are a major cause of injuries leading to disability, social isolation, and reduced quality of life [23]. People who fear falling tend to limit their daily activity and adopt a sedentary lifestyle, which further increases their risk of falling, dependence on others, and disability [24].

For the above reasons, exercises that improve balance and gait quality play a significant role in stroke rehabilitation [13]. To evaluate the ability of different types of exercise to improve balance in chronic stroke survivors, Van Duijnhoven et al. [25] conducted a systematic review and meta-analysis of 43 randomized clinical trials (RCTs) of moderate or high methodological quality (PEDro score ≥ 4) involving a total of 1.613 patients. The authors of most of the studies ($n=28$) assessed participants' postural balance using the Berg Balance Scale (BBS). Subgroup analyses of studies that reported BBS outcomes showed that only balance and weight-shifting training (3.75 points, +6.7%; 95% CI, 1.71–5.78; $p<0.01$; $I^2=52\%$) and gait training (2.26 points, +4.0%; 95% CI, 0.94–3.58; $p<0.01$; $I^2=21\%$) had a significant and positive effect on postural balance.

Programs to rehabilitate balance and gait quality in chronic stroke survivors use various approaches utilizing modern technologies, including treadmill training [10,26–31]. Treadmill exercises, especially those performed without body weight support (BWS) [10,31], are significantly more effective in improving gait speed [10,31] and step length and width [31] than overground training.

Perturbation-based balance training (PBT), which has in recent years been introduced as a therapy for balance and gait impairments of various origins, is usually performed using equipment inducing changes in ground surface compliance [32-34] or moveable floor platforms [35-40]. Also used are treadmills [30,41-47] where balance disturbances are induced by two independently moving belts [48], belt accelerations or decelerations [30,41,43,45,46] and forward-backward as well as lateral belt translations [44]. A systematic review of 8 RCTs by Mansfield et al. [49] found patients who completed the PBT to have a lower risk of falling (overall risk ratio 0.71, 95% CI 0.52–0.96, $p=0.02$) and to report fewer falls than controls who did not perform PBT (overall rate ratio 0.54, 95% CI 0.34–0.85, $p=0.007$). The RCTs involved 404 adults, including healthy and frail older adults (>60 years) and adults with Parkinson's disease.

To the authors' knowledge, there are only 4 RCTs [40,44,45,50] with chronic stroke patients performing PBT. In two of them, authored by Esmaeili et al. [45] and Hu et al. [44], participants had 9 [45] and 20 [44] training sessions spanning 3 [45] and 4 [44] weeks, respectively. In Esmaeili et al. [45], balance perturbations were induced by accelerating and decelerating the treadmill belt, while Hu et al. [44] also used lateral belt translations. The studies produced inconsistent results. Esmaeili et al. [45] reported that PBT improved participants' dynamic balance but not gait speed, whereas Hu et al. [44] observed improvement in gait speed but not found in dynamic balance. The authors of the other two RCTs [40,50] used moveable floor platforms [50] and applied changes in ground surface compliance [40]. Based on the outcomes of a single PBT session, the authors of one of the studies [40] concluded that PBT offered protection from falling by helping develop adaptive responses. The second study was a pilot RCT with only 12 patients, who were equally divided between two groups. After 20 PBT sessions performed over 4 weeks, its authors observed improvement in participants' dynamic balance and gait speed. Three clinical studies [46,47,51] where chronic stroke patients performed PBT did not have control groups. The studies only recruited 10 [51] and 12 [46,47] patients who performed 3 [46], 10 [51], and 15 [47] training sessions, respectively. All three studies reported improvements in participants' gait speed [47,51] and gait quality [46,51].

The cited studies indicate that PBT, including involving the use of a treadmill, is capable of improving balance and gait quality in chronic stroke patients. However, given that RCTs of this type are few and their results are inconsistent due to the variety of training methods used by their authors, more RCTs are needed to ascertain the most appropriate training methods and their ability to influence balance and gait quality in chronic stroke patients.

This RCT was designed to determine whether, and to what extent, treadmill perturbation-based balance training (TPBT) improves balance and gait quality and reduces fear of falling in chronic stroke patients. It also sought to establish whether the effect of TPBT on these parameters would be comparable or greater than in the case of overground gait and balance training.

2. Materials and Methods

2.1. Trial Design

This prospective, randomized, controlled clinical trial was designed to compare body balance, gait quality, and fear of falling in chronic stroke patients divided into two parallel groups that participated in conventional stroke rehabilitation enhanced by treadmill perturbation-based training (TPBT; the Experimental Group, EG), and in conventional stroke rehabilitation supplemented by traditional overground gait and balance training (the Control Group, CG). The trial adhered to the principles of the Declaration of Helsinki and was approved by the Bioethics Committee for Scientific Research at the Jerzy Kukuczka Academy of Physical Education in Katowice, Poland (Resolution No. 5/2020). It was prospectively registered with the International Standard Randomized Controlled Trial Number Registry: ISRCTN17138124.

2.2. Funding

The trial was co-financed by the European Regional Development Fund for the Kuyavian-Pomeranian Voivodeship (Poland; No. RPKK.01.02.01-04-0016/18).

2.3. Setting and Participants

All participants were under the care of the same single medical and rehabilitation center. They were recruited for the study based on the following eligibility criteria: age ≥ 18 years; first-ever ischemic or hemorrhagic stroke occurring ≥ 6 months prior; independent ambulation over 10 meters (assistive devices such as a cane or walker permitted); minimum gait speed of 0.4 km/h; spasticity of the affected lower limb graded between 0 and 2 on the Modified Ashworth Spasticity Scale; Brunnström Recovery Scale stages III–VI for the lower limb; and written informed consent to participate.

Excluded from the trial were patients who suffered more than one stroke; with contraindications to physical exercise or subarachnoid hemorrhage; unable to comprehend verbal instructions; with a Mini-Mental State Examination (MMSE) score ≤ 24 and a Geriatric Depression Scale (GDS) score ≥ 20 ; affected by severe aphasia impeding communication (assessed by a speech therapist); with hemianopsia or hemineglect; with stroke onset < 6 months prior; with complete hip joint ankylosis; with lower limb length discrepancy exceeding 3 cm; presenting with cardiopulmonary insufficiency precluding walking more than 10 meters or conditions affecting gait and balance other than related to stroke (central or peripheral nervous system disorders, fractures of the spine or limbs within the past year, osteoporosis, acute inflammatory diseases of internal organs or the musculoskeletal system, limb amputations, vision impairments, malignancies under treatment, post-chemotherapy neuropathies, diabetic neuropathy, etc.).

All participants completed outpatient and inpatient rehabilitation programs prior to enrollment in the trial, which was part of a broader rehabilitation plan. Their demographic data were collected through standard interviews, physical examinations, and a review of their medical records.

2.4. Randomization

A person unrelated to the trial received 50 slips of paper, 25 of which were marked with "A" (CG) and the other 25 with "B" (EG), and placed each slip in one of 50 envelopes according to a randomized computer-generated sequence. After sealing, the envelopes were delivered to the research manager, who opened them in the presence of a physiotherapist to randomly assign willing and consenting patients (or those who had consenting legal guardians) to either group.

2.5. Blinding

Both the physiotherapist who performed initial and final clinical assessments of the participants and the statistician in charge of data analysis were blinded to group assignments

2.6. Intervention. Post-Stroke Therapy Administered To Both Groups

All patients participated in a 3-week rehabilitation program based on conventional post-stroke therapy. Sessions of 2.5 hours, designed according to the best clinical practices, were delivered Monday through Saturday. The exercises they included aimed to improve participants’ movement patterns and normalize their muscle tone.

2.7. Treadmill Training in the EG

In addition to receiving conventional therapy, participants in the EG exercised on a treadmill (Balance Tutor; MediTouch, Ltd., Israel) controlled by software capable of inducing postural perturbations in the frontal and sagittal planes during walking. A harness connected to an overhead support system protected exercising patients from falling without supporting their body weight. Handrail use was prohibited. Sessions were performed daily for 3 weeks, also Monday through Saturday. The treadmill speed was always set according to patient preference and recorded. Exercise duration and difficulty were progressively increased (Table 1).

Table 1. Perturbation-based treadmill training protocol.

Exercise	Total exercise duration (min)	Walking forward without perturbations (min)	Lateral translations				Forward-backward translations		
			duration (min)	frequency	amplitude (cm)	direction	duration (min)	frequency	amplitude (cm)
1	10	7	3	every 30 sec	7	only toward the paralyzed side			
2					8				
3					10				
4	15		5	every 30 sec	15	toward the paralyzed and unaffected sides	10	every 30 sec	10
5									
6									
7	20		7	every 30 sec	18	toward the paralyzed and unaffected sides	13	every 30 sec	15
8									
9									
10									
11									
12									
13									
14					20				
15									
16									
17									
18									

2.8. Conventional Gait and Balance Training in the CG

The purpose of this training was to improve participants’ performance of functional tasks, such as standing under various conditions (with reduced sensory input, narrowed base of support, while reaching for and catching objects, responding to unexpected manual perturbations), sit-to-stand transfers, multidirectional stepping, overground walking, and walking up and down stairs. Emphasis was placed on stability and normal weight-bearing patterns during training tasks. The use of assistive devices was permitted if needed. Participants were encouraged to use postural control and movement strategies they developed in daily living. The length of sessions was progressively increased to match the duration of sessions in the EG: 10 minutes on days 1–3, 15 minutes on days 4–6, and 20 minutes between day 7 and day 18.

2.10. Measures

Clinical assessments of participants were performed twice, on the day preceding the 3-week rehabilitation program and on the first day after it ended. Their cognitive function was determined pre-intervention using the MMSE [52], and depressive symptoms were assessed with the GDS [53]. Motor function and the stages of lower limb recovery were measured using the Brunnström Recovery Scale [19,54], spasticity severity was evaluated with the Modified Ashworth Scale [55,56], and independence in activities of daily living was established using the 100-point Barthel Index [57].

Participants’ static and dynamic body balance, gait quality, and fear of falling were assessed pre- and post-intervention. Balance measurements were performed using functional tests: the BBS for static and dynamic balance [58], the Functional Reach Test (FRT) for dynamic balance [59], and the Timed Up and Go (TUG) Test for dynamic balance [60]. The BBS is a 14-item objective tool with excellent interrater reliability (ICC=0.97) and intrarater reliability (ICC=0.98) for chronic stroke patients [61]. It also has an adequate ability to predict fall occurrence (area under the curve [AUC] [95% CI]=0.813 [0.691–0.936], sensitivity=75%, and specificity=76.9%) [63]. The FRT assesses dynamic balance in simple tasks and has intersubject reliability of 0.987 (0.983–0.992) and intrasubject reliability of 0.983 (0.979–0.989) for stroke patients [64]. The TUG Test that evaluates mobility, balance, walking ability, and fall risk in older adults has excellent test-retest reliability (ICC=0.96) for chronic stroke patients [65]. Its results show a high correlation (r=0.86–0.92) with the results of other mobility, balance, exercise tolerance, and fall risk tests, such as the Comfortable Gait Speed Test, Fast Gait Speed Test, Stair Climbing Test, and 6-Minute Walk Test [65].

Participants’ static balance was additionally assessed using a stabilometric platform (Zebris FDM, Germany), which recorded forces and torques at a sampling rate of 80 Hz. During measurements, participants stood quietly for 60 seconds with eyes open, feet shoulder-width apart, and arms at their sides. Gait speed was assessed with the 10-Meter Walk Test (10MWT) [66], which measures walking speed over a short distance in meters per second. The test has excellent test-retest reliability (ICC)=0.95–0.99 [67] for chronic stroke patients, as well as excellent reliability for both

comfortable (ICC=0.94) and fast (ICC=0.97) gait speeds [65]. The 10MWT has also been demonstrated to have high predictive validity and excellent correlation with dependence in instrumental activities of daily living ($r=0.76$) and the Barthel Index ($r=0.78$) [68]. Spatiotemporal gait parameters were also evaluated on a treadmill (Zebris FDM-T; Rehawalk, MaxxusDaum h/p Cosmos Force). For patients to be able to find a comfortable walking speed, they walked on the treadmill to try it before the test; during this trial, the belt speed was decreased and increased twice. A 30-second measurement was taken and its result was included in the analysis.

Participants' fear of falling was assessed using the 16-item Falls Efficacy Scale-International (FES-I) [69,70], which showed excellent internal consistency (Cronbach's $\alpha=0.96$) and test-retest reliability (ICC=0.96) in a group of 704 seniors aged 60-95 years at risk of falls. Its high validity and reliability have also been confirmed by a study on individuals with neurological disorders, including vestibular disorders (ICC=0.94) [71] and Parkinson's disease (ICC=0.91 to 0.94) [72].

2.11. Outcomes. Primary Outcomes

Primary outcomes of the trial included static and dynamic body balance and gait speed, which were measured at baseline and after 3 weeks of the rehabilitation program using the BBS and the 10MWT, respectively.

2.12. Secondary Outcomes

Secondary outcomes included dynamic body balance assessed by the TUG Test and the FRT; static body balance assessed on a stabilometric platform (Zebris FDM-T; Rehawalk, MaxxusDaum h/p Cosmos Force); gait quality assessed by a walking test on a treadmill (Zebris FDM-T; Rehawalk, MaxxusDaum h/p Cosmos Force); and fear of falling assessed using the FES-I questionnaire. These tests, too, were conducted at baseline and after 3 weeks of rehabilitation.

2.13. Statistical Analysis. Sample Size Calculation

To determine the appropriate sample size for the EG and CG, a pilot study was conducted with 12 chronic post-stroke patients, randomized to receive either perturbation-based treadmill training (EG) or conventional overground gait and balance training (CG) according to clinical guidelines. Body balance and gait speed over 10 meters were measured after three weeks of intervention using the BBS and 10MWT, respectively. Given the unimodal distribution of scores and skewness and kurtosis values below 2.5, the arithmetic mean and standard deviation were used to describe central tendency and dispersion. For the sample size calculation, the significance level (Type I error) was set at $\alpha = 0.05$ and the Type II error at $\beta = 0.1$ (power = 0.90). A minimum clinically important difference (MCID) of 25% between pre- and post-intervention values was assumed. Based on these outcomes and Student's t-distribution, each group required at least 23 participants. To account for potential dropouts, two additional participants per group were recruited, resulting in a final sample size of 25 per group.

2.14. Intention-to-Treat Analysis

All 50 randomized patients were included in the intention-to-treat (ITT) analysis. For participants who did not complete the intervention, missing data were imputed using linear regression based on prior assessments and clinical similarity, according to the formula: $y = a \cdot x + b$, where a is the regression coefficient and b is the intercept. This approach assumed a linear trend in the variables under study. The impact of imputation was evaluated by sensitivity analysis comparing ITT and per-protocol outcomes; the absence of statistically significant differences indicated that imputation did not materially affect the trial's results.

2.15. Statistical Analysis

All statistical analyses were performed using Statistica software (version 15, StatSoft Polska Sp. z o.o.). A significance level of $p \leq 0.05$ was adopted for all tests. The normality of pre-intervention variable distributions was assessed using the Shapiro-Wilk test, and the homogeneity of variances was evaluated with Levene's test. As the data did not meet assumptions of normality and

homogeneity of variance, non-parametric tests were used throughout the analysis. For descriptive statistics, both means with standard deviations and medians with interquartile ranges were reported, reflecting the unimodal distributions and skewness/kurtosis values below 2.5. Baseline characteristics were compared between groups using the Mann–Whitney U test for continuous variables and the chi-square test for categorical variables. Within-group pre- and post-intervention results were compared using the Wilcoxon signed-rank test. Between-group comparisons of outcome changes were performed using the Mann–Whitney U test.

For all primary and secondary outcomes, effect sizes were estimated using Cohen’s d, calculated from group means and pooled standard deviations. This approach provides a standardized measure of the magnitude and precision of observed effects, facilitating interpretation and comparison across outcomes and studies. All analyses adhered to the intention-to-treat principle, and sensitivity analyses were conducted to confirm the robustness of findings. All 50 randomized participants were included in the intention-to-treat analysis. Sensitivity analysis comparing ITT and per-protocol populations revealed no significant differences in the main outcomes.

3. Results

Between July 1, 2020, and June 30, 2022, 64 patients were screened for the trial. Fifty patients who met the inclusion criteria were randomly assigned to either the EG and CG. Five patients (10%) did not complete the trial. Two patients in the EG and two in the CG withdrew due to a deterioration in health unrelated to the procedures used in the study, while one patient in the CG withdrew without providing a reason. The remaining 45 participants completed the intervention. The participant flow is presented in Figure 1.

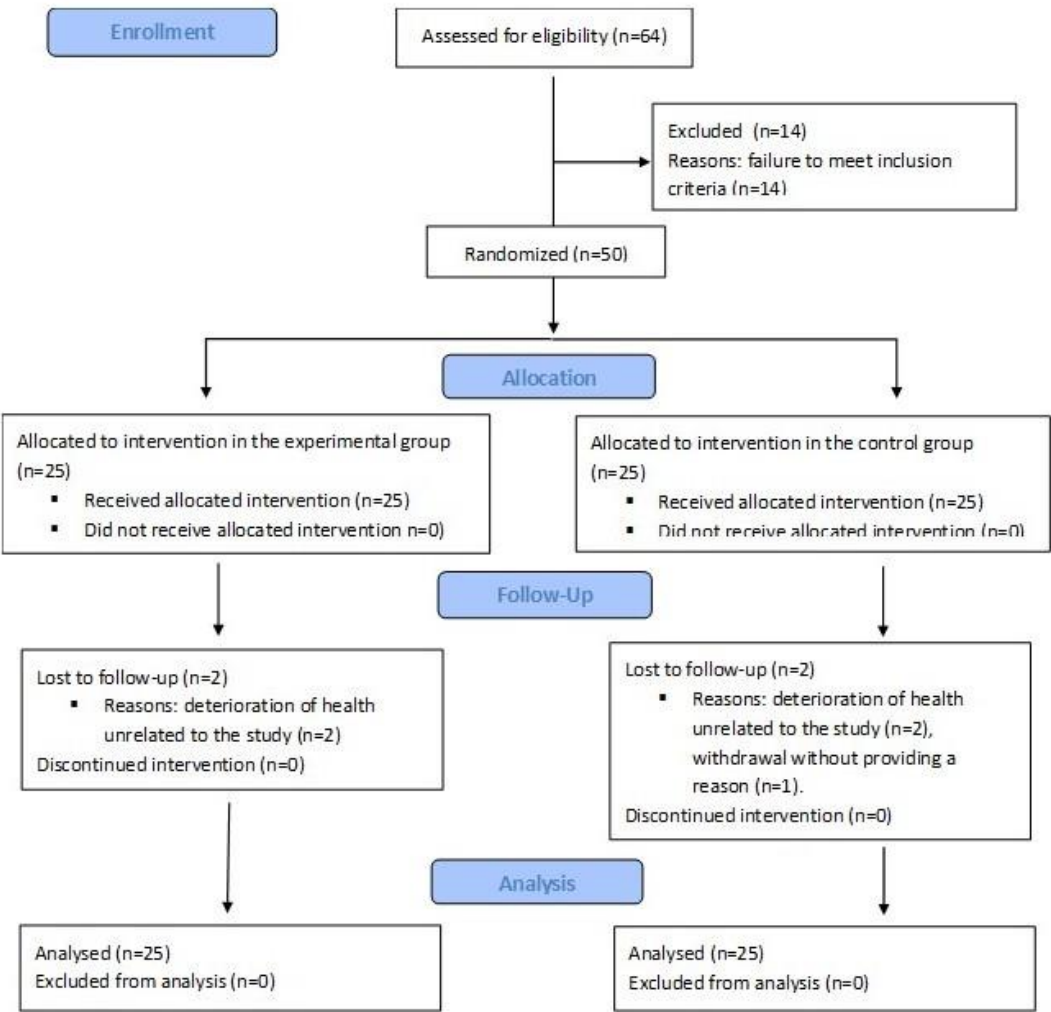


Figure 1. Diagram flow of the study.

3.1. Baseline Characteristics

Participants’ ages ranged from 45 to 82 years. BMI distribution was as follows: 15 participants (30%) had normal weight (BMI 18.5–24.99 kg/m²), 27 (54%) were overweight (BMI 25.0–29.99 kg/m²), 4 (8%) had obesity class I (BMI 30.0–34.99 kg/m²), and 4 (8%) had obesity class II (BMI 35.0–39.99 kg/m²). All participants (100%) had suffered an ischemic stroke 6–28 months prior to enrollment. Twenty-four participants (48%) had right-sided paresis, and 26 (52%) had left-sided paresis. In 24 patients (48%), the dominant limb was affected; in 26 (52%), the non-dominant limb. Brunnstrom Recovery Stages for the lower limb were: stage 3 in 4 (8%), stage 4 in 6 (12%), stage 5 in 8 (16%), and stage 6 in 32 (64%) participants. Increased muscle tone was not observed in 9 (58%) participants (grade 0, Modified Ashworth Scale), was slight in 9 (18%, grade I), and moderate in 3 (6%, grade II). Apart from 1 participant (2%) with severe dependence in activities of daily living (Barthel Index 21–60), all others (98%) were moderately dependent (Barthel Index 61–90). At baseline, there were no statistically significant differences between the EG and CG for any demographic or clinical variables (Tables 2 and 3).

Table 2. Perturbation-based treadmill training protocol.

Characteristics	Experimental group (n=25)	Control group (n=25)
¹ Gender: female / male [n (%)]	10 (40%) / 15 (60%)	9 (36%) / 16 (64%)
² Age [years]:		
Mean (SD)	60.87 (11.01)	64.20 (6.38)
Median (Q1 – Q3)	62.0 (54.6-69.4)	65.0 (60.7-67.3)
¹ BMI [no. of Pts (%)]:		
< 18.5 (underweight)	0 (0%)	0 (0%)
18.5 – 24.99 (normal)	8 (32%)	7 (28%)
25.0 – 29.99 (overweight)	13 (52%)	14 (56%)
30.0 – 34.99 (class I obesity)	2 (8%)	2 (8%)
35.00 – 39.99 (class II obesity)	2 (8%)	2 (8%)
¹ Ischemic stroke / hemorrhagic stroke [no. of Pts (%)]:	25 (100%) / 0 (0%)	25 (100%) / 0 (0%)
² Time since stroke [months]:		
Mean (SD)	12.33 (6.56)	11.83 (5.95)
Median (Q1 – Q3)	12.0 (7.6-16.4)	12.0 (7.0-15.0)
¹ Affected side: right / left	11 (44%) / 14 (56%)	13 (52%) / 12 (48%)
¹ Affected side [dominant / non-dominant] [no. of Pts (%)]	10 (40%) / 15 (60%)	14 (56%) / 11 (44%)
¹ Brunnström Recovery Scale [number of Pts (%)]		
Stage III	1 (4%)	3 (12%)
Stage IV	4 (16%)	2 (8%)
Stage V	5 (20%)	3 (12%)
Stage VI	15 (60%)	17 (68%)
¹ Modified Ashworth Spasticity Scale: 0 / I / II [number of Pts (%)]		
Grade 0	18 (72%)	21 (84%)
Grade 1	5 (20%)	3 (12%)
Grade 2	2 (8%)	1 (4%)
¹ Barthel Scale [points]:		
Mean (SD)	94.5 (9.5)	95.83 (6.83)
Median (Q1 – Q3)	95.0 (88.0–100.0)	97.0 (91.0–100.0)

0-20 points (total dependence)	0 (0%)	0 (0%)
21-60 points (severe dependence)	1 (4%)	0 (0%)
61-90 points (moderate dependence)	24 (96%)	25 (100%)
² Berg Balance Scale [points]:		
Mean (SD)	45.83 (8.85)	46.00 (11.05)
Median (Q1 – Q3)	47.0 (39.0-53.0)	46.0 (38.6-53.4)
² Functional Reach Test [cm]:		
Mean (SD)	33.23 (11.09)	29.87 (9.29)
Median (Q1 – Q3)	33.0 (25.5-40.5)	30.0 (23.7-36.3)
² Timed Up and Go Test [s]:		
Mean (SD)	13.86 (9.61)	13.07 (6.56)
Median (Q1 – Q3)	12.0 (6.5-19.5)	12.0 (7.6-18.4)
² 10 Meter Walk Test [m/s]:		
Mean (SD)	0.64 (0.21)	0.63 (0.25)
Median (Q1 – Q3)	0.62 (0.50-0.78)	0.62 (0.46-0.80)
² Falls Efficacy Scale – International [points]:		
Mean (SD)	32.59 (11.83)	28.47 (8.96)
Median (Q1 – Q3)	32.0 (24.0-40.8)	28.0 (22.0-34.0)

Pts – patients; SD – standard deviation; Q1 – lower quartile; Q3 – upper quartile. ¹Chi-square test; ²Mann–Whitney U test; The groups did not differ at baseline for any patients’ characteristics (p>0.05).

Table 3. Pre-intervention characteristics of the groups, cont’d.

Characteristics	Experimental group (n=25)	Control group (n=25)
	Mean (SD)	
	Median (Q1, Q3)	
Assessment of postural balance on a stabilometric platform (60 s)		
CoP path length [mm]	668.10 (378.70)	622.45 (450.46)
	701.0 (412.57, 923.63)	688.41 (318.57, 926.33)
95% confidence ellipse area [mm²]	11.10 (6.27)	10.50 (7.25)
	11.90 (6.87, 15.33)	10.12 (5.61, 15.39)
Spatiotemporal gait parameters		
Left side: step length [cm]	27.5 (8.9)	27.6 (9.0)
	27.8 (21.50, 33.50)	27.9 (21.53, 33.67)
Left side: stance phase [%]	71.1 (4.5)	69.7 (3.5)
	71.4 (68.06, 74.14)	69.94 (67.34, 72.06)
Right side: step length [cm]	27.4 (8.2)	27.2 (8.1)
	27.95 (21.87, 32.93)	27.75 (21.74, 32.66)
Right side: stance phase [%]	69.0 (4.6)	68.5 (4.0)
	69.31 (65.90, 72.10)	68.77 (65.80, 71.20)
Stride length [cm]	55.2 (15.9)	55.7 (13.6)
	56.27 (44.48, 65.92)	56.62 (46.53, 64.87)
Stride time [s]	1.4 (0.24)	1.5 (0.22)
	1.42 (1.24, 1.56)	1.52 (1.35, 1.65)
Step width [cm]	13.1 (3.9)	12.2 (4.1)
	13.36 (10.47, 15.73)	12.48 (9.43, 14.97)
Double stance phase [%]	41.1 (8.5)	40.3 (6.4)
	41.67 (35.37, 46.83)	40.73 (35.98, 44.62)
Cadence [step/min]	82.4 (14.7)	80.9 (17.2)
	83.39 (72.48, 92.32)	82.06 (69.30, 92.50)
Velocity [km/h]	1.40 (0.4)	1.30 (0.2)
	1.43 (1.13, 1.67)	1.31 (1.17, 1.43)

Scheme 1. – lower quartile; Q3 – upper quartile. The groups did not differ at baseline for any patients’ characteristics (Mann–Whitney U test $p>0.05$).

3.2. Primary Study Outcomes

BBS. After the intervention, both groups improved significantly on the BBS. In the EG, the mean BBS score increased from 43.83 (SD 8.85) to 49.50 (SD 7.82) (within-group $p=0.001$). In the CG, the mean increased from 46.00 (SD 9.80) to 49.23 (SD 9.80) (within-group $p=0.009$). The between-group difference in BBS change was 2.44 points (CI: –8.93 to 13.81), with a Cohen’s d of 0.27 (CI: –0.99 to 1.52), indicating a small effect size and no statistically significant difference between groups (pre-intervention $p=0.408$, post-intervention $p=0.256$; Table 4).

10MWT. Gait speed improved significantly only in the CG, increasing from 0.63 m/s (SD 0.25) to 0.70 m/s (SD 0.21) (within-group $p=0.015$). The between-group difference in change was –0.07 m/s (CI: –0.37 to 0.23), Cohen’s $d = -0.30$ (CI: –1.55 to 0.96), again indicating a small and non-significant effect (pre-intervention $p=0.948$, post-intervention $p = 0.543$; Table 4).

3.3. Secondary Study Outcomes

FRT. Functional reach increased significantly post-intervention only in the CG (from 29.87 [SD 9.29] cm to 34.50 [SD 8.64] cm, $p=0.021$). The between-group difference in change was 4.63 cm (99.99% CI: –5.24 to 14.50), Cohen’s $d = 0.52$ (CI: –0.60 to 1.63); however, this difference was not statistically significant (pre $p=0.150$, post $p=0.870$; Table 4).

TUG Test. The CG required significantly less time post-intervention (from 13.07 [SD 6.56] to 11.13 [SD 4.88] seconds, $p=0.009$). The between-group difference in change was –1.94 seconds (CI: –8.30 to 4.42), Cohen’s $d = -0.34$ (CI: –1.44 to 0.77), with no significant difference between groups (pre $p=0.958$, post $p=0.623$; Table 4).

FES-I. A significant decrease in fear of falling was observed only in the CG (from 28.47 [SD 8.96] to 26.10 [SD 9.10], $p=0.002$). The between-group difference in change was –2.37 points (CI: –12.31 to 7.57), Cohen’s $d = -0.26$ (CI: –1.37 to 0.84); differences between groups were not significant (pre $p=0.525$, post $p=0.527$; Table 4).

Static Balance (Stabilometric Platform). No statistically significant changes were observed in CoP path length or 95% confidence ellipse area in either group (EG: $p=0.385$ and $p=0.367$; CG: $p=0.824$ and $p=0.741$). Between-group differences in change were 0.00 (CI: –11.01 to 11.01), Cohen’s $d = 0.00$ (CI: –1.10 to 1.10), with no significant differences at baseline or post-intervention (CoP path length: $p=0.678$ and $p=0.675$; ellipse area: $p=0.597$ and $p=0.672$; Table 5).

Spatiotemporal Gait Parameters. Significant changes post-rehabilitation were observed only in the EG, where step length increased for both legs (right: from 27.4 [SD 8.2] cm to 30.3 [SD 9.0] cm, $p=0.015$; left: from 27.5 [SD 8.9] cm to 30.1 [SD 9.8] cm, $p=0.449$). The between-group differences in step length change were 2.90 cm (right leg: CI: –6.12 to 11.92), Cohen’s $d = 0.35$ (CI: –0.76 to 1.46), with no significant differences between groups (right: $p=0.932$; left: $p=0.750$).. In the EG, cadence decreased significantly (from 82.4 [SD 14.7] to 79.6 [SD 15.9] steps/min, $p=0.029$), but the between-group difference in change was not significant ($p=0.250$). Other gait parameters showed no significant within- or between-group differences (Table 6).

Table 4. Within- and between-group comparison of functional tests’ results and fear of falling (n=50).

Characteristics	Experimental group	Control group	² Between-group level of significance (p)
	(n=25)	(n=25)	
	Mean (SD) Median (Q1, Q3)		
Berg Balance Scale [points]			
Before	45.83 (8.85)	46.00 (11.05)	0.408
	44.84 (39.86, 51.80)	45.67 (38.55, 53.45)	
After	49.50 (7.82)	49.23 (9.80)	0.256
	49.10 (44.23, 54.77)	49.22 (42.62, 55.84)	

¹ Within-group level of significance (p):	0.001	0.009	
Functional Reach Test [cm]			
Before	33.23 (11.09) 33.20 (25.76, 40.70)	29.87 (9.29) 29.82 (23.61, 36.13)	0.150
After	34.47 (9.01) 34.41 (28.40, 40.54)	34.50 (8.64) 34.53 (28.68, 40.32)	0.870
¹ Within-group level of significance (p):	0.513	0.021	
Timed Up and Go Test [s]			
Before	13.86 (9.61) 13.84 (7.38, 20.34)	13.07 (6.56) 13.04 (8.65, 17.49)	0.958
After	12.70 (7.49) 12.67 (7.65, 17.75)	11.13 (4.88) 11.11 (7.82, 14.44)	0.623
¹ Within-group level of significance (p):	0.047	0.009	
10 Meter Walk Test [s]			
Before	0.64 (0.21) 0.62 (0.50, 0.78) 0.66 (0.23) 0.70 (0.55, 0.82)	0.63 (0.25) 0.60 (0.46, 0.80)	0.948
After		0.70 (0.21) 0.71 (0.56, 0.86)	0.543
¹ Within-group level of significance (p):	0.170	0.015	
Falls Efficacy Scale – International [points]			
Before	32.59 (11.83) 32.56 (24.62, 40.56)	28.47 (8.96) 28.45 (22.43, 34.51)	0.525
After	30.54 (11.83) 30.51 (22.57, 38.51)	26.10 (9.10) 26.12 (19.96, 32.24)	0.527
¹ Within-group level of significance (p):	0.160	0.002	

Scheme 1. – lower quartile; Q3 – upper quartile. ¹The Wilcoxon signed-rank test; ²The Mann–Whitney U test.

Table 5. Within- and between-group comparison of postural balance control assessments (60 s).

Characteristics	Experimental group (n=25)	Control group (n=25)	² Between- group level of significance (p)
	Mean (SD)		
	Median (Q1, Q3)		
CoP path length [mm]			
before	668.10 (378.70)	622.45 (450.46)	0.678
	687.04 (412.80, 923.40)	599.93 (318.84, 926.06)	
after	637.73 (400.82)	585.80 (398.27)	0.675
	657.77 (367.58, 907.88)	565.89 (317.37, 854.23)	

¹ Within-group level of significance (p):	0.385	0.824	
95% confidence ellipse area [mm²]			
before	11.10 (6.27)	10.50 (7.25)	0.597
	11.41 (6.87, 15.33)	10.14 (5.61, 15.39)	
after	10.63 (6.60)	9.77 (6.60)	0.672
	10.96 (6.18, 15.08)	9.44 (5.32, 14.22)	
¹ Within-group level of significance (p):	0.367	0.741	

CoP - center of pressure; SD – standard deviation; Q1 – lower quartile; Q3 – upper quartile. ¹The Wilcoxon signed-rank test; ²The Mann–Whitney U test.

Table 6. Within- and between-group comparison of gait analysis results.

Characteristics	Experimental group (n=25)	Control group (n=25)	² Between- group level of significance (p)
	Mean (SD)		
	Median (Q1, Q3)		
Left side - step length [cm]			
Before	27.5 (8.9)	27.6 (9.0)	0.698
	29.5 (23.5, 35.5)	26.0 (19.9, 32.1)	
After	30.1 (9.8)	27.3 (7.4)	0.750
	28.0 (21.4, 34.6)	28.5 (23.5, 33.5)	
¹ Within-group level of significance:	0.045	0.736	
Left side - stance phase [%]:			
Before	71.1 (4.5)	69.7 (3.5)	0.6735
	70.0 (66.0, 74.0)	71.0 (68.6, 73.4)	
After	68.0 (5.1)	69.8 (3.3)	0.4781
	69.5 (66.1, 72.9)	68.0 (65.8, 70.2)	
¹ Within-group level of significance:	0.335	0.958	
Right side - step length [cm]:			
Before	27.4 (8.2)	27.2 (8.1)	0.9323
	25.0 (19.5, 30.5)	28.0 (22.5, 33.5)	
After	30.3 (9.0)	27.4 (8.4)	0.3192
	32.0 (25.9, 38.1)	26.0 (20.3, 31.7)	
¹ Within-group level of significance:	0.015	0.655	
Right side - stance phase [%]:			
Before	69.0 (4.6)	68.5 (4.0)	0.4187
	70.5 (67.4, 73.6)	67.0 (64.3, 69.7)	
After	67.9 (5.0)	68.4 (3.9)	0.3630
	66.0 (62.6, 69.4)	69.0 (66.4, 71.6)	
¹ Within-group level of significance:	0.954	0.708	
Stride length [cm]			
Before	55.2 (15.9)	55.7 (13.6)	0.466
	58.0 (47.3, 68.7)	53.0 (43.8, 62.2)	
After	59.1 (16.8)	55.1 (12.2)	0.825
	57.0 (45.7, 68.3)	56.0 (47.8, 64.2)	
¹ Within-group level of significance:	0.079	0.859	0.466

Stride time [s]			
Before	1.4 (0.2)	1.5 (0.2)	0.610
	1.5 (1.37, 1.63)	1.4 (1.27, 1.53)	
After	1.52 (0.2)	1.52 (0.2)	0.955
	1.4 (1.27, 1.53)	1.6 (1.47, 1.73)	
¹ Within-group level of significance:	0.816	0.653	
Step width [cm]			
Before	13.1 (3.9)	12.2 (4.1)	0.057
	12.0 (9.4, 14.6)	13.5 (10.7, 16.3)	
after	13.8 (4.2)	12.7 (4.3)	0.302
	15.0 (12.2, 17.8)	11.5 (8.6, 14.4)	
¹ Within-group level of significance:	0.444	0.150	
Double stance phase [%]			
Before	41.1 (8.5)	40.3 (6.4)	0.644
	39.0 (33.3, 44.7)	42.0 (37.7, 46.3)	
after	40.3 (7.9)	41.1 (6.9)	0.835
	41.5 (36.2, 46.8)	39.0 (34.4, 43.6)	
¹ Within-group level of significance:	0.763	0.519	
Cadence [step/min]			
Before	82.4 (14.7)	80.9 (17.2)	0.555
	84.0 (74.1, 93.9)	79.0 (67.4, 90.6)	
after	79.6 (17.0)	83.6 (18.1)	0.250
	77.0 (65.6, 88.4)	86.0 (73.8, 98.2)	
¹ Within-group level of significance:	0.029	0.354	
Velocity [km/h]			
Before	1.43 (0.36)	1.31 (0.2)	0.605
	1.50 (1.26, 1.74)	1.25 (1.11, 1.39)	
After	1.59 (0.39)	1.36 (0.2)	0.300
	1.53 (1.27, 1.79)	1.40 (1.26, 1.54)	
¹ Within-group level of significance:	0.314	0.409	

Scheme 1. The Wilcoxon signed-rank test; Q1 – lower quartile; Q3 – upper quartile ²The Mann–Whitney U test.

4. Discussion

The BBS scores showed that both treadmill perturbation-based training performed six days a week for three weeks (the EG) and overground gait and balance training of matching frequency and duration (the CG) significantly improved body balance in chronic stroke patients. The post-intervention outcomes of the 10MWT demonstrated that overground walking speed significantly improved only in the CG, but the change was not statistically significantly bigger compared with the EG. Spatiotemporal gait measurements obtained for participants walking on the treadmill indicated a statistically significant increase in step length (cm) and a statistically significant decrease in cadence [steps/min] only in the EG. Even so, the spatiotemporal gait parameters in the EG were not significantly better post-intervention than in the CG. These results are inconclusive as to whether three weeks of treadmill perturbation-based training and conventional overground gait training of the same duration can improve gait efficiency in chronic stroke patients.

4.1. Comparison of This Study’s Results with Other Studies

To the authors' knowledge, there are only two RCTs [44,45] that are comparable to this study because both of them used treadmill perturbation-based training and chronic stroke patients. However, they are also different from our trial in some respects. Esmaeili et al. [45] conducted a pilot study with only 18 participants divided between the EG (n=10) and the CG (n=8), which did treadmill perturbation-based training and treadmill training without balance perturbations, respectively. In both groups, the treadmill belt speed was set according to participants' preferences. In the EG, balance perturbations were induced by changes in the belt speed. The training session duration was tailored to patients' capacity and did not extend beyond 30 minutes. *In the CG, the training session duration was set for each participant so that it matched the time completed by EG participants with similar overground walking speeds.* Both groups completed a total of nine sessions over three weeks. As in our study, dynamic balance was assessed using the Mini-BESTest, and walking speed was measured using the 10MWT. Post-intervention measurements showed that while dynamic balance improved significantly more in the EG than in the CG ($p=0.007$), walking speed did not significantly differentiate the groups, whether at a preferred pace ($p=0.594$) or a maximum speed ($p=0.424$). The results reported by Esmaeili et al. [45] are, therefore, consistent with our findings, which also show improved dynamic balance in chronic stroke patients after treadmill perturbation-based training.

The other RCT was conducted by Hu et al. [44] with 40 chronic stroke patients with gait impairments, who were equally divided into the EG and the CG (n=20 each group). Both groups exercised 30 minutes per day, five days a week, over four weeks. The number of training sessions (20) was thus comparable to that in our trial (18). As in our study, the CG participants received conventional overground gait and balance training, while the EG performed treadmill perturbation-based training. In the first two weeks, the treadmill walking speed was gradually increased to tailor it to the participants' capacity; in the following two weeks, balance perturbations induced by belt speed changes (forward/backward translations) and its side-to-side movements (lateral translations) were introduced. The amplitude (cm), velocity (cm/s), and acceleration (cm/s²) of the perturbations were gradually increased from session to session. The protocol of perturbation-based training used by Hu et al. [44] was similar to that in our trial. Measurements performed after 2 and 4 weeks showed significant improvements in normal and fast walking speeds in the EG ($p < 0.05$) but not in the CG ($p > 0.05$); moreover, in the EG, they were statistically significantly greater in the other group ($p < 0.05$). Dynamic balance during fast walking speed measured with the TUG Test also showed significant improvement only in the EG ($p < 0.05$ vs. $p > 0.05$), but intergroup differences were not statistically significant ($p > 0.05$). Based on these findings, Hu et al. [44] concluded that treadmill perturbation-based training could improve ambulation in chronic stroke patients, but its ability to enhance their dynamic balance was not significant. Therefore, although the research methodology used by Hu et al. [44] and in our trial was similar, our participants showed improvement in dynamic balance but not in walking speed. Hu et al. [44] recruited younger patients than we did (EG: 48.7 ± 14.8 years; CG: 43.1 ± 16.2 years), but the time since stroke was similar between our studies (mean 15.1 ± 16 months). Lower limb motor recovery assessed with the Brunnstrom scale was also comparable; in our study, it was stage 4 for most of the participants (64%) and stage 3 for only 8%. In Hu et al. [44], stage 4 patients dominated the sample (48.5%), and stage 6 patients were the fewest (12.1%).

The effects of PBT on gait quality in chronic stroke patients were also analyzed in three clinical studies without control groups [46,47,51]. However, they were conducted with only 10 [51] and 12 [46,47] participants, respectively. In the study by Punt et al. [51], 10 patients at least one-year post-stroke who had fallen at least once in the past six months participated in 10 training sessions involving treadmill walking over six weeks. The length of a single session ranged from 30 to 60 minutes and depended on participants' physical capacity. The treadmill belt, whose speed was set to their preference, was accelerated, decelerated, and tilted laterally to induce perturbations. The study authors noted post-intervention statistically significant improvements ($p < 0.05$) in participants' gait speed and step length, as well as reductions in step time, stride time, and swing time, which led them to report an overall improvement in gait quality. Dusane et al. [46] recruited 12 patients who suffered a stroke at least six months prior and exposed them to simulated slips (12 m/s²) and trips (16.75 m/s²) while they walked on a treadmill at their preferred speed. Each patient participated in three consecutive training sessions during which slips, trips, and a combination thereof were successively

applied. During each session, postural stability (center of mass [CoM] position and velocity), trunk angle, the number of steps, and compensatory step length were measured. Slip training shifted the CoM forward, increased step length, and reduced the number of compensatory steps ($p<0.05$), while trip training decreased step length, number of steps, and trunk angle ($p<0.05$) without affecting the CoM position ($p>0.05$). Mixed training reduced step length and trunk angle ($p<0.05$) but CoM and step count remained unchanged. Dusane et al. [46] suggested that PBT was capable of preventing falls by helping develop beneficial compensatory trunk and limb movements. The last of the three studies was conducted by Osman et al. [47] and had 12 patients who were at least six months post-stroke. The study spanned six weeks, during which patients walked on a split-belt treadmill. Perturbations were induced by increasing the belt speed to 15 m/s² for 0.25 second and then reducing it to the previous speed. Each patient completed 15 sessions of 90 seconds, which consisted of a pre-perturbation phase (30 seconds), a perturbation phase (30 seconds), and a post-perturbation phase (30 seconds). Perturbations were randomly induced in the stance phase of the non-paretic leg. While exercising, participants wore a safety harness that protected them from falls. Walking speed improved statistically significantly for both preferred ($p=0.003$) and maximum pace ($p=0.010$), and the number of treadmill falls decreased ($p=0.015$). The authors concluded that PBT improves chronic stroke patients' gait speed and compensatory movements, thus making them less likely to fall.

Although our findings and those reported by other authors [44-47,51] are not entirely consistent, they confirm the ability of TPBT to help chronic stroke patients improve dynamic balance and gait. Our study and that by Esmaeili et al. [45] found that the TPBT improved participants' postural balance but did not influence their gait quality, Hu et al. [44] reported improved gait and no changes in balance, Osman et al. [47] observed improvements in both these parameters, Punt et al. [51] noted gait improvements and Dusane et al. [46] found their patients to develop protective compensatory movements following TPBT. These findings are promising, but given the limited number of such studies and the inconsistency of their results arising from the variety of research methodologies used, more RCTs are needed to unambiguously determine PBT types that will be the most effective in enhancing postural balance and gait quality in chronic stroke patients, and in reducing their fear of falling.

4.2. Strengths of the Study

The study was designed as a randomized controlled trial with a control group. The sizes of the EG and the CG were determined based on the results of a pilot study. All training sessions were provided at the same rehabilitation center and were supervised by physiotherapists to ensure that both groups exercised in a uniform and reliable manner. All assessments were carried out by the same team of physiotherapists. Results for 4 participants who failed to complete the trial were approximated and processed statistically using intention-to-treat (ITT) analysis.

4.3. Limitations of the Study

One limitation of the trial is that the intervention results were only compared with the baseline values of the parameters under study, without considering TPBT's long-term impacts. Unfortunately, a follow-up assessment could not be performed because most of the trial participants lived in locations that were distant from the rehabilitation center. Because of the nature of the intervention, blinding of the participants and medical personnel was not possible, either.

5. Conclusions

The trial demonstrated that 18 sessions of treadmill perturbation-based training performed by chronic stroke patients over 3 weeks positively influenced their body balance, comparably to conventional overground gait and balance training. However, the PBT neither reduced participants' fear of falling nor increased their walking speed. In the EG, spatiotemporal gait analysis revealed a significant increase in step length (cm) and a significant decrease in cadence [steps/min]. These changes do not conclusively indicate whether three weeks of the PBT can improve gait efficiency in chronic stroke patients. More RCTs are needed to create PBT protocols that will improve balance and gait and reduce the fear of falling in these patients the most effectively

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Abbreviations

The following abbreviations are used in this manuscript

UI	Uncertainty interval
RR	Relative risk
CI	Confidence interval
PBT	Perturbation-based balance training
TPBT	Treadmill perturbation-based balance training
RCT	Randomized clinical trial
EG	Experimental group
CG	Control group
ISRCTN	International Standard Randomized Controlled Trial Number
MMSE	Mini-Mental State Examination
GDS	Geriatric Depression Scale
BBS	Berg Balance Scale
FRT	Functional Reach Test
TUG	Timed Up and Go
ICC	Intraclass Correlation Coefficient
AUC	Area Under the Curve
10MWT	10-Meter Walk Test
FES-I	Falls Efficacy Scale–International
ITT	Intention-to-treat
SD	Standard deviation
Q1	Lower quartile

Q3	Upper quartile
CoP	Center of pressure
CoM	Center of mass

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