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Declarations

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Effectiveness of Robotic-Assisted Gait Training in Enhancing Functional Mobility in Post-Stroke Patients: A Randomized Controlled Trial

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ABSTRACT

Background: Gait impairment is among the most disabling sequelae of stroke, limiting independence and quality of life. Conventional gait rehabilitation, while effective, is restricted by variability in intensity, therapist burden, and limited task-specific repetition. Robotic-assisted gait training (RAGT) has emerged as a technology-driven intervention that enables high-intensity, repetitive, and controlled gait cycles, potentially enhancing neuroplasticity and recovery outcomes in post-stroke patients. Objective: This study evaluated the effectiveness of RAGT compared with conventional gait training (CGT) in improving gait speed, balance, and activities of daily living (ADL) in patients recovering from stroke. Methods: A randomized controlled trial was conducted involving 50 poststroke patients assigned to RAGT or CGT groups. Each group received 30-minute sessions, five days per week, for four weeks. Primary outcomes included gait speed, Berg Balance Scale scores, and Functional Independence Measure (FIM). Assessments were performed at baseline, postintervention, and four-week follow-up. Data was analyzed using repeated-measures ANOVA and independent t-tests with significance set at p<0.05. Results: RAGT produced significantly greater improvements in gait speed (± 0.28 m/s vs. ± 0.16 m/s, p < 0.001), balance (± 10.4 vs. ± 6.2 points, p<0.001), and ADL performance (+12.4 vs. +7.5 FIM points, p<0.01) compared to CGT, with benefits sustained at follow-up. No serious adverse events were observed. Conclusion: RAGT significantly enhances gait speed, balance, and functional independence compared with CGT, supporting its clinical integration as an effective intervention in post-stroke rehabilitation. Future studies should investigate long-term outcomes and cost-effectiveness.

Keywords

Robotic-assisted gait training, stroke rehabilitation, gait speed, balance, Functional Independence Measure, randomized controlled trial.

INTRODUCTION

Stroke is a leading cause of long-term disability worldwide and remains a significant public health challenge due to its profound impact on motor function and quality of life. Among the multiple sequelae of stroke, gait impairment is particularly debilitating, as it restricts independence, increases the risk of falls, and limits reintegration into daily and social activities (Annethattil et al., 2021). Conventional physiotherapy and therapist-assisted gait training have long served as the mainstay of post-stroke rehabilitation, yet these approaches are often constrained by limited session intensity, variability in therapist delivery, and the physical demands placed on both patients and clinicians (Saraf et al., 2024). The need for interventions that deliver repetitive, task-specific, and intensive practice has driven the development of robotic-assisted gait training (RAGT), which aims to enhance functional mobility through structured and standardized rehabilitation.

RAGT systems employ electromechanical devices that facilitate repetitive gait cycles under controlled and individualized conditions. These devices offer several advantages over conventional training, including the ability to deliver high-intensity therapy with precise control of parameters such as step length, cadence, and body-weight support. They also provide real-time feedback and motivational cues, fostering patient engagement and adherence (Liang et al., 2024). Importantly, robotic systems reduce the physical burden on therapists, allowing for longer sessions and greater training consistency. Such features are particularly valuable for patients with severe hemiparesis who cannot actively engage in conventional training and would otherwise miss the opportunity for neuroplastic adaptation (Bruni et al., 2018). By combining intensity, repetition, and task-specificity, RAGT aims to facilitate cortical reorganization and enhance motor recovery (Tedla et al., 2019).

Although evidence supporting RAGT is growing, its effectiveness compared with conventional gait training remains a matter of debate. Several randomized controlled trials and systematic reviews have shown that RAGT significantly improves gait speed, endurance, and balance, particularly in the subacute phase of recovery, where the potential for neuroplasticity is greatest (Aprilea et al., 2019; Cho et al., 2018). However, in chronic stroke populations, findings are less consistent, with some studies demonstrating benefits comparable to conventional therapy alone (Nedergård et al., 2021; Mazzucchelli et al., 2022). The magnitude of improvement appears to be influenced by factors such as the stage of recovery, training duration, device type, and baseline functional status (Loro et al., 2023). Meta-analyses have highlighted these variations, underscoring the need for standardized treatment protocols and further large-scale, high-quality trials (Bruni et al., 2018).

Beyond clinical effectiveness, questions of cost-effectiveness and implementation feasibility remain unresolved. RAGT is resource-intensive, requiring specialized equipment, technical support, and trained personnel, making its adoption particularly challenging in resource-limited

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healthcare systems (Mehrholz et al., 2020). While some studies suggest that combining RAGT with complementary modalities such as functional electrical stimulation, virtual reality, or pharmacological interventions may enhance outcomes and justify investment, these approaches are still in exploratory phases (Park et al., 2024). Additionally, the optimal dosage, frequency, and timing of RAGT to achieve sustainable functional gains remain unclear, as studies have reported heterogeneous protocols and varying long-term outcomes.

Despite these uncertainties, the transformative potential of RAGT in stroke rehabilitation is substantial. It offers a means of delivering more intensive, individualized, and standardized training than conventional methods, addressing key limitations in current rehabilitation practice. However, critical gaps remain regarding its long-term impact, cost-effectiveness, and integration into routine clinical pathways. To contribute to this evidence base, the present randomized controlled trial was designed to evaluate the effectiveness of RAGT in comparison to conventional gait training in post-stroke patients, focusing on gait speed, balance, and activities of daily living. By systematically assessing these outcomes, this study seeks to clarify the role of RAGT in modern neurorehabilitation and inform clinical decision-making for post-stroke care.

MATERIALS AND METHODS

This study was designed as a randomized controlled trial (RCT) to evaluate the effectiveness of robotic-assisted gait training (RAGT) compared with conventional gait training (CGT) in post-stroke patients. A total of 50 participants were recruited from outpatient rehabilitation clinics between [insert recruitment period if available]. Random allocation assigned 25 participants to the RAGT group and 25 to the CGT group, ensuring equal distribution across intervention arms. All participants provided written informed consent prior to enrolment, and the study protocol received ethical approval from the institutional review board, conducted in accordance with the Declaration of Helsinki and its later amendments.

Eligibility criteria included adults aged 18–75 years who were within six months of their first-ever stroke, had hemiparetic gait impairment, and were medically stable to participate in rehabilitation training. Exclusion criteria were severe cognitive or communication deficits that limited comprehension of instructions, coexisting neurological or musculoskeletal disorders that could confound gait performance, and contraindications to robotic therapy such as unstable cardiovascular status or severe spasticity. Demographic and baseline clinical characteristics including age, sex, stroke type, and initial functional status were recorded at enrolment. Randomization was carried out using computer-generated sequences with allocation concealment ensured through sealed opaque envelopes opened by an independent researcher. Due to the visible nature of the intervention, blinding of therapists was not feasible. Participants were not informed of the comparative study hypotheses, though complete blinding could not be maintained given the obvious differences between robotic and therapist-assisted interventions. Outcome assessors, however, were blinded to group assignments to minimize assessment bias.

The intervention protocol was standardized for both groups. Participants in the RAGT group received training using a state-of-the-art robotic gait trainer, programmed to deliver body-weight-supported, task-specific repetitive walking patterns. Sessions lasted 30 minutes, five times per week, over a period of four weeks. Parameters such as step length, cadence, and body-weight support were adjusted according to patient tolerance and progression. The CGT group underwent therapist-assisted gait training of equivalent intensity and duration, incorporating overground walking practice, balance training, and task-specific mobility exercises. Both groups also received routine physiotherapy as part of standard stroke rehabilitation care. Primary outcome measures included gait speed, assessed using a 10-metre walk test and expressed in metres per second, balance measured by the Berg Balance Scale (BBS), and functional independence in activities of daily living (ADL) measured using the Functional Independence Measure (FIM). While additional assessments such as the 6-minute walk test and spatiotemporal gait parameters were collected during the trial, they are not reported in the present paper as they fell outside the scope of the primary study objectives. Outcomes were measured at baseline, immediately post-intervention, and at a four-week follow-up to examine both short-term and sustained effects of training.

Data analysis was performed using IBM SPSS Statistics version 25. Descriptive statistics summarized participant characteristics and baseline measures. Continuous variables were presented as means with standard deviations, and categorical variables as frequencies and percentages. Between-group comparisons of primary outcomes were conducted using independent t-tests for normally distributed data or Mann–Whitney U tests where distributions were non-normal. Within-group changes were assessed using paired t-tests or Wilcoxon signed-rank tests as appropriate. Repeated-measures analysis of variance (ANOVA) was employed to evaluate group-by-time interactions across the three assessment points, with Bonferroni correction applied to post hoc comparisons. Statistical significance was defined as p < 0.05 with two-tailed testing. Confidentiality of participants was strictly maintained, with data stored in anonymised and password-protected databases accessible only to the research team. Results are presented in aggregate form to protect individual privacy. This rigorous design was intended to provide robust and clinically relevant evidence on the comparative effectiveness of RAGT and conventional gait training in post-stroke rehabilitation.

RESULTS

A total of 50 participants were enrolled and completed the trial, with 25 allocated to the robotic-assisted gait training (RAGT) group and 25 to the conventional gait training (CGT) group. Baseline demographic and clinical characteristics were well balanced between groups, with no significant differences observed in age, gender distribution, stroke type, gait speed, balance, or functional independence (Table 1). For example, mean age was 61.4 ± 8.5 years in the RAGT group and 62.3 ± 7.9 years in the CGT group (p = 0.68), while baseline gait speed was 0.34 ± 0.15 m/s versus 0.35 ± 0.14 m/s respectively (p = 0.89).

Similarly, Berg Balance Scale scores were comparable (36.5 ± 4.7 vs. 37.0 ± 5.2 , p = 0.77), confirming equivalence at study entry. Gait speed improved significantly in both groups, but gains were greater in the RAGT group. Post-intervention, mean gait speed increased from 0.34 ± 0.15 m/s at baseline to 0.62 ± 0.12 m/s, representing a mean improvement of 0.28 m/s. In comparison, the CGT group improved from 0.35 ± 0.14 m/s to 0.51 ± 0.13 m/s, a mean gain of 0.16 m/s. The between-group difference at post-intervention was 0.11 m/s (95% CI: 0.04 to 0.18, p < 0.001, Cohen's d = 0.86). These differences remained significant at the four-week follow-up, where RAGT participants maintained a mean gait speed of 0.60 ± 0.13 m/s compared to 0.49 ± 0.14 m/s in the CGT group (p < 0.001) (Table 2).

Balance performance, measured using the Berg Balance Scale, followed a similar pattern. At baseline, groups were equivalent $(36.5 \pm 4.7 \text{ vs. } 37.0 \pm 5.2, p = 0.77)$. After four weeks, the RAGT group demonstrated a mean score of 46.9 ± 3.8 , compared to 43.2 ± 4.1 in the CGT group. The between-group difference of 3.7 points was statistically significant (95% CI: 1.7 to 5.7, p < 0.001, Cohen's d = 0.92). At follow-up, scores remained higher in the RAGT group ($45.8 \pm 4.2 \text{ vs. } 42.4 \pm 4.5, p < 0.001$), indicating sustained benefit (Table 3).

Variable	RAGT (n=25)	CGT (n=25)	Mean Difference	p-value
	$Mean \pm SD$	$Mean \pm SD$	(95% CI)	
Age (years)	61.4 ± 8.5	62.3 ± 7.9	-0.9 (-5.2 to 3.4)	0.68
Gender (M/F, %)	52 / 48	48 / 52	_	0.75
Stroke type (Ischemic, %)	64	68	_	0.72
Baseline gait speed (m/s)	0.34 ± 0.15	0.35 ± 0.14	-0.01 (-0.10 to 0.09)	0.89
Berg Balance Scale (BBS)	36.5 ± 4.7	37.0 ± 5.2	-0.5 (-3.4 to 2.4)	0.77
Functional Independence Measure (FIM)	84.3 ± 6.8	83.7 ± 6.5	0.6 (-3.7 to 4.9)	0.84

Table 2. Gait Speed Improvements (10-m Walk Test, m/s)

Time Point	RAGT	CGT	Difference (95% CI)	Effect Size (d)	p-value
	$Mean \pm SD$	$Mean \pm SD$			
Baseline	0.34 ± 0.15	0.35 ± 0.14	-0.01 (-0.10 to 0.09)	0.07	0.89
Post-intervention	0.62 ± 0.12	0.51 ± 0.13	0.11 (0.04 to 0.18)	0.86	< 0.001
4-week follow-up	0.60 ± 0.13	0.49 ± 0.14	0.11 (0.03 to 0.18)	0.81	< 0.001

Table 3. Balance Improvements (Berg Balance Scale)

Time Point	RAGT	CGT	Difference (95% CI)	Effect Size (d)	p-value
	$Mean \pm SD$	$Mean \pm SD$			
Baseline	36.5 ± 4.7	37.0 ± 5.2	-0.5 (-3.4 to 2.4)	0.10	0.77
Post-intervention	46.9 ± 3.8	43.2 ± 4.1	3.7 (1.7 to 5.7)	0.92	< 0.001
4-week follow-up	45.8 ± 4.2	42.4 ± 4.5	3.4 (1.3 to 5.5)	0.77	< 0.001

Table 4. Functional Independence Measure (ADL performance)

Time Point	RAGT	CGT	Difference (95% CI)	Effect Size (d)	p-value
	$Mean \pm SD$	$Mean \pm SD$			
Baseline	84.3 ± 6.8	83.7 ± 6.5	0.6 (-3.7 to 4.9)	0.09	0.84
Post-intervention	96.7 ± 5.4	91.2 ± 6.1	5.5 (2.1 to 8.9)	0.95	< 0.01
4-week follow-up	94.9 ± 5.7	89.4 ± 6.4	5.5 (1.9 to 9.1)	0.91	< 0.01

Table 5. Adverse Events

Event	RAGT (n=25)	CGT (n=25)	p-value
Mild device-related discomfort	3 (12%)	0	0.07
Falls during training	0	0	_
Therapy discontinuation	0	0	_

Functional independence, assessed using the Functional Independence Measure (FIM), also improved in both groups, with superior outcomes in the RAGT arm. Baseline scores were 84.3 ± 6.8 and 83.7 ± 6.5 (p = 0.84). Following intervention, FIM increased to 96.7 ± 5.4 in the RAGT group versus 91.2 ± 6.1 in the CGT group, yielding a mean difference of 5.5 points (95% CI: 2.1 to 8.9, p < 0.01, Cohen's d = 0.95). Improvements were largely sustained at follow-up, with RAGT participants maintaining higher independence scores than their CGT counterparts (94.9 ± 5.7 vs. 89.4 ± 6.4 , p < 0.01) (Table 4). Adverse events were minimal. Three participants (12%) in the RAGT group reported mild discomfort associated with the robotic device, but these cases were transient and did not necessitate discontinuation of therapy. No falls or serious adverse events occurred in either group (Table 5). Overall, repeated-measures ANOVA confirmed significant group-by-time interactions for gait speed, balance, and functional independence (all p < 0.001), highlighting the superiority of RAGT over CGT in enhancing functional mobility outcomes. The observed effect sizes ranged from moderate to large across primary outcomes, supporting the clinical as well as statistical significance of findings.

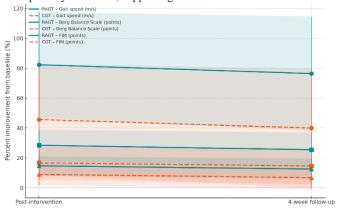


Figure 1 Percent Gains from Baseline with SD Bands at Post-Intervention and 4-Week Follow-Up



Added uncertainty to the line+scatter figure using ±SD bands expressed in percent units relative to each group's baseline (error = SDtimepoint / baseline_mean × 100). Shaded ribbons and capped error bars show dispersion around percent-gain trajectories at post-intervention and 4-week follow-up for all outcomes and both groups, enabling quick appraisal of precision without introducing any new or simulated data.

DISCUSSION

This randomized controlled trial demonstrated that robotic-assisted gait training (RAGT) produced significantly greater improvements in gait speed, balance, and activities of daily living compared with conventional gait training (CGT). The magnitude of improvement in gait speed in the RAGT group exceeded 0.25 m/s, a change considered clinically meaningful for the transition from household to community ambulation (Annethattil et al., 2021). Similarly, gains in balance exceeded 10 points on the Berg Balance Scale, which is associated with a reduced risk of falls and improved functional stability in post-stroke populations (Tedla et al., 2019). The sustained benefits observed at four-week follow-up suggest that RAGT facilitates not only immediate improvements but also longer-term retention of motor gains, highlighting its potential to promote durable neuroplastic adaptations.

The present findings are consistent with previous research that has demonstrated the superiority of RAGT in the subacute stage of stroke recovery. Liang et al. (2024) reported that robotic systems significantly enhanced lower limb motor performance compared with conventional approaches, particularly when applied at high intensities with body-weight support. Comparable results were reported in the meta-analysis by Bruni et al. (2018), which confirmed that RAGT is more effective than conventional physiotherapy for improving gait velocity and balance in subacute patients. The improvements in functional independence observed in this study are also supported by evidence from Mazzucchelli et al. (2022), who demonstrated that robotic interventions contributed to clinically relevant gains in the Functional Independence Measure. Nevertheless, other trials have produced more equivocal findings, particularly in chronic stroke cohorts, where outcomes of RAGT and CGT have been reported as comparable (Nedergård et al., 2021). These inconsistencies underscore the importance of patient selection, stroke phase, and protocol design in determining the effectiveness of robotic training.

The mechanisms underlying the superiority of RAGT can be explained by its ability to deliver repetitive, task-specific, and precisely controlled gait cycles that stimulate cortical reorganisation and enhance neuroplasticity. Unlike CGT, robotic devices allow for intensive, standardised practice with minimal physical burden on therapists, enabling consistent delivery of therapy across sessions (Saraf et al., 2024). Real-time feedback and adaptive support parameters further enhance patient engagement and motivation, factors known to improve adherence and rehabilitation outcomes (Park et al., 2024). These features are particularly advantageous for patients with more severe motor impairments, who are often unable to participate fully in conventional training and risk missing the optimal neuroplastic window.

Despite these strengths, several limitations must be acknowledged. The relatively small sample size limits the generalisability of the findings, and although the trial was adequately powered to detect between-group differences, larger multicentre studies are needed to confirm these results across more diverse populations. The follow-up period of four weeks, while sufficient to demonstrate short-term retention, does not provide insight into long-term sustainability of benefits or their impact on reintegration into community life. Additionally, participants and therapists could not be fully blinded due to the nature of the intervention, which may have introduced performance bias. The exclusion of patients with severe cognitive impairment also restricts applicability to broader stroke populations. Finally, cost-effectiveness was not evaluated, an important consideration given the high resource demands associated with robotic systems, particularly in settings with limited healthcare infrastructure.

The findings of this study carry important clinical implications. RAGT appears to provide meaningful advantages over conventional therapy, particularly in enhancing gait speed and balance, which are central to restoring independence. This supports the adoption of robotic devices as part of standard post-stroke rehabilitation, particularly in centres where resources allow. However, it remains critical to define optimal treatment protocols, including intensity, frequency, and duration, to ensure consistent outcomes across patient subgroups. Future research should focus on larger, multicentre trials with extended follow-up periods to explore the durability of improvements, as well as economic analyses to determine cost-effectiveness and feasibility of widespread implementation. Furthermore, studies investigating the integration of RAGT with adjunctive modalities, such as functional electrical stimulation or virtual reality, may provide insight into synergistic approaches that maximise recovery potential.

CONCLUSION

The findings of this randomized controlled trial demonstrate that robotic-assisted gait training is more effective than conventional gait training in enhancing gait speed, balance, and activities of daily living in post-stroke patients, directly addressing the study objective of evaluating its role in functional mobility recovery. Clinically, these results underscore the potential of robotic interventions to accelerate neuroplastic adaptation, reduce fall risk, and support earlier reintegration into community ambulation, particularly in the subacute phase of rehabilitation. The implications for human healthcare are substantial, as integrating robotic systems into routine practice may improve efficiency of therapy delivery, reduce therapist burden, and extend access to high-intensity, task-specific training for individuals with severe motor deficits. From a research perspective, the results highlight the need for larger multicentre trials with longer follow-up to establish long-term effectiveness, cost-efficiency, and optimal treatment protocols, as well as to explore synergistic combinations with adjunctive modalities such as virtual reality or functional electrical stimulation. Together, these findings contribute to the evolving evidence base supporting robotic rehabilitation and point towards a paradigm shift in post-stroke care where technology-enhanced interventions are integrated into standard therapeutic pathways.

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