Experimental Gerontology 210 (2025) 112882

Contents lists available at ScienceDirect

Experimental Gerontology

journal homepage: www.elsevier.com/locate/expgero

Effects of walking training with and without a robot and standard care on clinical and mobility outcomes: A randomized clinical trial in acute ischemic stroke patients

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A R T I C L E I N F O

Section Editor: Christiaan Leeuwenburgh

Keywords:
Aging
Walking
Stroke
Robot
Standard therapy
Comparative efficacy

A B S T R A C T

Background: Stroke incidence rises with age. A stroke can severely affect walking ability, requiring therapy. Robot-assisted walking therapy (ROB) has been advocated as one form of walking rehabilitation in stroke patients. However, its comparative efficacy remains controversial and three-group comparisons are scant. We compared the effects of ROB, walking training therapy without a robot (WTT) and standard treatment therapy (STT) on clinical and mobility outcomes in acute ischemic stroke patients.
Methods: Individuals ($n = 45$, 71 % males, age 64.4y ±6.34), who have recently experienced an ischemic stroke, were randomized to ROB, WTT or STT. Clinical and mobility outcomes were assessed before and after each intervention (3 weeks, 5 sessions/week) and after 5 weeks of no-intervention follow-up.
Results: Outcomes did not differ between groups at baseline ($p > 0.05$). Modified Rankin Scale (primary outcome), improved ($p < 0.05$) after ROB and WTT vs. STT. These improvements were retained relative to baseline ($p < 0.05$) after follow-up. Barthel index, Berg Balance Scale, 10-m walking speed, the distance while walking with and without the robot for six minutes, and center pressure velocity in standing improved most after ROB (all $p < 0.001$), exceeding the changes after WTT which in turn were greater than the changes after STT ($p \leq 0.040$).
Conclusion: Older adults shortly after an ischemic stroke can quickly learn to walk with a soft robot and retain substantial clinical and mobility improvements at follow-up.

1. Introduction

Stroke incidence rises with age. Strokes occur at particularly high rates in Eastern Europe, accompanied by a one-year recurrence of 15 % and mortality of 10 % (Bejot et al., 2016; Policies OEOoHSa, 2017; Szocs et al., 2016). Nearly 60 % of these older person(s) with stroke (PwST) suffer from gait dysfunction and 40 % develop chronic mobility disability, severely reducing physical activity, community ambulation, societal participation, and quality of life (Grau-Pellicer et al., 2019; Wevers et al., 2009). A hallmark of walking disability in PwST is reduced walking speed and balance (Afschrift et al., 2023). Restoring gait to the before-stroke level to slow or stop its deterioration is thus an important goal of stroke rehabilitation in older adults (Chen et al., 2024).

While various forms of physical therapy involving gait training can

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https://doi.org/10.1016/j.exger.2025.112882
Received 2 July 2025; Received in revised form 22 August 2025; Accepted 31 August 2025
Available online 1 September 2025

reduce walking dysfunction in older PwST (Bowden et al., 2013; Combs et al., 2012; Moncion et al., 2024; Tapp et al., 2024; Vistamehr et al., 2019), there is also evidence that such interventions might not be optimal to improve the paretic leg's plantarflexor and dorsiflexor force to push off forcefully and clear the ground (Chen et al., 2024; Bowden et al., 2013; Combs et al., 2012). Benefits of robot-assisted gait training include reduced patient effort and therapist burden, consistent, precise, reproducible, and task-specific assistance of ankle movements, feasibility, safety, comfort, and enjoyment (Yang et al., 2023; Gillespie et al., 2023). For example, the ReStore Soft Exo Suit allows therapists to set and online modify plantarflexor and dorsiflexor assistance according to individual patients' needs (Awad et al., 2017; Awad et al., 2020a; Awad et al., 2020b). However, the comparative effectiveness of robot-assisted walking training therapy so far has been unconvincing. Systematic reviews noted that there are often equal number of studies reporting significant vs. no significant differences between robot-assisted walking therapy (ROB) and walking therapy without a robot in Berg Balance test, Timed up and Go Test, 10-m walking test, step symmetry, 6-min walking test, and other functional outcomes in PwST (Chen et al., 2024; Yang et al., 2023; Zheng et al., 2019). The usual experimental design in the studies synthesized by these reviews is a two-group ROB vs. walking training therapy (WTT) comparison or ROB vs. standard treatment therapy (STT) but not a comparison between all three groups, i.e., ROB, WTT, and STT. While one meta-analysis has identified a handful of studies with a three-group design (Zheng et al., 2019), the comparisons in those studies focused primarily on balance. A three-group design reduces between-group variation due to randomization and allows the determination of comparative effectiveness with a higher fidelity. These reviews (Chen et al., 2024; Yang et al., 2023; Zheng et al., 2019) identified virtually no studies examining to what extent PwST retain walking ability after a given treatment is stopped in particular with respect to a comparison of retention between ROB, WTT, and STT. While PwST tend to retain cardiovascular fitness for up to 1y after rehabilitation ends (Machado et al., 2022), it is unclear to what extent walking capacity is retained after ROB and WTT after the rehabilitation program ends (Fini et al., 2021; Saunders et al., 2020; Tollár et al., 2023; van de Port et al., 2006). Finally, responsiveness of PwST tends to be greater in the (sub) acute than chronic state, many studies applied ROB in PwST several months or even years after the stroke had occurred (Chen et al., 2024; Yang et al., 2023). Indeed, there was a specific call for studies to examine acute PwST in a study design that includes follow-up (Mehrholz et al., 2020). Therefore, the purpose of the present study was to compare the effects of ROB, WTT, and STT on clinical and mobility outcomes in individuals with an acute, ischemic stroke and determine if the intervention effects were maintained after a five-week-long no-intervention follow-up period. Based on data from recent meta-syntheses, we hypothesized that ROB would have superior effects compared with WTT and that the effects of ROB and WTT would be both superior to the effects induced by STT also with respect to retention. Such data are highly needed especially in developing countries where stroke rates are high and technological advancements penetrate rehabilitation of PwST slowly (Bejot et al., 2016; Policies OEOoHSa, 2017; Szocs et al., 2016).

2. Methods

2.1. Participants and design

Fig. 1 shows the experimental design of this assessor-blinded, pre-post and no-intervention follow-up randomized clinical trial. Assessor-blinding was maintained by having contracted therapists perform the assessments who were not present at the location where the intervention was conducted. A neurologist identified and examined each PwST for admission to the study. All PwST were in the sub-acute state and resided in the hospital's in-patient care for five days after stroke. They were then discharged and visited hospital's rehabilitation center as out-patients and recruited for the study. During this five-day period, PwST received STT. A physical therapist not involved in the trial performed the concealed randomization by drawing a colored ribbon from a covered box and attached one ribbon to each patient folder. Inclusion criteria: CT- or MRI-diagnosed first-ever ischemic stroke; 5 days after stroke; mobility and postural limitation determined by a neurological exam, and a modified Rankin Scale (mRS) score ≥ 2. Exclusion criteria: A history of multiple strokes; resting systolic blood pressure (BP) <120 or > 160 mm·Hg; orthostatic hypotension; carotid artery stenosis; severe heart disease; hemophilia; traumatic brain injury; seizure disorders; uncontrolled diabetes; abnormal EEG; Mini Mental State Examination (MMSE) score < 22; abnormal blood panel; sedative use; irregular medication schedule; serious aphasia; serious visual or hearing impairments; serious sensory dysfunction; serious orthopedic problems; neurological conditions affecting motor function (Parkinson's, multiple sclerosis, multiple system atrophy, Guillain–Barré syndrome); alcoholism; recreational drug use; inability to walk a minimum of 100 m with or without a walking aid in six minutes; Berg Balance Scale (BBS) score ≤ 32; Barthel Index (BI) score ≤ 70, or current PwST in a self-directed or formal group exercise program other than STT. Treatment groups: (ROB, $n = 15$), (WWT, n = 15), and STT (n = 15). Before the intervention, PwST performed baseline testing (Test 1) that was repeated 2–3 days after the last intervention day (Test 2) and re-administered for a third time after a five-week-long no-intervention follow-up period ('de-training') (Test 3). Of the 60 PwST screened for eligibility, ultimately, 45 completed the study (Fig. 1). The trial took place in the rehabilitation gym and the long hallways of the hospital as

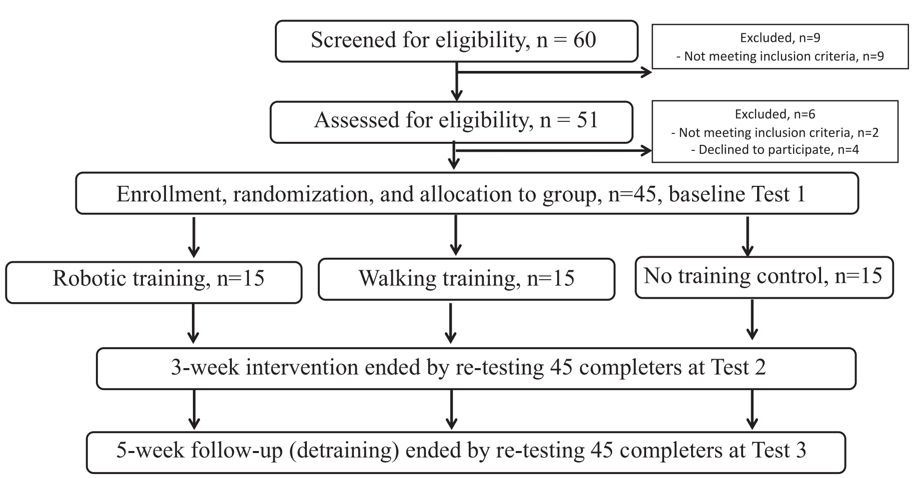

Fig. 1. Experimental design.

well as in local physical therapy clinics (for STT only). Each PwST signed a written informed consent. The Institutional Research Ethics Committee approved the study protocol (IKEB/2022/02), which was registered as a clinical trial (NCT05947773).

3. Outcomes

Physical therapists not involved in the interventions assessed PwST at Tests 1, 2, and 3. Details of the outcomes were reported previously (Tollár et al., 2023; Tollar et al., 2021). Briefly, the primary outcome was the modified Rankin Scale (mRS): a reliable, valid, and sensitive-to-change clinical assessment that measures independence in activities of daily living. mRS was assessed by a physical therapist specifically trained in mRS. A change of 1 unit in mRS is clinically meaningful (Balu, 2009; Banks and Marotta, 2007; Tilson et al., 2010). The Barthel Index measures performance in activities of daily living. The Berg Balance Scale measures fall risk. The 10-m walking test measures walking speed. The 6-min walk test (6MWT) measures walking capacity. After familiarization, we measured static balance by sway path velocity of the center of pressure while standing on a force platform in a wide and narrow stance with eyes open and closed, using one, 20-s-long trial per condition. In the current study, each PwST ($n = 45$) also completed the 6MWT while walking with the robot at Tests 1, 2, and 3.

3.1. Intervention

Interventions consisted of 15 sessions over three weeks. Each session lasted ~60 min. ROB used the ReStore Soft Exoskeleton Robot that mechanically assist push-off and swing phases of gait (Awad et al., 2017; Awad et al., 2020a; Siviy et al., 2023). This robot comprises soft, textile-based components and enables an unrestricted walking motion. ROB was designed to have PwST to learn to walk with the robot and improve walking speed, walking capacity, and walking balance. The calf wrap comprises sensors to detect forces in the anterior and posterior directions. The insole provides attachment points for cables. Motion sensors are mounted on the lateral aspect of each shoe and provide foot position data. Equipment setup (5 min) was followed by general joint mobilization warm-up (5 min). During the specific warm-up, PwST walked for 5 min at a slow pace without the robot. They were then equipped with the robot (5 min) and walked for10min with the robot along a 100-m-long hallway. The 10-min-long segment when PwST walked with the robot included five, two-minute-long exercises of obstacle avoidance and slalom walking over a 20-m course. There were 1-m gaps between adjacent obstacles. We asked PwST to perform the slalom walk at a maximum speed. The last element was a 6-min-long walking element by alternating self-selected with vigorous pace every 50 m. A therapist walked along each PwST. Heart rate was monitored. The robot was then removed and PwST rested (5 min) and the session concluded with 10 min of stretching.

The WTT intervention was designed to improve walking mobility, walking capacity. Set-up, general warm-up, and slow-paced walking as specific warm-up took each 5 min. As ROB, but without the robot, PwST in WTT also performed 5 times 2 min of obstacle and slalom walking tasks over a 20-m-long course. Next, PwST in WTT also performed the slow (50 m)-vigorous (50 m) fluctuating paced walking for six minutes. A therapist walked along each PwST. Heart rate was monitored. Session concluded with seated rested (5 min) and stretching (10 min).

The STT intervention consisted of the government health insurance-prescribed standard program, delivered at local clinics chosen by each PwST. This program has a 30-min-long element of seated exercises followed by 30 min of personalized physical therapy. This latter involved walking and balance exercises. The seated exercises are designed to improve upper body and core muscle strength through activities such as lifting, lowering, and rotating medicine balls and weighted sticks. The exercises focused on improving lower body function, incorporating various stepping patterns (forward, backward, diagonal) while balancing on one leg, redistributing weight, coordinating arm movements during walking with and without sensory aids, and performing squats with arm support on a chair backrest to strengthen lower body extensor mechanism.

After ROB, WTT, and STT, all 45 PwST received lower extremity therapeutic massage (20 min). During each intervention, we measured: rate of perceived exertion on 20-point Borg scale; seated blood pressure before and after each of the 15 training sessions, and heart rate before, during, and after intervention sessions. PwST were instructed to maintain their usual diet, medication, and physical activity routines throughout the study, and were provided with a logbook to document any symptoms, which was reviewed by therapists on a daily basis. The logs were not analyzed systematically in the present study.

3.2. Statistical analyses

Data are reported as mean ± SD or median and interquartile range. An a priori power analysis using G*Power with the following input parameters was conducted to obtain medium-sized Group × Time interaction for distance walked over six minutes: effect size of $f = 0.25$), type I error of 0.05, type II error of 0.80, three groups, three measurements moments, and a correlation of $r = 0.50$ between repeated measures (Faul et al., 2007). These analyses were based on prior data (Tollár et al., 2023; Tollar et al., 2021). Our analyses revealed a total sample size of ~48, i.e., 16–17 participants per group before an expected dropout of 20 %.

The three groups' baseline characteristics were compared with a one-way analysis of variance (ANOVA). The main analysis was a Group (ROB, WTT, STT) by Time (pre, post, follow-up) ANOVA with repeated measures on Time followed by Tukey post-hoc contrasts. The within group changes were further characterized by Cohen's effect size ($d \leq 0.49$: small; $0.50 \leq d \leq 0.79$: medium; $d \geq 0.80$: large) (Cohen, 1988). mRS and the Barthel Index data were analyzed with non-parametric analyses. For these variables, we performed Friedman tests to determine the effects of the interventions an outcome over time. Kendall's W quantified the effect size. A significant Friedman test was followed by a Wilcoxon Test as a post-hoc analysis to determine if changes pre to post and post to follow-up were significant. The effect size for these within-group changes were computed through the test of probability of superiority for dependent samples (PSdep; a value of 0 or 1 denote maximal, a value of 0.5 denotes an effect size of zero) (Grissom and Kim, 2012). Between-group differences at pre, post, and follow-up were assessed by the Mann-Whitney Test and the effect size characterized by $\eta^2 = 0.01$: small effects; $\eta^2 = 0.06$: medium effects; $\eta^2 = 0.14$: large effects). The level of significance was set for all analyses at $p < 0.05$. Statistical analyses were done in SPSS version 29.

4. Results

4.1. Baseline characteristics

Table 1 shows the descriptive data for the three groups (71 % males, age 64.4y ±6.34). There were no between-group differences in descriptive characteristics at baseline (all $p > 0.05$). Nearly 70 % of strokes occurred in the left hemisphere in each group. 60–70 % of PwST smoked and ~ 25 % reported high levels of alcohol consumption in each group. Hypertension (27 %), ischemic heart disease (16 %), and diabetes (16 %) were the most frequent co-morbidities.

4.2. Intervention effects

There were no between-group differences in primary and secondary outcomes at baseline (all $p > 0.05$, Table 2).

Table 1
Descriptive characteristics of the three groups of patients.

	ROB		WTT		STT	
Variable	Mean	±SD or n	Mean	±SD or n	Mean	±SD or n
Frequency, n (males)	15	(11)	15	(11)	15	(10)
Age, y	64.8	5.89	64.7	7.16	64.7	7.16
Height, m	1.76	0.06	1.75	0.07	1.75	0.07
Mass, kg	80.7	11.93	79.9	8.43	82.0	9.23
BMI, kg·m^{-2}	25.9	3.26	26.1	2.68	26.8	3.15
Days after stroke	5	0.00	5	0.00	5	0.00
Stroke location, n						
Left hemisphere	11		3		10	
Right hemisphere	3		10		3	
Cerebellum	1		2		2	
Smoking, n						
Yes	11		6		9	
No	4		9		6	
Alcohol, n						
Yes	4		11		4	
No	11		4		11	
Comorbidities, n						
Atherosclerosis	0		1		1	
Diabetes	2		2		2	
Fibrillation	1		0		0	
Fibromyalgia	3		2		2	
Gastroenteritis	1		0		0	
Hyperchol.	1		0		0	
Hypertension	2		7		7	
Ischemic HD	3		2		2	
Rheumatoid a.	1		2		2	
Osteoporosis	0		1		0	
Thyroid disease	3		0		0	

ROB, Robot-assisted walking therapy group.
WTT, Walking training therapy group.
STT, Standard treatment therapy group.
BMI, body mass index.
Hyperchol., hypercholesterolemia.
Ischemic HD, ischemic heart disease.
Rheumatoid a., rheumatoid arthritis.

4.3. Primary outcome

A Friedman Test revealed that ROB improved mRS median scores (Table 2, Friedman $\chi^2 = 27.8$, $p = 0.001$, Kendall's W effect size = 0.93). Post-hoc analyses showed that the 1.3 pre-to-post improvement in the median score was significant after ROB treatment (Wilcoxon post-hoc test, p = 0.001, PSdep effect size = 0.99) and the additional 0.5-point improvement in the median score at follow-up was also significant ($p = 0.008$, PSdep effect size = 0.79).

Friedman Test revealed that WTT improved mRS median scores (Friedman $\chi^2 = 25.2$, p = 0.001, Kendall's W effect size = 0.84). Post-hoc analyses showed that the 1.3 pre-to-post improvement in the median score was significant after the WTT intervention (Wilcoxon post-hoc test, $p = 0.020$, PSdep effect size = 0.78). The additional 0.3-unit improvement at follow-up was not significant ($p = 0.221$, PSdep effect size = 0.51).

Friedman Test revealed that STT improved mRS median scores (Friedman $\chi^2 = 13.0$, $p = 0.002$, Kendall's W effect size = 0.43). Post-hoc analyses revealed that the 0.7-unit pre-to-post improvement was significant after STT intervention ($p = 0.032$, PSdep effect size = 0.71) but did not change further by follow-up ($p = 0.180$, PSdep effect size = 0.50).

Kruskall-Wallis Test (H = 20.9, $p = 0.001$) showed that the mRS median scores were 1.0 median unit lower (better) (p = 0.001) after the interventions in ROB and WTT than STT. At follow-up, each group differed ($p \leq 0.024$) by 1.0 median unit from each other (H = 28.9, $p = 0.001$).

4.4. Secondary outcomes

4.4.1. Barthel index

Friedman test revealed that ROB improved median score (Friedman $\chi^2 = 27.4$, $p = 0.001$, Kendall's W effect size = 0.912). Post-hoc analyses showed that the 20-point pre-to-post improvement by ROB was significant (Wilcoxon post-hoc test, $p = 0.001$, PSdep effect size = 0.97) and this improved score did not change further at follow-up ($p = 0.157$). Friedman test revealed that WTT improved median score (Friedman $\chi^2 = 27.1$, $p = 0.001$, Kendall's W effect size = 0.904) which did not improve further at follow-up ($p > 0.05$). Post-hoc analyses revealed that the 10-point pre-to-post improvement in WTT was significant (p = 0.001, PSdep effect size = 0.941) but did not change further by follow-up ($p = 0.059$). Friedman test showed that STT improved median score (Friedman $\chi^2 = 21.2$, p = 0.001, Kendall's W effect size = 0.709) which did not improve further at follow-up (p > 0.05). Post-hoc analyses revealed that the 10-point pre-to-post improvement by STT was significant (p = 0.001, PSdep effect size = 0.851) but did not change further by follow-up (p = 0.059). Kruskall-Wallis Test showed that the median scores were 10.0 median units higher (n.s.) after the interventions in ROB than in the other two groups. At follow-up, ROB vs. STT differed by 10 median points (n.s.).

4.4.2. Berg balance scale

The Group by Time interaction (F = 5.6, $p < 0.001$, $\eta^2 = 0.21$) revealed that ROB improved (p < 0.001) by 8.1 points (±2.37, 41 % ±13, d = 3.61) vs. WTT (4.9 ± 3.31, 26 % ±23, d = 1.69) and STT (4.2 ± 3.26, 22 % ± 18, d = 1.47), with the only between-group difference after intervention between ROB vs. STT ($p < 0.05$). These improvements did not further change by follow-up (all $p > 0.05$).

4.4.3. 10-m maximal walking speed

The Group by Time interaction (F = 10.2, $p < 0.001$, $\eta^2 = 0.39$) revealed that ROB improved by 0.48 m/s (±0.16, 63 % ±28, d = 4.49), WTT improved by 0.32 m/s (±0.10, 40 % ±15, d=,4.03), and STT improved by 0.24 m/s (±0.11, 31 % ±16, d = 2.83, all $p < 0.001$). ROB further improved by 0.12 m/s (±0.21, 10 % ±16, d = 0.85) and STT also further improved by 0.11 m/s (±0.11, 11 % ±11, d = 1.39, both $p < 0.001$) by follow-up but not WTT (d = 0.69, $p > 0.05$).

6MWT — 6MWT without the robot showed a Group by Time interaction (F = 66.5, $p < 0.001$, $\eta^2 = 0.76$). ROB improved by 168 m (±26, 147 % ±32, d = 7.01), more than the 100 m in WTT (±36, 84 % ±35, d = 3.58), which was in turn more than the 35 m in STT (±13, 29 % ±13, d = 2.07, all changes and group-differences p < 0.001). These improvements did not further change (all $p > 0.05$) at follow-up.

The 6MWT while wearing the robot showed a Group by Time interaction (F = 17.7, p < 0.001, $\eta^2 = 0.46$). ROB improved the distance walked by 111 m (±40, 50 % ±23, d = 3.58), which was more than the 64 m in WTT (±47, 30 % ±23, d = 1.77, both p < 0.001) and the 25 m increase in STT (±37, 11 % ±16, d = 0.52, p > 0.05). ROB only further increased ($p < 0.021$) the distance walked by 33 m (±29, 10 % ±9, d = 1.17) at follow-up.

Fig. 2 shows the Group by Time interaction (F = 2.6, $p = 0.041$, $\eta^2 = 0.11$) for the difference in the distance walked with and without the robot during the 6MWT at baseline, after the interventions, and at follow-up. At baseline, the 45 PwST walked 114 m (±40, 97 % ±37, d = 3.63, $p = 0.001$) longer distance with vs. without wearing the robot. The difference in distance walked with vs. without the robot remained the greatest in STT (101 ± 36, red symbols in Fig. 2), 78 m (±38, black) WTT, and 60 m (±33, green) in ROB (all differences $p < 0.001$). At follow-up, the 45 patients still walked 83 m (±32) longer (p < 0.001) distance with than without the robot over six minutes.

4.4.4. COP velocity

The Group by Time interaction (F = 5.7, $p = 0.001$, $\eta^2 = 0.21$) revealed that COP velocity, i.e., sway velocity decreased by 6.9 cm/s

Table 2
Intervention effects on primary and secondary outcomes.

Variable	Group	Pre		Post		Follow-up	
		Mean	±SD	Mean	±SD	Mean	±SD
Primary outcome							
mRS (Md, IQR)	ROB	4.0	1.00	2.0	0.00	1.0	1.00
	WTT	3.0	1.00	2.0	1.00	2.0	0.00
	STT	3.0	1.00	3.0	0.00	3.0	0.00
Secondary outcomes							
Barthel index score	ROB	60.0	0.00	80.0	7.50	80.0	5.00
(Md, IQR)	WTT	60.0	7.50	70.0	10.00	75.0	10.00
	STT	60.0	10.0	70.0	10.00	70.0	5.00
Berg Balance Scale score	ROB	20.1	1.58	28.1	2.56	28.5	3.40
	WTT	20.8	3.14	25.7	2.50	25.4	1.88
	STT	21.1	3.28	25.3	1.83	25.2	1.93
10-m walk, m/s	ROB	0.80	0.11	1.28	0.10	1.40	0.15
	WTT	0.81	0.08	1.13	0.08	1.18	0.09
	STT	0.81	0.09	1.06	0.08	1.17	0.08
6MWT no robot, m	ROB	116	16	284	27	289	24
	WTT	123	14	223	32	205	24
	STT	126	17	161	17	183	18
6MWT with robot, m	ROB	233	35	344	24	377	32
	WTT	237	37	301	35	294	29
	STT	238	39	263	53	256	31
COP velocity, cm/s	ROB	21.1	1.78	14.2	1.19	12.7	1.15
	WTT	20.5	2.21	15.8	1.79	14.7	1.55
	STT	20.4	1.99	16.2	1.74	15.4	1.22

The text accompanying the Table provides the detailed statistical analyses.
ROB, Robotic-assisted walking therapy.
WTT, Walking training therapy.
STT, Standard therapy treatment.
mRS, Modified Rankin Scale.
Md, median.
IQR, interquartile range.
6MWT, distance covered during the six-minute walk test.
COP, center of pressure.

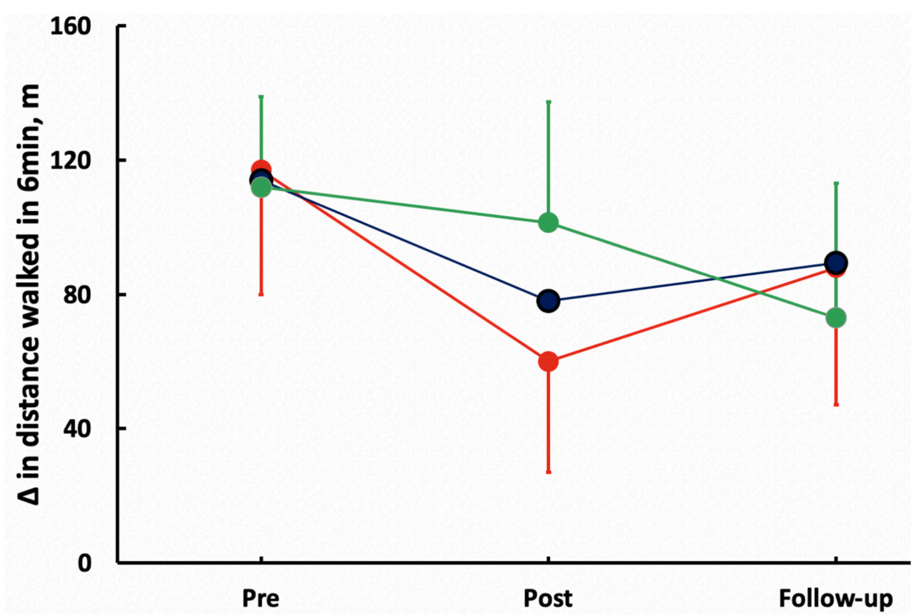

Fig. 2. Difference (Δ) in distance walked during the six-minute walk test with and without the robot before (pre) and after (post) the three interventions and at follow-up. Green, standard treatment therapy intervention; Black, Walking training therapy intervention; Red, Robot-assisted walking therapy intervention. Vertical bars denote + or – 1 SD. For clarity, SD bars are omitted from black symbols. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

(±1.4, −32 % ±5, d = 4.37) after ROB and this decrease was greater ($p < 0.001$) than the decreases in WTT (−4.7 cm/s ± 2.20, −22 % ±10, d = 2.31) and STT (−4.3 cm/s ± 2.20, −20 % ±11, d = 2.27) (all decreases in COP velocity $p < 0.001$). These decreases did not further change at follow-up in either group (all $p > 0.05$). (MediBalance Pro).

4.5. Cardiovascular and rate of perceived exertion data (Supplement 1)

4.5.1. Rate of perceived exertion during intervention

According to a Group main effect ($F = 54.4$, $p = 0.001$, $\eta^2 = 0.72$), rate of perceived exertion was higher in ROB (14.6 ± 1.26) and WTT (14.5 ± 1.170) compared with STT (12.5 ± 1.18) and did not change across the 15 sessions.

4.5.2. Heart rate during intervention

From the Group (ROB, WTT, STT) by Time (pre, post) by Session (1–15) ANOVA only was there a Time main effect ($\eta^2 = 0.469$, $p = 0.001$): heart rate decreased by −2.7 b·min^{-1} (±4.74, −3.2 %, ±4.99) after compared with before the interventions.

Peak heart rate measured during each session was highest in ROB (132 b·min^{-1} ± 7.06) compared with WTT (126 ± 6.32) and STT (120 ± 3.73, all different, $F = 97.4$, $p = 0.001$, $\eta^2 = 0.83$) and tended to decrease most in ROB (−5.0 b·min^{-1} ± 6.66, $p = 0.038$, $d = 1.03$) compared with WTT (−1.9 b·min^{-1}) and STT (−1.7 b·min^{-1}, both $p > 0.05$; Group by Session interaction, $F = 1.5$, $p = 0.042$, $\eta^2 = 0.07$).

4.5.3. Blood pressure before and after intervention and during exercise

Seated heart rate, systolic and diastolic blood pressure at baseline, respectively, was 83.9 (±4.92) b·min^{-1}, 132.2 (±9.19), mm·Hg and 89.7 (±9.14) mm·Hg. The most relevant element of the Group (ROB, WTT, STT) by Time (pre, post) by Session (1–15) ANOVA suggested a −3.1 mm·Hg (±8.21, −2.4 %, $d = 2.32$, $p = 0.001$) overall reduction in systolic blood pressure measured after each of the 15 sessions ($p = 0.001$, $d = 1.77$). This pre-to-post session reduction was the most in STT (3.9 mm·Hg ±6.62, 3 %, $d = 2.22$) followed by the reductions of −3.3 mm·Hg (±7.29, −2.5 %, $d = 1.13$, $p = 0.022$) in WTT and − 2.2 mm·Hg (±7.2, −1.7 %, $d = 0.45$, $p = 0.222$) in ROB.

5. Discussion

We compared the effects of ROB, WTT, and STT on clinical and mobility outcomes in older adults (age 65y) with an acute, ischemic stroke and assessed if the intervention effects were maintained after a five-week-long no-intervention follow-up period, i.e., de-training. The data seem to support the hypothesis that ROB compared with WTT can have impactful intervention and retention effects and that the effects of ROB and WTT would be both greater than the effects induced by STT in most outcomes.

5.1. Sample characteristics at baseline

The current sample of older male and female PwST was of normal body mass, blood pressure with a relatively high resting heart rate, number of smokers, alcohol consumers, and medication-controlled hypertensive individuals (Table 1). Five days after stroke at baseline of the study, the mRS and Barthel Index scores suggested moderately severe levels of ADL-specific disability (Table 2). While walking speed of 0.8 m/s reflects mild levels of mobility disability (Studenski et al., 2011), the ~120 m 6MWT performance ($n = 45$) is indicative of severely impaired walking capacity. Indeed, this is the shortest distance in our own samples of PwST (Tollár et al., 2023; Tollar et al., 2021), Parkinson's disease (232 m), multiple sclerosis (334 m), and healthy older adults (529 m) (Tollar et al., 2019a; Tollar et al., 2018; Tollar et al., 2019b; Tollár et al., 2020). As also specifically indicated (Mehrholz et al., 2020), we selected PwST in a subacute state because such individuals are in the most urgent need of recovery and also respond favorably to intensive mobility interventions (Tollár et al., 2023; Tollar et al., 2021; Wiener et al., 2019).

5.2. Intervention and follow-up ('de-training') effects on the clinical and mobility outcomes

5.2.1. Primary outcome

ROB and WTT but not STT improved mRS by up to 2.0 median points (Table 2), equaling or exceeding the clinically meaningful change of 1.0 point (Balu, 2009; Banks and Marotta, 2007; Tilson et al., 2010). Only a few studies report changes in mRS and these changes are much smaller (0.58) (Ho et al., 2019; Tong et al., 2019) and did not include robot-assisted training (Chen et al., 2024; Yang et al., 2023; Zhang et al., 2023; Zheng et al., 2019; Mehrholz et al., 2020). The present data are overall in line with our high-intensity exergaming studies in subacute ischemic stroke patients, producing changes of up to 1.8 points in mRS. (Tollár et al., 2023; Tollar et al., 2021) We thus provide evidence that not only high-intensity exergaming but ROB and WTT can clinically meaningfully improve independence in activities of daily living and that improvements are retained after 5 weeks of no-intervention follow-up in subacute PwST (Table 2).

5.2.2. Secondary outcomes

The Barthel Index, a general measure of the perceived ability to perform activities of daily living, also improved preferentially after ROB compared with WTT and STT, complementing the stroke-specific changes in mRS. These 10–20-pont improvements were sustained without between-group differences at follow-up (Table 2) and agree with improvements in daily function induced by electromechanical-assisted training for walking after stroke (Mehrholz et al., 2020). Across past and the present data it seems that the Barthel Index is probably not an optimal outcome to measure changes in daily function in conjunction with robotic gait training in acute PwST.

Ber Balance Scale measures fall risk and the changes in this outcome did not differ between ROB (41 %) and WTT (26 %) and did not further change at follow-up. These intervention effects agree with previous studies reporting also no preferential improvements in this outcome after robot-assisted training regardless of device type (Mehrholz et al., 2020; Kim et al., 2019; Gandolfi et al., 2019; Forrester et al., 2014; Cho et al., 2015; Belas Dos Santos et al., 2018) but disagree with significant improvements in five others studies summarized in a review (Yang et al., 2023). The inconsistencies might be related to PwST being in an acute (Mehrholz et al., 2020) vs. chronic state (Yang et al., 2023). Because several studies reported no effects in the Berg Balance Scale, it is also possible that this test is insensitive to intervention effects, including the changes produced by robot-assisted training (Zhang et al., 2023). This idea is reflected by the substantial and preferentially greater changes in sway velocity during standing in ROB (−32 %) vs. the other two groups (~ − 20 %).

Strongly preferentially greater improvements occurred in 10-m maximal walking speed after ROB (63 %) vs. WTT (40 %) and STT (31 %). The interventions effectively corrected the ~0.8 m/s impaired walking speed at baseline to non-impaired, functional walking and these changes further improved at follow-up (Table 2). Reviews summarizing many robot-assisted walking trials in PwST reported 0.06–0.07 m/s improvements only (Chen et al., 2024; Yang et al., 2023; Mehrholz et al., 2020) which were in some cases significant but functionally probably not relevant (Studenski et al., 2011). Indeed, there were several studies reporting up to by −0.13 m/s worsening of fast walking speed after robot-assisted training on treadmill (Chen et al., 2024). We did not perform biomechanical gait and step symmetry analysis and thus cannot tell if the improved walking speed in our PwST would mean an improved motion pattern but a meta-synthesis found no evidence for such changes after robot-assisted gait training in acute PwST (Chen et al., 2024). Further biomechanical studies are needed to understand how robot-assisted training improves the cyclic skill of walking in PwST and the mechanism of how this skill is transferred to overground walking without the robot.

We observed strong, 147 %, improvements in 6MWT after ROB compared with the 84 % and 29 % improvements after WTT and STT, respectively (Table 2). Differences in changes between the two primary interventions groups we observed (ROB:168 m; WTT: 100 m) was 68 m, several-fold surpasses the distance of the standardized mean difference of ~11 m in 24 studies (Mehrholz et al., 2020) and ~ 38 m between robot-trained vs. standard care control in 12 studies examining acute PwST (Chen et al., 2024). As mentioned at the start of the Discussion, all of our PwST had very poor walking capacity at baseline (range 100 to 160 m, $n = 45$, Table 1). The distance walked at baseline and the interventions induced changes in distance walked correlated ($r = -0.37$, $p = 0.012$), suggesting that the low initial walking capacity might have played a role in the robust responses to the interventions which in turn might be related to the very short time, i.e., 5 days, between stroke and enrollment. Another factor contributing to the large increases in walking capacity is the intensity of ROB and WTT. The rate of perceived exertion was ~15/20, 'Hard', accompanied by peak heart rates of ~130 $b{\cdot}min^{-1}$ (84 % of age-predicted maximum heart rate) in both groups (Supplement 1) and reductions of resting heart rate and blood pressure measured before each of the 15 sessions, suggesting cardiovascular adaptations. Indeed, there is a recent trend toward the use of high-intensity exercise in the gait rehabilitation of acute PwST (Tapp et al., 2024; Tollár et al., 2023; Tollar et al., 2021; Wiener et al., 2019; Gjellesvik et al., 2020; Luo et al., 2020; Hortobágyi et al., 2022; Porciuncula et al., 2023). While these results are encouraging, we note that even after the interventions and at follow-up our acute PwST's walking capacity was well below the distances acute PwST walked at baseline in many studies, especially the 161 m covered by STT (Table 2) (Chen et al., 2024; Zhang et al., 2023).

An important and novel observation was that PwST ($n = 45$) walked 114 m longer distance in the 6MWT at baseline with vs. without wearing the robot (Fig. 2, Table 2). This means that our familiarization protocol was appropriate and adequate: PwST quickly got used to the robot and learned to walk with it effectively. These data also mean that PwST tolerated wearing the robot well, as they were able to walk with it at a faster speed for a longer distance during 6MWT. Because STT did not practice with the robot, the distance walked with vs. without the robot was, as expected, the greatest (101 m) compared with ROB (33 m) and WTT (78 m, Fig. 2, Table 2). We assume that ROB experienced motor learning because these PwST actually increased the performance in 6MWT while wearing the robot by walking 50 m longer at follow-up vs. the 30 m and 11 m increases in WTT and STT (Table 2). The high efficacy of ROB might be related to the specific robotic device we used, i.e., ReStore Soft Exoskeleton Robot that allows event detection-based online adjustments of ankle motion support through flexible adjustments in cable retraction and force generation (Awad et al., 2017; Awad et al., 2020a; Siviy et al., 2023). Comparison with other locomotor robots is difficult, as the over 50 studies recently reviewed seemed to not to have included a single study using this specific robot (Chen et al., 2024; Yang et al., 2023; Zhang et al., 2023).

5.3. Limitations, conclusion

While we instructed PwST not to change their physical activity, diet, and medication, we did not systematically monitor these activities nor did we check changes in medication schedules. Many PwST experience fatigue during the day but we did not monitor fatigue. Thus, we cannot exclude the possibility of systematic effects caused by these variables. However, examination of patients' logs did not seem to suggest any marked and systematic changes in these behaviors. Another potential confounding variable is the presence of a Hawthorne effect, as participants might have unconsciously altered their behavior affecting intervention outcomes through a placebo effect. Other than STT, ROB and WTT were delivered in a hospital by specialized staff and in dedicated spaces. Even though current trends favor therapy delivered at home remotely (Perrochon et al., 2019; Steen Krawcyk et al., 2019), it is not feasible to deliver ROB or even WTT unsupervised at home. We performed an a priori sample size and power estimation, it is likely that the present study was still underpowered, illustrated by the small-to-medium effect sizes. We acknowledge the limitation that the magnitude of between-group differences may still not justify the use of an expensive walking robot that also requires trained staff and dedicated space. Future studies will determine whether or not the wide-spread use of walking robots is feasible in the rehabilitation of PwST. We discussed briefly how ROB and WTT could improve walking mobility through motor learning. However, our study is severely limited by a lack of measurements of gait kinematics, kinetics, stride patterns, cost of transport, or neurophysiological markers. Without measuring such variables, we cannot examine intervention-induced mechanistic longitudinal changes (Hortobágyi et al., 2022; Sloot et al., 2023). In conclusion, older adults (age 64.4y) shortly after an ischemic stroke can quickly learn to walk with a soft robotic suit and retain the substantial clinical and mobility improvements at follow-up.

CRediT authorship contribution statement

József Tollár: Writing – review & editing, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Szilvia Kóra:** Methodology, Investigation. **Klaudia Széphelyi:** Methodology, Investigation. **István Drotár:** Software, Methodology, Investigation. **Péter Prukner:** Project administration, Methodology, Investigation. **Blanka Törő:** Supervision, Project administration, Methodology, Investigation. **Nándor Prontvai:** Supervision, Project administration, Methodology, Investigation. **Bence Csutorás:** Supervision, Project administration, Methodology, Investigation. **Tamás Haidegger:** Software, Methodology. **Tibor Hortobágyi:** Writing – original draft, Formal analysis.

Ethical approval

IKEB/2022/02.

Clinical trial

NCT05947773

Funding

Supported in part by the Department of Neurology, Somogy County Kaposi Mór.

Teaching University Hospital and by a 'Regional Health Development' award from the Doctoral School of the Faculty of Health Sciences.

Declaration of competing interest

The other authors declare no competing interests.

Acknowledgements

This study was supported in part by: Department of Neurology, Somogy County Kaposi Mór Teaching University Hospital; "Regional Health Development" award from the Doctoral School of the Faculty of Health Sciences, University of Pécs, NKFIH-OTKA-project number: 147167, JT was supported in part by the János Bolyai Research Scholarship of the Hungarian Academy of Science, Hungary; TH was supported by the International Visegrád Fund #2232023 and by the National Research, Development, and Innovation Office MEC_SZ #149083. Funding agencies did not influence the content of the manuscript.

Data availability

Data will be made available on request.

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