Title: Effects of gait training with body weight support on a treadmill vs. overground for individuals with stroke

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Conflict of interest

The authors declare no conflict of interest

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Abstract

Objective: To investigate the effects of gait training with body weight support on a treadmill vs. overground in individuals with chronic stroke.

Design: Randomized controlled trial.

Setting: University research laboratory

Participants: Twenty-eight individuals with chronic stroke (> 6 months).

Interventions: Participants were randomly assigned to receive gait training with BWS on a treadmill (n=14) or overground (n=14) three times a week for six weeks.

Main Outcome Measures: Overground gait speed, 6-minute walk test, motor domain of the functional independence measure, lower extremity domain of Fugl-Meyer movement assessment, step length, step-length symmetry ratio and single limb support duration. Measurements were obtained at baseline (T0), immediately after (T1) and six weeks after (T2) the training session.

Results: At T1, both groups improved in all outcome measures except paretic step-length and step-symmetry, which were only improved in the overground group ($p=0.01$ and $p=0.01$ respectively). At T2, all improvements remained and the treadmill group also improved paretic step length ($p<0.001$) but not step-symmetry ($p>0.05$).

Conclusions: Individuals with chronic stroke equally improve gait speed and other gait parameters after 18 sessions of BWS gait training on either treadmill or overground. Only the overground group improved step symmetry, suggesting a role for integrating overground walking into BWS interventions post-stroke.

Keywords. Stroke rehabilitation, partial body weight support, gait training, spatial-temporal parameters, functional recovery

List of abbreviations:

10MWT	10-meter walk test
6MWT	6-minute walk test
ANOVA	analysis of variance
BWS	body weight support
FIM	functional independence measure
FM	Fugl-Meyer movement assessment
MANOVA	multivariate analysis of variance
OGG	overground training group
T0	baseline test
T1	test after the last gait training session
T2	test 6 weeks after the last training session
TMG	treadmill training group

Partial body weight support systems (BWS) have been widely used for gait rehabilitation post-stroke.[1-7] For individuals with stroke, these systems improved body weight distribution between paretic and nonparetic limbs as erect posture is facilitated,[5] and they promote improvement in spatial-temporal gait characteristics, including interlimb symmetry of stance and swing phases, muscle activity and joint angle excursions of the lower limbs.[8] BWS employed with treadmills facilitates performance of a high number of symmetrical and consistent steps,[9] as well as allowing for control of walking speed. On the other hand, the requirements for walking on treadmills are different than those for overground walking, mainly in terms of propulsion and balance.[10, 11]

Treadmills may provide a degree of passive movement to the lower limbs with little change in muscular activation,[8, 9, 12-14] limiting the extent of skill transfer to overground walking. This raises a question about whether BWS alone promotes improvement on gait performance, or whether this is due to the interaction between BWS and treadmill. A related question is whether employing BWS with overground gait training would yield any differences in gait improvement vs. BWS on the treadmill.

Only two studies have employed BWS overground in individuals with stroke, including a case study[15] and a single arm study with a small sample.[16] Sousa et al.[16] reported improvements in walking speed, step-length symmetry and also increased stride lengths and segmental angle rotations[17] after overground BWS gait training, but the study lacked a treadmill comparison group. Comparing BWS gait training in a controlled treadmill vs. overground experiment may reveal differential effects due to use of BWS on a moving vs. stationary walking surface. The purpose of this study was to investigate the effects of moving vs. stationary walking surfaces during BWS gait training on measures of spatial-temporal gait parameters and clinical function in individuals with chronic stroke. It was hypothesized that overground BWS training would elicit greater improvement of walking performance compared to treadmill BWS, as the former would reduce the need for skill transfer from the externally driven treadmill to fully self-generated control of overground mobility tasks.

Methods

A randomized controlled trial was conducted using CONSORT guidelines. The study was approved by the research ethics committee of xxxx and was registered at ClinicalTrials.gov (xxxx). All procedures were performed with adequate understanding and written, signed informed consent of the participants provided before entry into the study.

Setting and Participants

From April 2014 to June 2015, 114 individuals with stroke were contacted and invited to join the study (Figure 1). One physical therapist researcher screened all potential participants. Inclusion criteria were: chronic hemiparetic gait after an ischemic or hemorrhagic stroke, more than six months from the stroke event, absence of cardiac (or medical clearance for participation), orthopedic or pulmonary pathology or other neurologic impairment that could compromise gait or training, ability to follow two-step verbal commands and ability to walk 10m with or without assistance. Individuals who presented with uncontrolled blood pressure were excluded. All stages of the study were conducted in the xxxx.

Insert Figure 1 here

Randomization and blinding

After baseline testing (T0), and using a computer-based algorithm, participants were randomly allocated to 2 BWS groups: treadmill training group (TMG) or overground training group (OGG). The researcher who did the randomization and the data analyses was not involved in any assessment or training session. Complete and continuous blinding of researchers who performed the training sessions and the assessments was not feasible due to personnel constraints. Participants were not blind to the training conditions but were unaware of the hypothesis of the study.

Intervention protocols

The BWS system used for the TMG consisted of a treadmill TK35 (CEFISE)[a] and a metal frame with an instrumented load cell to register the amount of supported body weight. The BWS system used for the OGG consisted (Figure 2) of a suspended rail (7m) mounted on the ceiling (3m) and supported by two steel beams (FENIX)[b]. A moving cart was attached to the bottom of the rail allowing for backward and forward movements and controlled by a belt system linked to a servomotor. A customized program (LabView)[c] was developed to control displacement, velocity and acceleration of the moving cart. In addition, a second servomotor controlled unloading of body weight through a harness and instrumented load cell system.

Insert Figure 2 here

Training sessions were conducted three times weekly, with at least one day between sessions, for six weeks totaling 18 training sessions. Each session lasted up to 45 min. Throughout training sessions, each participant's heart rate was monitored and blood pressure was measured at the beginning and end of each session. Rest intervals were provided according to individual needs.

The amount of BWS during training sessions ranged from 30% to 0% of body weight. The amount of BWS was based upon individual alignment of trunk and limbs with proper weight shift and bearing onto the hemiplegic limb during the loading phases of gait. Walking speed was set to match participants' comfortable level on the treadmill or overground. The OGG walked back and forth along the walkway. Participants were allowed to use the front handrail of the treadmill (TMG) or the therapist's hand (OGG), but through training sessions, all participants were encouraged to walk without any external assistance other than the BWS system.

Progression of the training was achieved by decreasing the BWS, increasing the gait speed and/or reducing the patient support from the handrail for the TMG and the therapist's hand for the OGG. The training parameter changes to progress the training were implemented at the beginning of each session. The progression was maintained as long as the participants could maintain alignment of trunk and limbs with proper weight shift and bearing onto the hemiplegic limb during the loading phases of gait. If not, the parameter change was decreased to the previous value. Two trained therapists conducted all training sessions of both groups and provided similar verbal and manual cues.

Outcome measures and follow-up

Participants were assessed one week before the first training session (T0), one week after the last gait training session (T1) and 6 weeks after the last training session (T2). One experienced researcher took the lead on all assessments and standardized instructions for each test were given to assure consistency in test administration. Participants underwent the following evaluations: 10-meter walk test (10MWT)[18-20], 6-minute walk test (6MWT)[21], motor domain of functional independence measure (FIM)[22, 23], lower extremity domain of Fugl-Meyer movement assessment (FM)[24] and quantitative gait analyses (see below). Rest intervals were provided between tests and according to individual's needs, when necessary.

The primary outcome was gait speed measured by 10MWT. During this test the participants were required to walk 10m at a comfortable speed. Two photocells (CEFISE)[a] measured the time required to cover the intermediate 6m in order to exclude periods of acceleration and deceleration. The average of three trials was calculated.

Secondary outcomes included: endurance measured by the 6MWT, functional independence measured by FIM motor domain, lower limb recovery measured by lower extremity FM which evaluated the subscales of joint pain, passive joint motion, sensibility, voluntary movement, reflex activity and coordination. Finally, the paretic and nonparetic step-length, step-length symmetry ratio and paretic and nonparetic single limb support were measured by a computerized gait analysis system during walking at a comfortable speed. For both 10MWT and 6MWT, participants were allowed to use assistive devices if necessary.

The gait analysis was performed on a 7m walkway equipped with two embedded force platforms (Kistler[d], model 9286BA). A computerized gait analysis system VICON[e] with seven infrared cameras (Bonita 10) was used to acquire data from reflective markers that were placed on the main body landmarks (Vicon Plug-In Gait model).[25] After a calibration trial, participants were asked to walk at a comfortable, self-selected speed. They were not allowed to use any assistive devices but, when necessary, a therapist offered her hand to assist their balance without providing any meaningful mechanical support (see results).

Data processing of gait analysis

Two consecutive and steady state strides (paretic and nonparetic) (four steps) per trial by each participant were analyzed, for a total of three selected trials for each evaluation. A stride (walking cycle) was defined by two consecutive initial contacts of the same limb with the ground along the progression line. In addition, foot contacts and toe-offs during a stride were identified for subsequent calculation of the spatial-temporal organization of walking, for both paretic and nonparetic sides.

The gait outcome measures analyzed in this study were: step-length, calculated as the distance between initial contact of each foot along the progression line (determined by the position of the heel markers), the step-length symmetry ratio, calculated as the ratio between shorter step and longer step (we were interested in the magnitude of asymmetry rather than its direction),[26] and duration of single limb support (determined by the time interval the limb supports total body weight while the contralateral limb swings). Data analysis was performed using a customized routine written in Matlab[f]. Data from three trials under each evaluation were averaged for each participant and considered for further analyses.

Statistical analysis

For all outcome measures, comparisons between assessments T0 and T1, and T0 and T2 were made. One participant from OGG missed assessment T2 and her scores from T1 were used to replace missing data, a conservative assumption.[27, 28] We used a schematic boxplot for the primary outcome measurement to test for the existence of outliers and we did not find any outlier. Two-way analysis of variance (ANOVA) and multivariate analysis of variance (MANOVA) were employed using group (TMG and OGG) and time of assessment (T0 and T1, T0 and T2) as factors. The dependent variables for the ANOVAs were 10MWT, 6MWT, FIM, FM and step-length symmetry ratio. The dependent variables for the MANOVAs were step-length and single limb support of paretic and non-paretic sides. When necessary, Tukey post hoc tests were employed. An alpha level of 0.05 was adopted for all statistical tests, which were conducted using SPSS[g] software.

Within-group effect sizes (T0-T1 and T0-T2) were calculated as the difference in mean values from each assessment divided by the pooled standard deviation. Effect sizes were defined using Cohen *d* classifications (*d*=.2, small; *d*=.5, medium, *d*=.8, large).[29]

Results

Thirty-two individuals with an average age of 58.2±9.1 years were randomized into the study. Random assignment generated groups that were comparable in terms of age and time post-stroke. Twenty-eight participants completed the training protocol in the allocated group and were included in the final analyses (Table 1).

During each set of assessments, 11 participants (5 from the OGG and 6 from the TMG) used assistive devices to perform the 10MWT and 6MWT and 8 of these participants (4 from each group) used light hand assistance for balance from the same therapist during their gait analyses. All individuals were interested, motivated and cooperative throughout the training period and assessments and none of them reported any intervention-related adverse effects. All participants performed all assessments, except the 6-minute walk test, which 6 individuals did not perform (3 from the OGG and 3 from the TMG) because this test was added to the study after they had begun training, and after these individuals had self-reported walking longer distances.

Insert Table 1 about here

Throughout the training period, no differences were observed between groups for the percentage of BWS (TMG=16.81±7.62% and OGG=14.89±6.59%), or for session duration (TMG=37±6 minutes e OGG=36±5 minutes). However, the mean comfortable speed set for the treadmill and the servomotor was different (TMG=.27±.07m/s and OGG=.52±.07) despite the fact that the groups were equal during baseline 10m walking.

Clinical evaluations

At T1, both groups demonstrated improvements in gait speed ($p=.049$, TMG, $d=.14$, OGG, $d=.16$), 6MWT ($p<.001$, TMG, $d=.35$, OGG, $d=.30$), FIM ($p<.001$, TMG, $d=.41$, OGG, $d=.27$) and FM ($p<.001$, TMG, $d=.82$, OGG, $d=.55$). At T2, both groups maintained these improvements in gait speed ($p<.001$, TMG, $d=.25$, OGG, $d=.32$), 6MWT ($p=.001$, TMG, $d=.36$, OGG, $d=.33$), FIM ($p<.001$, TMG, $d=.59$, OGG, $d=.63$) and FM ($p<.001$, TMG, $d=.99$, OGG, $d=.95$). However, there were no differences in improvement between groups for any of the clinical outcomes measures at either T1 or T2 (Table 2).

Insert Table 2 here

Gait analyses

At T1, both groups increased nonparetic step-length ($p<.001$, TMG, *d*=.32, OGG, *d*=.60), however only OGG increased paretic step-length ($p<.001$, *d*=.32) and improved step-length symmetry ($p<.001$, *d*=1.08), and both groups increased single limb support duration for the paretic limb only (p=.015, TMG, *d*=.06, OGG, *d*=.42). At T2, both groups increased step-length of both paretic ($p<.001$, TMG, *d*=.36, OGG, *d*=.44) and nonparetic ($p<.001$, TMG, *d*=.40, OGG, *d*=.56) sides, only participants from OGG improved step-length symmetry ratio ($p<.01$, *d*=1.08), and both groups increased single limb support duration for the paretic limb only (p=.006, TMG, *d*=.14, OGG, *d*=.79) (Table 3).

Insert Table 3 here

Discussion

This study is the first to investigate the effects of time-matched overground vs. treadmill gait training with BWS of individuals with stroke. We found that both groups improved their gait speed, endurance, recovery of lower limb motor function impairments, functional independence, nonparetic step-length and duration of paretic single limb support immediately after completion of training and at follow-up. Gait training with overground BWS had an additional benefit of improving step-length symmetry compared to treadmill BWS. In addition, overground BWS training also promoted immediate and durable improvement in paretic step length, while treadmill BWS training only improved this outcome at follow-up. Therefore, our hypothesis that the overground BWS would be superior to treadmill BWS training for improvement of walking performance was only supported for step-length symmetry.

Gait speed is one of the most common and important measures of functional in the clinical setting[30] and is closely associated with functional independence.[31, 32] Both of our study groups demonstrated improvements in gait speed immediately after the intervention and at follow-up. The average improvement in gait speed of 0.09 m/s demonstrated by both training groups would be considered a small to substantial meaningful change in gait speed for individuals with chronic stroke as defined by Perera et al.[33] This improvement was similar or greater than two previous studies[5, 34] of BWS treadmill training that also included a follow-up but was less than three other comparable studies.[3, 35, 36] However, all three of the studies that reported larger improvements used participants that had lower initial walking speeds and therefore may have had the potential to demonstrate greater gains than our participants. Additionally, two of these studies used longer training periods.[35, 36] The only previous study[16] that investigated the use of BWS overground reported a similar change in gait speed immediately following training but did not include follow-up testing. Based on the results of the present study, it appears that improvements in gait speed are similar between BWS treadmill and overground training. Therefore, if a primary goal is to improve gait speed, clinicians should rely on clinical judgment to determine which training method would be most appropriate for an individual patient based on factors such as patient preference, safety, comfort and other therapeutic goals.

Gains in other clinical measures suggest that our BWS paradigm, in either condition, has other benefits in addition to improving walking speed. Participants in both groups demonstrated a 50 m improvement in 6MWT distance immediately following training and at follow-up. This exceeds the 34.4 that has been suggested as the minimal clinically important difference for individuals with stroke.[37] It is also greater than, or similar to, other treadmill training studies with and without BWS. Lower extremity impairment, as measured by the Fugl-Meyer, also improved by over 7 points and exceeded the threshold for a perceived meaningful recovery (6 points) by individuals with chronic stroke,[38] and was greater than the 1.5 point improvement demonstrated in the only other BWS training study reporting Fugl-Meyer scores.[34] Finally, the average improvement of 3.9 points in the motor domain of the FIM for our participants was also greater than the 1.7 point change seen in a previous BWS treadmill training study.[39] In summary, the meaningful improvements in each of the clinical outcome measures support the use of BWS training either on a treadmill or overground with no differential benefits being observed.

The only outcome measure that was different between the OGG and TMG groups at follow-up was step-length symmetry. This is an important finding for several reasons. First, reduced step symmetry has been shown to be associated with an increase in fall risk.[40] Therefore, an improvement in step symmetry may contribute to a reduction in fall risk during walking. Second, individuals with stroke often desire to look more "normal"[41, 42] and having a more symmetrical gait may contribute to that goal especially when accompanied by an increase in speed and endurance. Third, improved symmetry may reduce the energetic cost of walking to increase the functional range or intensity in performance of daily live activities.[43, 44] Therefore, if a BWS system is available for overground walking it may be more useful than a treadmill-based system. While walking on a treadmill by itself will increase symmetry[9] this does not appear to carry over well to overground walking as reported in several studies.[5, 45] Indeed the overground requirement to intrinsically generate leg movements without extrinsic forcing (e.g., the moving TM surface) may be an important factor for promoting spatial symmetry.

One caveat to our finding that overground training improved step-length symmetry is that the TMG adopted a lower self-selected walking speed for training compared to OGG. It is typical for individuals to adopt a slower speed on the treadmill than overground partly because they initially feel less stable on a treadmill perhaps owing to the lack of visual flow and moving floor surface.[8, 46] Therefore, we cannot be certain that the improvement in step-symmetry was a result of the interaction with a stationary floor surface or from having more repetitions. Since all other variables, including the 10MWT improved similarly across the two groups and did not, therefore, show an effect of any increased repetition, we believe that the effect of walking overground in this study is the more likely explanation.

Study limitations

One limitation of the study was the lack of blinding to treatment by the testers. This could certainly cause bias although the testers had no specific *a priori* expectation of which outcomes were expected to improve differentially between the groups. In addition, the testers were effectively blinded during the gait analysis and could not, therefore, influence these variables including step-symmetry. A second limitation was a lack of a control group, which did not receive any gait training. The main purpose of the present manuscript was the employment of partial body weight support during gait training either on a treadmill (which is the most common use of BWS for gait interventions) or overground. Since our participants were in the chronic stage we made the assumption that a control group with no training would be unlikely to show any short-term or follow-up improvements. In addition, most of our participants presented relatively high mental and motor functions, but with some of them using assistive devices or hand assistance for balance during the assessments. This may limit the generalizability to the wider population with stroke. For future studies, we suggest the addition of a control group and inclusion of a greater range of deficit severity with randomization stratified by motor function.

Conclusion

The use of BWS training either on a treadmill or overground promoted meaningful and durable improvements in gait speed, walking endurance, lower limb function, functional independence and non-paretic step length. However, only overground training led to significant improvements in step length symmetry. Therefore, if BWS gait training is employed for post-stroke gait rehabilitation, it may be useful to include overground training if one of the therapeutic goals is to improvement step-symmetry.

Suppliers

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Figure Legends

Figure 1. Flow diagram of the study following CONSORT guideline.

Figure 2. Representation of the body weight support system adopted by the over the ground group.

Figure 1

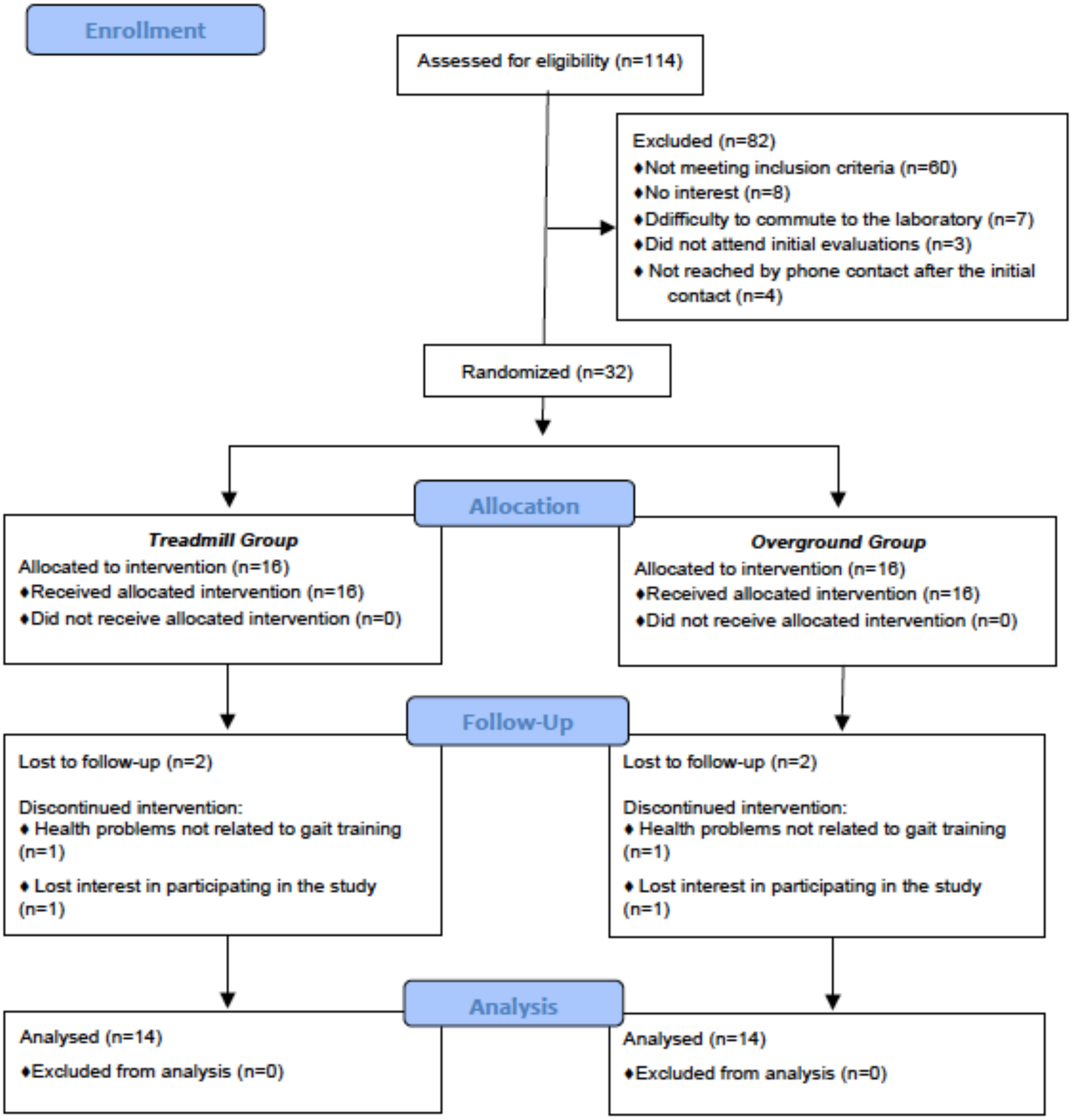
Enrollment
Assessed for eligibility (n=114)
Excluded (n=82)
♦Not meeting inclusion criteria (n=60)
♦No interest (n=8)
♦Ddifficulty to commute to the laboratory (n=7)
♦Did not attend initial evaluations (n=3)
♦ Not reached by phone contact after the initial contact (n=4)
Randomized (n=32)
Allocation
Treadmill Group
Allocated to intervention (n=16)
♦Received allocated intervention (n=16)
♦Did not receive allocated intervention (n=0)
Overground Group
Allocated to intervention (n=16)
♦Received allocated intervention (n=16)
♦Did not receive allocated intervention (n=0)
Follow-Up
Lost to follow-up (n=2)
Discontinued intervention:
♦ Health problems not related to gait training (n=1)
♦ Lost interest in participating in the study (n=1)
Lost to follow-up (n=2)
Discontinued intervention:
♦ Health problems not related to gait training (n=1)
♦ Lost interest in participating in the study (n=1)
Analysis
Analysed (n=14)
♦Excluded from analysis (n=0)
Analysed (n=14)
♦Excluded from analysis (n=0)

Figure 2

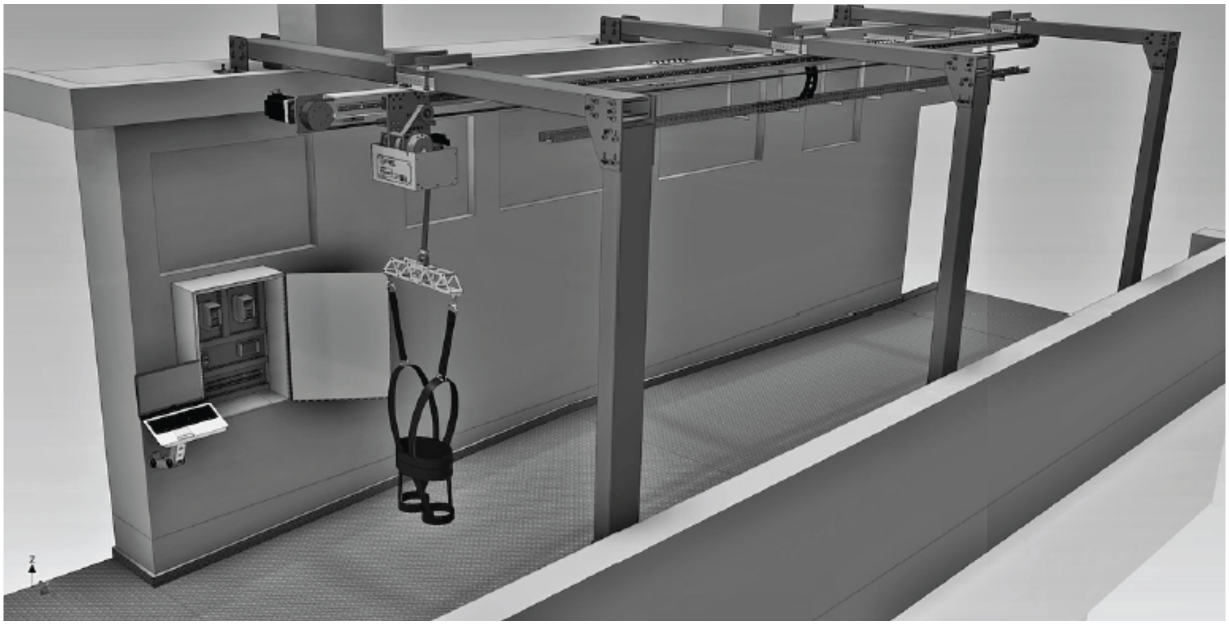

Table 1. General baseline characteristics of individuals.

Characteristics	TMG	OGG	*p-value*
Sex (F/M)	7/7	8/6	.71[a]
Age (years)	58.7±8.4	57.7±10.1	.78
Mass (kg)	66.7±11.1	66.0±12.4	.86
Height (m)	1.63±.08	1.60±.11	.43
Time post-stroke (months)	60.2±55.4	53.8±42.2	.73
Type of Lesion (I/H)	12/2	10/4	.37[a]
Hemiparesis side (R/L)	5/9	8/6	.27[a]
Mini Mental State Examination Score	24.43±3.98	21.85±6.87	.23[a]
Baseline 10-m walk test (m/s)	.69±.25	.73±.28	.81
Baseline 6-minute walk test (m)	244±119	240±152	.94
Baseline FIM score (max 91)	80.6±7.31	83.0±7.1	.46
Baseline FM score (max 84)	69.2±6.7	70.9±8.6	.83

M=male; F=female; TMG=treadmill group; OGG=over the ground group; [a]= χ^2test

Table 2. Outcome measures of clinical assessments

Variable	T0		T1		T2	
	Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI
10-m walk test (m/s)						
TMG	.66±.29	.50-.82	.70±.30*	.52-.88	.74±.34***	.56-.93
OGG	.69±.30	.53-.85	.74±.34*	.56-.92	.79±.33***	.60-.97
6-minute walk test (m)						
TMG	244±119	158-330	291±148***	201-382	294±159**	199-389
OGG	240±152	154-325	283±139***	193-373	289±144**	193-384
FIM score (max 91)						
TMG	80.4±7.6	76.3-84.4	83.3±6.6***	79.8-86.8	84.5±6.3***	81.5-87.5
OGG	82.4±7.1	78.4-86.5	84.2±6.1***	80.7-87.7	86.1±4.3***	83.1-89.0
FM score (max 84)						
TMG	68.7±7.1	64.3-73.1	74.9±6.7***	70.7-79.0	75.7±7.0***	71.9-79.5
OGG	69.4±8.8	64.9-73.8	74.1±8.2***	70.0-78.3	76.9±6.8	73.1-80.6

T0=baseline; T1=post-training; T2=follow-up;

TMG=treadmill group; OGG=over the ground group

Statistic effect for T0 x T1 and T0 x T2; *$p<0.05$ **$p< 0.01$ ***$p<0.001$

Table 3. Gait analyses parameters

Variable	T0		T1		T2	
	Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI
Step-length (m)						
TMG						
P	.40±.11	.33-.47	.42±.12	.35-.48	.44±.11***	.37-.51
NP	.35±.11	.28-.42	.39±.14***	.32-.45	.40±.14***	.32-.47
OGG						
P	.39±.14	.32-.46	.46±.11*	.39-.52	.45±.13***	.38-.52
NP	.37±.13	.31-.44	.44±.10***	.37-.51	.44±.12***	.37-.51
Step-length ratio						
TMG	.80±.14	.73-.87	.82±.13	.76-.87	.81±.13	.76-.86
OGG	.84±.11	.77-.91	.93±.04*	.87-.98	.93±.04*	.88-.98
Single limb support duration (%)						
TMG						
P	25.7±8.1	21.6-29.6	26.2±7.6*	22.7-29.8	26.8±7.2**	23.2-30.4
NP	36.1±4.6	32.9-39.3	36.0±4.9	33.0-38.9	36.4±3.3	33.8-39.0
OGG						
P	26.0±6.33	22.0-30.0	28.4±4.9*	24.9-31.9	30.8±5.8**	27.2-34.5
NP	36.9±6.8	33.8-40.2	37.6±5.9	34.7-40.6	37.6±5.9	35.0-40.2

T0=baseline; T1=post-training; T2=follow-up; P=paretic side; NP=nonparetic side;

TMG=treadmill group; OGG=over the ground group

Statistic effect for T0 x T1 and T0 x T2; *p<0.05 **p< 0.01 ***p<0.001