

Synchronized Dual-Task Training During Robot-Assisted Gait Training After Stroke: A Three-Arm Randomized Controlled Trial

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Research Article

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Posted Date: October 27th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-11253155/v1>

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Additional Declarations: No competing interests reported.

Title Page and Abstract

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Running Title

Synchronized Robot–Dual-Task Training After Stroke

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Keywords

stroke; robot-assisted gait training; dual-task training; lower-limb motor function; randomized controlled trial; MeSH: Robotics; Cognition; Gait

Funding

This study was supported by the 2026 Chongqing Science and Health Joint Medical Research Project: "Multimodal Assessment of Walking Function after Stroke — A Clinical Study of Lower-Limb Robotics and Dual-Task Training Combined with Diffusion Tensor Imaging" (grant number 2026MSXM083).

Abstract

Background: Robot-assisted gait training (RAGT) and dual-task training (DTT) each improve walking after stroke, but whether delivering dual tasks synchronously during

RAGT confers additive benefit is unknown. We compared synchronized robot–dual-task training (RDT) against each component alone.

Methods: In this single-center, three-arm, assessor- and statistician-blinded randomized controlled trial, 99 patients with post-stroke walking dysfunction were allocated to RDT (n = 33), RAGT (n = 33), or DTT (n = 33) (after removal of one duplicate data-entry record), each added to conventional rehabilitation (20 min/day, 5 days/week, 8 weeks). The primary outcome was the Fugl-Meyer Assessment of the Lower Extremity (FMA-LE); secondary outcomes were the Berg Balance Scale (BBS), activities of daily living (ADL; Modified Barthel Index), and six-minute walk test (6MWT) categories. Between-group change scores were compared by ANCOVA adjusted for baseline values, with pairwise post hoc comparisons.

Results: All groups improved significantly on all outcomes (all within-group $P < 0.001$). FMA-LE gains were greatest with RDT ($\Delta 14.27 \pm 4.99$) versus RAGT ($\Delta 8.55 \pm 2.72$; adjusted mean difference 4.87, 95% CI 3.39–6.35; $P = 1.1 \times 10^{-8}$; $d = 1.43$) and DTT ($\Delta 6.39 \pm 2.84$; adjusted mean difference 5.99, 95% CI 4.38–7.61; $P = 3.8 \times 10^{-10}$; $d = 1.94$); RAGT also exceeded DTT (adjusted mean difference 1.54, 95% CI 0.40–2.69; $P = 0.009$). BBS and ADL improved most with RDT ($\Delta 21.67$ and $\Delta 31.52$, respectively); all nine pairwise comparisons across outcomes were statistically significant, including ADL RDT versus RAGT (adjusted mean difference 5.33, 95% CI 1.03–9.62; $P = 0.016$, not surviving Bonferroni correction). Week-8 6MWT categories favored RDT ($P = 0.006$ vs RAGT; $P < 0.001$ vs DTT); 66.7% of RDT participants walked >300 m, and none were unable to complete the test. Findings were robust in baseline-stratified analyses, in a sensitivity analysis excluding 13 over-age participants, and in an ordinal logistic regression of 6MWT categories adjusted for baseline grade.

Conclusions: In this completed three-arm randomized trial, synchronized dual-task training during RAGT was associated with greater improvements than dual-task training alone across all evaluated outcomes—lower-limb motor function, balance, activities of daily living, and walking endurance—and with greater improvements in FMA-LE, BBS, and ADL than robot training alone, although the ADL contrast versus RAGT was modest and did not survive Bonferroni correction. Diffusion tensor imaging correlates of these clinical gains and longer-term follow-up will be reported separately.

Trial registration: Chinese Clinical Trial Registry (ChiCTR), <http://www.chictr.org.cn/>; registration number ChiCTR2500115695; date of registration: 29 December 2025. National Medical Research Registration and Filing Information System record MR-50-25-090484.

1 Introduction

Stroke remains a leading cause of death and long-term adult disability worldwide: the Global Burden of Disease Study 2019 estimated 12.2 million incident strokes and 101 million prevalent survivors globally, ranking stroke as the second-leading cause of death [1]. The burden is particularly heavy in China, where an estimated 17.8 million people aged 40 years or older were living with stroke in 2020, with 3.4 million incident cases that year

[2]. Walking dysfunction is among the most prevalent and disabling post-stroke impairments: the Copenhagen Stroke Study showed that approximately 22% of patients never regain walking function and 14% walk only with assistance [3], and only a minority of survivors achieve functional community ambulation after rehabilitation [4]. Impaired walking restricts independence in activities of daily living (ADL), increases fall risk, and burdens families and health-care systems; restoring walking ability is therefore a central goal of stroke rehabilitation.

Lower-limb robot-assisted gait training (RAGT) delivers high-repetition, task-specific stepping practice with body-weight support and externally guided physiological gait patterns, enabling standardized, intensive training with reduced therapist labour. The Cochrane review by Mehrholz et al. (62 trials, 2440 participants) concluded that electromechanical-assisted gait training combined with physiotherapy increases the odds of independent walking after stroke—particularly in the subacute phase and among non-ambulatory patients—although gains in gait speed and walking endurance are limited [5]. A meta-analysis by Moucheboeuf et al. similarly found improved walking independence but inconsistent superiority in speed [6], and a Lokomat meta-analysis found improved functional mobility but no significant advantage over conventional therapy on the Berg Balance Scale (BBS) [7]. Notably, the multicentre LEAPS trial found body-weight-supported treadmill training no better than a progressive home-based balance and strength programme in subacute stroke, suggesting that technological sophistication alone does not guarantee better outcomes and that the content and cognitive engagement of training matter [8]. Thus RAGT, while effective for restoring basic walking independence, may be insufficient for the attentional and cognitive demands of real-world walking.

Walking in daily life is rarely performed in isolation; it typically occurs while talking, planning, or reacting to the environment. Gait recruits executive and attentional resources, and dual-task costs on gait are exaggerated in neurological populations [9]; after stroke, cognitive-motor interference during walking and functional mobility is markedly greater than in healthy controls [10,11], contributing to slower gait, instability, and falls. Dual-task gait training, in which a cognitive or secondary motor task is practised concurrently with walking, has therefore been proposed to improve walking automaticity and transfer to everyday ambulation. In a randomized pilot trial, Liu et al. showed that cognitive and motor dual-task gait training improved dual-task walking performance after stroke in a training-specific manner [12]. A meta-analysis by Plummer and Iyigün found moderate evidence that exercise interventions incorporating dual-task practice improve dual-task gait speed after stroke [13], and a randomized trial in chronic stroke showed that walking training with simultaneous cognitive demand improved walking automaticity [14]. Nevertheless, dual-task protocols vary widely, and the optimal content, dosage, and delivery mode remain unclear [13,15].

A logical yet rarely tested strategy is to combine these paradigms—delivering dual tasks *synchronously* during robot-assisted gait training, so that high-dose, precisely controlled stepping and attentionally demanding task practice occur simultaneously. Direct randomized evidence for this synchronized paradigm is scarce, and to our knowledge no three-arm randomized controlled trial has compared synchronized RAGT plus dual-task training against each component alone, all added to conventional rehabilitation (we

searched PubMed and the Cochrane Library through 2026 using the terms “robot-assisted gait training” AND “dual-task” AND “stroke” and identified no such three-arm randomized controlled trial). Such a comparison is needed to determine whether the combined paradigm yields additive or synergistic benefits on lower-limb motor function, balance, walking capacity, and ADL.

In parallel, elucidating the neural mechanisms of any clinical benefit requires objective biomarkers. Diffusion tensor imaging (DTI), particularly fractional anisotropy (FA) of the corticospinal tract, is an established framework for studying structural connectivity and motor recovery after stroke [16]: lower corticospinal tract FA predicts poorer long-term motor outcome [17], and early FA changes carry prognostic value for subsequent recovery [18]. DTI-derived FA therefore offers a promising route to link behavioural improvements from synchronized RAGT with dual-task training to white-matter reorganization.

Accordingly, this single-center, three-arm randomized controlled trial compared (i) RAGT alone, (ii) dual-task training alone, and (iii) synchronized RAGT with dual-task training—each superimposed on conventional rehabilitation—in patients with post-stroke walking dysfunction. We hypothesized that all three interventions would improve lower-limb motor function, balance, walking endurance, and ADL, with the greatest improvements in the synchronized group. This article reports the clinical outcomes of the completed trial; DTI data collection is ongoing within the study framework and, although not included here, constitutes the planned mechanistic extension of the trial.

2 Methods

2.1 Study Design

This was a single-center, three-arm, parallel-group, assessor- and statistician-blinded randomized controlled trial conducted at the Department of Rehabilitation Therapy, Jiangbei District Hospital of Traditional Chinese Medicine, Chongqing, China. Participants were enrolled between January 2026 (after ethics approval) and August 2026, when the planned sample size was reached. The protocol was approved by the Ethics Committee of Jiangbei District Hospital of Traditional Chinese Medicine, Chongqing (approval number JZY-IRB-202526; approved 26 December 2025), the study followed the Declaration of Helsinki and Good Clinical Practice guidelines, and written informed consent was obtained from all participants before enrolment. Because diffusion tensor imaging (DTI) data collection and follow-up assessments are still ongoing, only clinical outcomes of the completed trial cohort are reported here; imaging and follow-up results will be reported separately. The trial was registered in the Chinese Clinical Trial Registry (ChiCTR; registration number ChiCTR2500115695; date of registration: 29 December 2025; <http://www.chictr.org.cn/>) and recorded in the National Medical Research Registration and Filing Information System (record number MR-50-25-090484; made public on 29 December 2025).

2.2 Sample Size

The sample size was calculated from the study protocol based on pilot response rates for the primary comparison (DTT 0.041 vs RAGT 0.375). With a two-sided α of 0.05 and 90% power, 26 participants per group (78 in total) were required; inflating for an anticipated 25% dropout rate yielded a target of 33 participants per group (99 in total). Enrollment was completed at the planned target of 99 participants (33 per group), and the present report is the final analysis of the completed trial cohort.

2.3 Participants

Hospitalized patients with post-stroke walking dysfunction were screened for eligibility. Protocol-specified inclusion criteria were: (1) stroke confirmed by cranial computed tomography or magnetic resonance imaging, diagnosed according to the Chinese national guidelines for cerebral hemorrhage (2019) and acute ischemic stroke (2023), with disease duration ≤ 6 months; (2) post-stroke walking dysfunction; (3) age 18–75 years; (4) stable vital signs; (5) relatively preserved cognition (Mini-Mental State Examination [MMSE] ≥ 17 or Montreal Cognitive Assessment [MoCA] ≥ 24); and (6) ability to comply with the protocol and provision of written informed consent. Protocol-specified exclusion criteria were: (1) walking dysfunction predating the index stroke; (2) visual impairment or unilateral spatial neglect; (3) severe cognitive impairment or post-stroke depression; (4) metallic implants (e.g., cardiac pacemaker); (5) severe comorbidities such as New York Heart Association class IV heart failure or severe chronic obstructive pulmonary disease; and (6) concurrent participation in another clinical trial.

Withdrawal and dropout criteria were predefined, including serious adverse events, intercurrent severe illness, poor adherence (attendance below 80% or above 120% of scheduled sessions), voluntary withdrawal, and loss to follow-up. All randomized participants who completed baseline and 8-week assessments were analyzed. During blinded data cleaning, one record in the DTT group was found to share an identical hospital admission number and identical values across all variables with another record and was therefore judged to be a duplicate data entry and removed, leaving 99 participants in the analysis set (RDT $n = 33$, RAGT $n = 33$, DTT $n = 33$). Thirteen enrolled participants were older than the protocol-specified upper age limit of 75 years (RDT 4, RAGT 5, DTT 4), constituting a protocol deviation; they were retained on the basis of clinical judgment at screening, and the robustness of the findings to their inclusion was verified in a prespecified sensitivity analysis excluding them.

2.4 Randomization and Blinding

Participants were randomly allocated to one of three groups using simple randomization based on a random-number table generated with SPSS 22.0 (IBM Corp., Armonk, NY, USA). Allocation concealment was ensured using random-number cards sealed in opaque envelopes kept by a designated custodian not otherwise involved in the trial; upon enrolment, an independent third party opened the envelope and implemented the allocated intervention. The trial was assessor- and statistician-blinded: outcome assessors were trained rehabilitation professionals not involved in the intervention, unaware of allocation,

and instructed to minimize unnecessary communication with participants; and the statistician was blinded to group identity. Owing to the nature of the interventions, participants could not be blinded to their treatment allocation; however, they were not informed of the study hypotheses or of any expectations regarding the relative superiority of the three interventions. We acknowledge that simple randomization without stratification or blocking was a limitation, as it offers no protection against chance baseline imbalance in prognostic variables—an imbalance that in fact occurred for baseline FMA-LE and was addressed analytically (see Statistical Analysis).

2.5 Interventions

All participants received conventional rehabilitation for 90 minutes per day, 5 days per week, for 8 weeks, comprising routine medical management (blood pressure, glycemic, and lipid control; neurotrophic treatment; improvement of microcirculation) and standardized physiotherapy: range-of-motion training for the hip, knee, and ankle; muscle strengthening (body-weight and resistance exercises); motor control and coordination training; balance training (sitting/standing balance, paretic-side weight bearing, weight shifting, dynamic stability); gait correction for hemiparetic deviations; and ADL training (turning over, sitting up, transfers).

Group A (robot-assisted gait training [RAGT] plus conventional rehabilitation).

Participants received additional robot-assisted gait training for 20 minutes per day, 5 days per week, for 8 weeks, using the A3 gait training and evaluation system (Guangzhou Yikang Medical Equipment Industrial Co., Ltd., Guangzhou, China). After individual adjustment of the device and straps and a 1-minute warm-up, the standing angle, stepping mode (single- or both-leg), and hip/knee range of motion (0–25°) were set according to each participant's condition, with a stepping cadence of 20–30 steps per minute.

Group B (dual-task training [DTT] plus conventional rehabilitation). Participants received additional dual-task training for 20 minutes per day, 5 days per week, for 8 weeks. Cognitive dual tasks performed during walking included calculation tasks (serial addition/subtraction, e.g., repeatedly subtracting 3 from 100), verbal communication tasks (conversation requiring explicit, elaborated responses), and auditory feedback tasks (responding to target digits embedded in auditory signals). Motor dual tasks comprised basic training (sit-to-stand transfers, weight shifting, stepping/step-back postural maintenance within parallel bars) progressing to marching in place, stepping, and treadmill walking, with task complexity (e.g., ball tossing/catching, cued visual shifts) increased as tolerated.

Group C (synchronized RAGT with dual-task training [RDT] plus conventional rehabilitation). Participants received dual-task training performed synchronously during robot-assisted gait training on the A3 system, 20 minutes per day, 5 days per week, for 8 weeks, following a graded four-phase protocol stratified by the Fugl-Meyer Assessment of the Lower Extremity (FMA-LE), BBS, and Modified Barthel Index (MBI). Phase 1 (severe: FMA-LE 0–10, BBS 0–20, MBI ≤40) used fully passive robot mode with 60–80% body-weight support, speed 0.15–0.25 m/s, and no dual task. Phase 2 (moderate: FMA-LE 11–22, BBS 21–40, MBI 41–60) used active-passive cooperative mode with 40–60% body-weight

support, speed 0.25–0.40 m/s, and low-load cognitive tasks (auditory vigilance, object naming, orientation questions, short-term memory recall) alternating with walking. Phase 3 (mild-assist: FMA-LE 23–28, BBS 41–48, MBI 61–80) used active-assistive mode with 20–40% body-weight support, speed 0.4–0.6 m/s, and moderate-load tasks performed synchronously throughout (backward counting, semantic fluency, simple serial subtraction, simplified Stroop colour naming). Phase 4 (community-independence: FMA-LE 29–34, BBS 49–56, MBI 81–100) used resisted gait mode with 0–20% body-weight support, speed 0.6–0.8 m/s, variable speed and turning programs, and high-load tasks (standard Stroop, serial subtraction by 3, working memory, N-back). Body-weight support and guidance force were reduced by 5–10% every 1–2 weeks and speed increased by 0.05–0.1 m/s, provided gait remained normal; resistance was increased by one level every 2 weeks if gait speed declined by less than 10%. Task difficulty was downgraded or dual-tasking paused if gait asymmetry exceeded 40%, balance deteriorated, or task errors became frequent; an increase in FMA-LE of more than 3 points permitted early advancement to the next phase.

2.6 Outcome Measures

Outcomes were assessed at baseline and after 8 weeks of intervention by assessors blinded to group allocation. The primary outcome was the FMA-LE (total score 0–34; higher scores indicate better lower-limb motor function). Secondary outcomes were the BBS (0–56; higher scores indicate better balance), ADL assessed with the MBI (0–100; higher scores indicate greater independence), and walking endurance assessed by the six-minute walk distance, recorded as categorical grades. The six-minute walk test has excellent test–retest reliability in people with stroke (pooled intraclass correlation coefficient 0.98) [19], and is a widely used measure of walking capacity in this population [20]. The modified Rankin Scale (mRS) was recorded at baseline to characterize global disability. Baseline demographic and clinical characteristics (age, sex, stroke type, disease duration, affected side, MMSE/MoCA) were documented. Adverse events occurring during the intervention period were recorded, including their nature, onset date, severity, management, outcome, and relationship to treatment.

2.7 Statistical Analysis

Analyses were performed using SPSS 22.0 (IBM Corp., Armonk, NY, USA). Normality was examined with the Shapiro–Wilk test. Normally distributed continuous data are presented as mean $\pm$ standard deviation and non-normally distributed data as median (25th, 75th percentiles); categorical data as frequencies and percentages. Normally distributed continuous variables were compared among groups using one-way analysis of variance (ANOVA), and non-normally distributed variables using the Kruskal–Wallis test with Mann–Whitney U tests for pairwise comparisons. Within-group baseline-to-week-8 changes used paired-samples t tests or Wilcoxon signed-rank tests, as appropriate. Between-group differences in change-from-baseline values were analyzed using ANOVA supplemented by analysis of covariance (ANCOVA) with the baseline value as covariate; because a baseline imbalance in FMA-LE among groups was detected despite randomization, ANCOVA adjusted for baseline FMA-LE was used for the primary comparison of change scores. Pairwise comparisons were performed as pairwise contrasts

within the ANCOVA model, with the baseline value of the respective outcome entered as a covariate. Results of the ANCOVA models are reported as baseline-adjusted mean differences with 95% confidence intervals. Effect sizes were expressed as Cohen's d, calculated from the change scores using the pooled standard deviation. The homogeneity-of-slopes assumption was examined by testing the group $\times$ baseline interaction for each outcome; where this interaction was significant, unadjusted ANOVA of change scores and a baseline-stratified sensitivity analysis across three baseline FMA-LE strata (≤ 8 , 9–16, and ≥ 17) were additionally performed. Pairwise post hoc comparisons were not formally adjusted for multiplicity; statistical robustness was evaluated post hoc against a Bonferroni-corrected threshold. Categorical variables were compared using the Pearson chi-square test, and ordinal variables (six-minute walk distance grades) using the Mann-Whitney U or Kruskal-Wallis test; in addition, week-8 6MWT grades were analyzed using ordinal logistic regression adjusted for the baseline grade. A sensitivity analysis excluding the 13 participants older than 75 years ($n = 86$) was performed for all outcomes. All tests were two-sided with $\alpha = 0.05$; $P < 0.05$ was considered statistically significant.

3 Results

3.1 Participant Flow

This completed trial included 99 randomized participants with post-stroke walking dysfunction: 33 in the combined robot-dual-task (RDT) group, 33 in the robot-assisted gait training (RAGT) group, and 33 in the dual-task training (DTT) group. One duplicate data-entry record was identified and removed during data cleaning. All participants completed the 8-week intervention and both assessment time points; no dropout or missing data were recorded for any outcome in the present dataset.

3.2 Baseline Characteristics

Baseline characteristics are summarized in Table 1. The three groups did not differ significantly in age (Kruskal-Wallis, $P = 0.289$), sex distribution ($\chi^2 = 5.452$, $P = 0.065$), stroke type ($\chi^2 = 4.942$, $P = 0.293$), modified Rankin Scale score ($P = 0.876$), number of comorbidities ($P = 0.090$), baseline BBS (ANOVA, $P = 0.675$), baseline ADL (ANOVA, $P = 0.352$), or baseline 6MWT category ($P = 0.720$). However, baseline FMA-LE scores differed significantly among groups (ANOVA, $P = 0.022$), with the DTT group showing higher baseline lower-limb motor function (14.52 ± 5.32) than the RAGT (12.30 ± 6.36) and RDT (10.27 ± 6.59) groups. Accordingly, between-group comparisons of outcome changes were performed using ANCOVA with the baseline value as a covariate.

Table 1. Baseline characteristics of participants

Characteristic	RDT (n = 33)	RAGT (n = 33)	DTT (n = 33)	Test	P
Age, y	61.30 $\pm$ 14.02	66.85 $\pm$ 9.57	64.55 $\pm$ 11.63	Kruskal-Wallis	0.289

Characteristic	RDT (n = 33)	RAGT (n = 33)	DTT (n = 33)	Test	P
Sex, male/female	26/7	18/15	25/8	$\chi^2 = 5.452$	0.065
Stroke type, ischemic/hemorrhagic/mixed	16/16/1	16/12/5	20/11/2	$\chi^2 = 4.942$	0.293
mRS, median (IQR)	4 (3–5)	4 (3–5)	4 (4–4)	Kruskal–Wallis	0.876
Comorbidities, n	2.27 ± 1.88	2.79 ± 2.19	3.42 ± 2.26	Kruskal–Wallis	0.090
FMA-LE	10.27 ± 6.59	12.30 ± 6.36	14.52 ± 5.32	ANOVA	0.022
BBS	12.91 ± 7.84	14.36 ± 7.29	12.94 ± 7.67	ANOVA	0.675
ADL	37.27 ± 14.42	35.61 ± 14.56	40.45 ± 12.21	ANOVA	0.352
6MWT baseline category, unable/<150 m/301–450 m, n	21/11/1	23/10/0	24/8/1	Kruskal–Wallis	0.720

Abbreviations: RDT, combined robot–dual-task; RAGT, robot-assisted gait training; DTT, dual-task training; mRS, modified Rankin Scale; IQR, interquartile range; FMA-LE, Fugl-Meyer Assessment lower extremity; BBS, Berg Balance Scale; ADL, activities of daily living (assessed with the Modified Barthel Index, MBI); 6MWT, 6-minute walk test.

3.3 Primary Outcome: FMA-LE

All three groups improved significantly in FMA-LE from baseline to week 8 (all paired tests $P < 0.001$; Table 2). Mean changes were 14.27 ± 4.99 in the RDT group, 8.55 ± 2.72 in the RAGT group, and 6.39 ± 2.84 in the DTT group. Between-group comparison of change scores was significant by one-way ANOVA ($F = 40.71$, $P = 1.6 \times 10^{-13}$) and remained significant after adjustment for baseline FMA-LE using ANCOVA (omnibus ANCOVA $P = 9.8 \times 10^{-14}$). Pairwise ANCOVA comparisons favored the RDT group over both the RAGT group (adjusted mean difference 4.87, 95% CI 3.39–6.35; $P = 1.1 \times 10^{-8}$; Cohen's $d = 1.43$) and the DTT group (adjusted mean difference 5.99, 95% CI 4.38–7.61; $P = 3.8 \times 10^{-10}$; $d = 1.94$), and favored the RAGT group over the DTT group (adjusted mean difference 1.54, 95% CI 0.40–2.69; $P = 0.009$; $d = 0.77$).

Group × baseline interaction

The test of the group × baseline interaction for FMA-LE was statistically significant ($P = 0.013$), indicating that the homogeneous-slopes assumption of ANCOVA was not fully met for this outcome. A sensitivity analysis using unadjusted one-way ANOVA of change scores yielded consistent conclusions ($F = 40.71$, $P = 1.6 \times 10^{-13}$), and the FMA-LE findings should therefore be interpreted with this caveat in mind. No significant group × baseline interaction was detected for BBS ($P = 0.528$) or ADL ($P = 0.326$).

3.4 Secondary Outcomes: BBS and ADL

BBS improved significantly within all groups (RDT: $\Delta 21.67 \pm 4.63$; RAGT: $\Delta 13.73 \pm 3.88$; DTT: $\Delta 11.45 \pm 3.73$; all within-group $P < 0.001$). Between-group differences in BBS change were significant (ANOVA $F = 56.49$, $P = 6.1 \times 10^{-17}$; omnibus ANCOVA $P = 2.2 \times 10^{-18}$).

Pairwise comparisons showed RDT > RAGT (adjusted mean difference 7.58, 95% CI 5.67–9.50; $P = 5.0 \times 10^{-11}$; $d = 1.86$), RDT > DTT (adjusted mean difference 10.21, 95% CI 8.24–12.18; $P = 3.3 \times 10^{-15}$; $d = 2.43$), and RAGT > DTT (adjusted mean difference 2.56, 95% CI 0.82–4.30; $P = 0.005$; $d = 0.60$); all three pairwise comparisons were statistically significant.

ADL improved significantly within all groups (RDT: $\Delta 31.52 \pm 8.15$; RAGT: $\Delta 26.52 \pm 9.96$; DTT: $\Delta 17.73 \pm 7.40$; all within-group $P < 0.001$). Between-group differences were significant (ANOVA $F = 21.88$, $P = 1.5 \times 10^{-8}$; omnibus ANCOVA $P = 1.7 \times 10^{-8}$). Pairwise comparisons showed RDT > RAGT (adjusted mean difference 5.33, 95% CI 1.03–9.62; $P = 0.016$; $d = 0.55$), RDT > DTT (adjusted mean difference 13.20, 95% CI 9.51–16.89; $P = 1.1 \times 10^{-9}$; $d = 1.77$), and RAGT > DTT (adjusted mean difference 7.38, 95% CI 3.42–11.35; $P = 4.2 \times 10^{-4}$; $d = 1.00$); all three pairwise comparisons were statistically significant.

Table 2. Within-group changes and between-group comparisons of clinical outcomes at baseline and week 8

Outcome	Group	Baseline	Week 8	Change	Within-group P	Between-group ANOVA	Omnibus ANCOVA P	Pairwise comparisons (adjusted mean difference [95% CI]; pairwise P; Cohen's d)
FMA-LE	RDT	10.27 $\pm$ 6.59	24.55 $\pm$ 4.47	14.27 $\pm$ 4.99	< 0.001	$F = 40.71$, $P = 1.6 \times 10^{-13}$	$P = 9.8 \times 10^{-14}$	RDT vs RAGT: 4.87 [3.39, 6.35], $P = 1.1 \times 10^{-8}$; RDT vs DTT: 5.99 [4.38, 7.61], $P = 3.8 \times 10^{-10}$; RAGT vs DTT: 1.54 [0.40, 2.69], $P = 0.009$
	RAGT	12.30 $\pm$ 6.36	20.85 $\pm$ 5.04	8.55 $\pm$ 2.72	< 0.001			

Outcome	Group	Baseline	Week 8	Change	Within-group P	Between-group ANOVA	Omnibus ANCOVA P	Pairwise comparisons (adjusted mean difference [95% CI]; pairwise P; Cohen's d)
BBS	DTT	14.52 ± 5.32	20.91 ± 4.58	6.39 ± 2.84	< 0.001			
	RDT	12.91 ± 7.84	34.58 ± 7.49	21.67 ± 4.63	< 0.001	F = 56.49, P = 6.1×10 ⁻¹⁷	P = 2.2×10 ⁻¹⁸	RDT vs RAGT: 7.58 [5.67, 9.50], P = 5.0×10 ⁻¹¹ ; RDT vs DTT: 10.21 [8.24, 12.18], P = 3.3×10 ⁻¹⁵ ; RAGT vs DTT: 2.56 [0.82, 4.30], P = 0.005
	RAGT	14.36 ± 7.29	28.09 ± 6.23	13.73 ± 3.88	< 0.001			
	DTT	12.94 ± 7.67	24.39 ± 7.56	11.45 ± 3.73	< 0.001			
ADL	RDT	37.27 ± 14.42	68.79 ± 15.21	31.52 ± 8.15	< 0.001	F = 21.88, P = 1.5×10 ⁻⁸	P = 1.7×10 ⁻⁸	RDT vs RAGT: 5.33 [1.03, 9.62], P = 0.016; RDT vs DTT: 13.20 [9.51, 16.89], P = 1.1×10 ⁻⁹ ; RAGT vs DTT: 7.38 [3.42, 11.35], P =

Outcome	Group	Baseline	Week 8	Change	Within-group P	Between-group ANOVA	Omnibus ANCOVA P	Pairwise comparisons (adjusted mean difference [95% CI]; pairwise P; Cohen's d)
								4.2×10^{-4}
	RAGT	35.61 ± 14.56	62.12 ± 13.81	26.52 ± 9.96	< 0.001			
	DTT	40.45 ± 12.21	58.18 ± 10.74	17.73 ± 7.40	< 0.001			

Omnibus ANCOVA P values refer to the overall among-group test adjusted for baseline; pairwise P values refer to post hoc baseline-adjusted comparisons between two groups. All pairwise comparisons for FMA-LE, BBS, and ADL were statistically significant. A group × baseline interaction was significant for FMA-LE (P = 0.013) but not for BBS (P = 0.528) or ADL (P = 0.326).

3.5 6MWT Categories

Baseline 6MWT category distributions did not differ among groups (mean category 0.42, 0.30, and 0.33; P = 0.720). Six-minute walk performance was recorded in distance categories rather than exact metre values; this categorical recording was adopted for feasibility and safety reasons in a hospitalized inpatient rehabilitation setting, and participants unable to complete the test were assigned to the lowest category. At week 8, mean categories were 2.76 (RDT), 1.88 (RAGT), and 1.42 (DTT), with significant within-group improvement in all groups (all P < 0.001). The week-8 category distributions differed significantly among groups (Kruskal–Wallis H = 16.64, P = 2.4×10^{-4} ; Table 3). Pairwise Mann–Whitney U tests showed RDT > RAGT (P = 0.006) and RDT > DTT (P = 9.7×10^{-5}), whereas RAGT vs DTT was not significant (P = 0.165). In the RDT group, 22 of 33 participants (66.7%) walked >300 m at week 8 (11 participants >450 m), and none failed to complete the test.

Table 3. Distribution of 6MWT categories at week 8, n

Category	RDT (n = 33)	RAGT (n = 33)	DTT (n = 33)
>450 m	11	3	3
301–450 m	11	12	6
150–300 m	3	1	1

Category	RDT (n = 33)	RAGT (n = 33)	DTT (n = 33)
<150 m	8	12	15
Unable to complete	0	5	8

Between groups: Kruskal–Wallis $H = 16.64$, $P = 2.4 \times 10^{-4}$. Pairwise (Mann–Whitney U): RDT vs RAGT, $P = 0.006$; RDT vs DTT, $P = 9.7 \times 10^{-5}$; RAGT vs DTT, $P = 0.165$.

3.6 Stratified and Sensitivity Analyses

Because the group $\times$ baseline interaction for FMA-LE was significant ($P = 0.013$), a baseline-stratified sensitivity analysis was performed across three baseline FMA-LE strata (severe ≤ 8 , $n = 33$; moderate 9–16, $n = 36$; mild ≥ 17 , $n = 30$). The RDT group showed the largest mean improvement within every stratum: severe, $\Delta 17.53 \pm 4.35$ ($n = 17$) versus RAGT $\Delta 10.73 \pm 1.90$ ($n = 11$) and DTT $\Delta 9.40 \pm 2.70$ ($n = 5$) ($P = 8.1 \times 10^{-6}$); moderate, $\Delta 12.12 \pm 2.70$ ($n = 8$) versus $\Delta 8.00 \pm 2.39$ ($n = 14$) and $\Delta 7.07 \pm 2.97$ ($n = 14$) ($P = 5.8 \times 10^{-4}$); mild, $\Delta 9.50 \pm 2.51$ ($n = 8$) versus $\Delta 6.50 \pm 2.27$ ($n = 8$) and $\Delta 4.64 \pm 1.22$ ($n = 14$) ($P = 2.2 \times 10^{-5}$). The interaction therefore reflects a larger RDT benefit among participants with lower baseline motor function rather than inconsistency of the group effect, and the FMA-LE findings are not driven by the baseline imbalance.

A second sensitivity analysis excluded the 13 participants older than 75 years ($n = 86$; RDT 29, RAGT 28, DTT 29). All between-group conclusions were unchanged: FMA-LE (omnibus $P = 7.2 \times 10^{-12}$; RDT vs RAGT $P = 1.7 \times 10^{-7}$; RDT vs DTT $P = 4.9 \times 10^{-9}$; RAGT vs DTT $P = 0.038$), BBS (omnibus $P = 1.8 \times 10^{-16}$; all pairwise $P \leq 0.010$), and ADL (omnibus $P = 2.8 \times 10^{-7}$; RDT vs RAGT $P = 0.023$; RDT vs DTT $P = 1.8 \times 10^{-8}$; RAGT vs DTT $P = 0.0014$)—with all nine pairwise contrasts remaining statistically significant.

For the 6MWT, an ordinal logistic regression of the week-8 category adjusted for the baseline category (reference: DTT) corroborated the rank-based findings: RDT vs DTT odds ratio (OR) = 11.21 ($P = 5.7 \times 10^{-6}$); RAGT vs DTT OR = 2.47 ($P = 0.068$); baseline category OR = 20.6 per level ($P < 0.001$).

3.7 Safety and Adverse Events

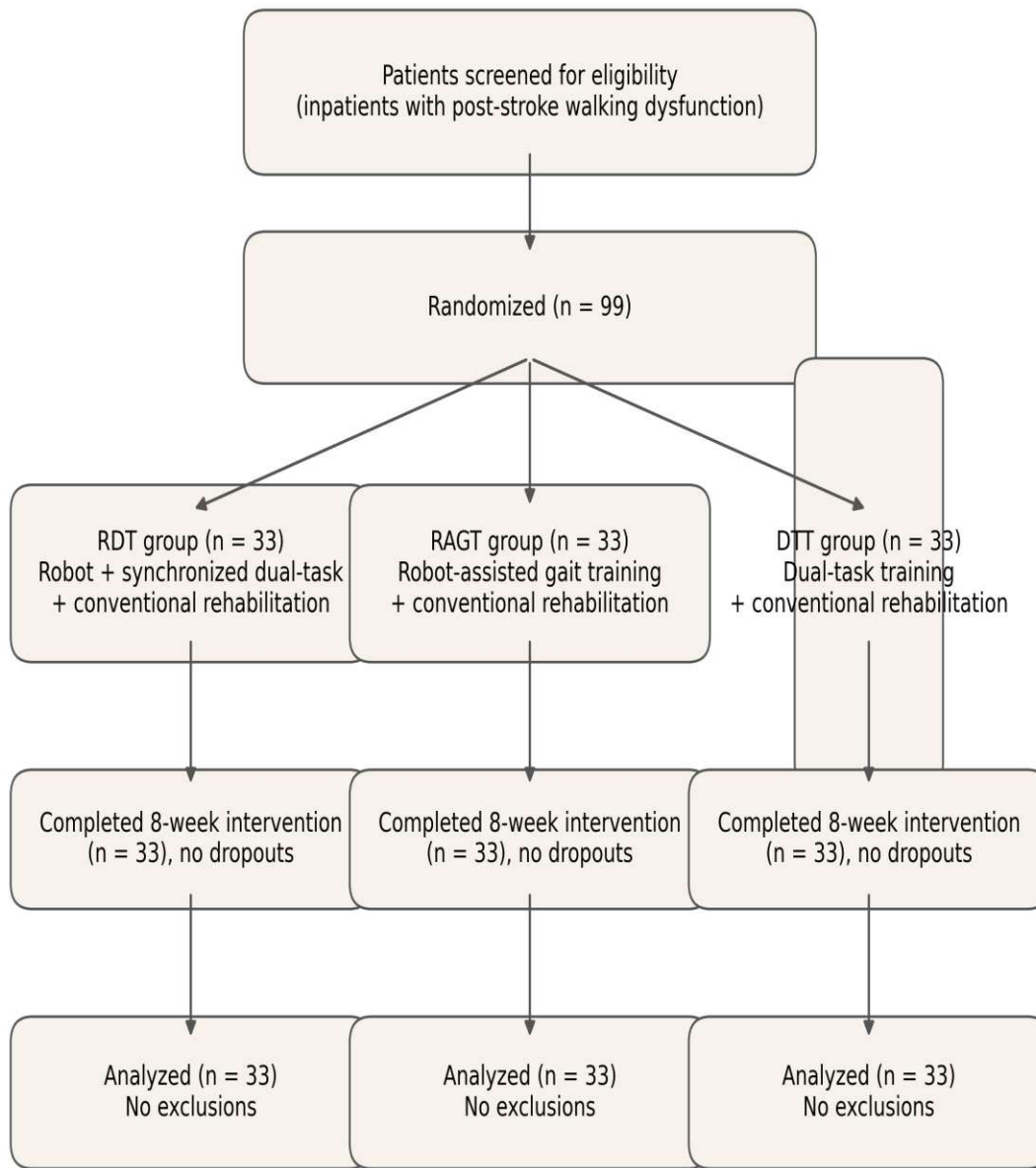
Three non-serious adverse events (AEs) were recorded during the 8-week intervention, all resolving without injury or study discontinuation (Table 4). Two were device-related, occurring during robot-assisted sessions in the robot-using groups: (1) mild groin skin abrasion caused by friction from an overly tight harness strap in a participant with a high body-mass index (judged possibly related to the device; resolved after strap adjustment and local wound care); and (2) a sudden breakage of the body-weight-support rope during a training session, in which the device's automatic safety stop activated immediately and no injury occurred (device malfunction; reported to the manufacturer and repaired under maintenance). One event was related to dual-task training: a near-fall during a dual-task walking session in the DTT group, in which the participant was promptly protected by the therapist and caregiver without injury (judged possibly related to the intervention). No serious adverse events, no falls with injury, and no AE-related withdrawals occurred in any

group. The overall AE incidence was 3/99 (3.0%); per protocol causality grading, all three events were rated as “possibly related.”

Table 4. Adverse events during the 8-week intervention.

Adverse event	Intervention context	Severity	Causality (per protocol)	Outcome
Groin skin abrasion (harness friction)	Robot-assisted training	Mild	Possibly related	Resolved; no withdrawal
Body-weight-support rope breakage (auto-stop activated, no injury)	Robot-assisted training	Moderate (device malfunction, no harm)	Possibly related (device)	Resolved; manufacturer maintenance
Near-fall during dual-task walking (protected, no injury)	Dual-task training	Mild (no harm)	Possibly related	Resolved; no withdrawal

3.8 Figure Legends



Completed enrollment; one duplicate data-entry record removed before analysis.

Figure 1

Figure 1. CONSORT participant flow diagram. Ninety-nine randomized participants completed the trial and were included in the final analysis (RDT n = 33, RAGT n = 33, DTT n = 33 after removal of one duplicate data-entry record); there were no dropouts and all participants were analyzed.

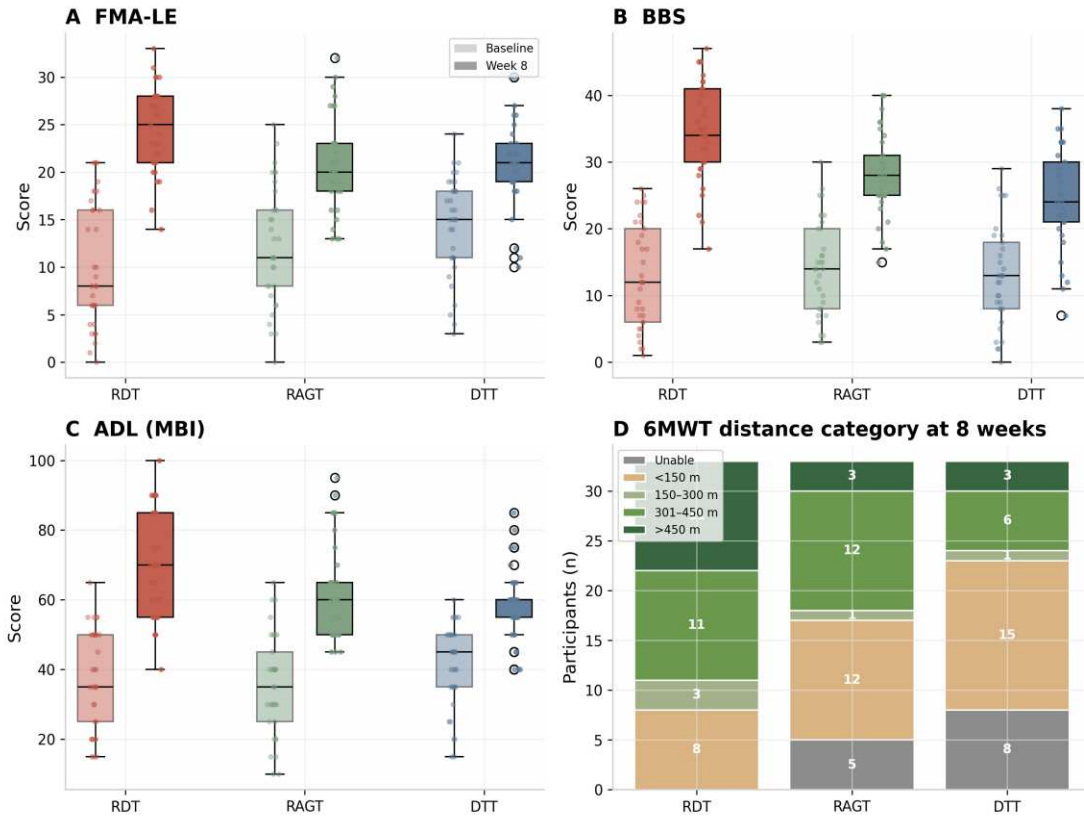


Figure 2

Figure 2. Clinical outcomes at baseline and after 8 weeks of intervention in the RDT (n = 33), RAGT (n = 33), and DTT (n = 33) groups. Box plots show FMA-LE (A), BBS (B), and ADL (C) scores at baseline and week 8 for each group; boxes denote interquartile ranges, horizontal lines denote medians, and whiskers denote observed ranges. Panel D shows the stacked distribution of week-8 6MWT categories (>450 m, 301-450 m, 150-300 m, <150 m, unable to complete) by group.

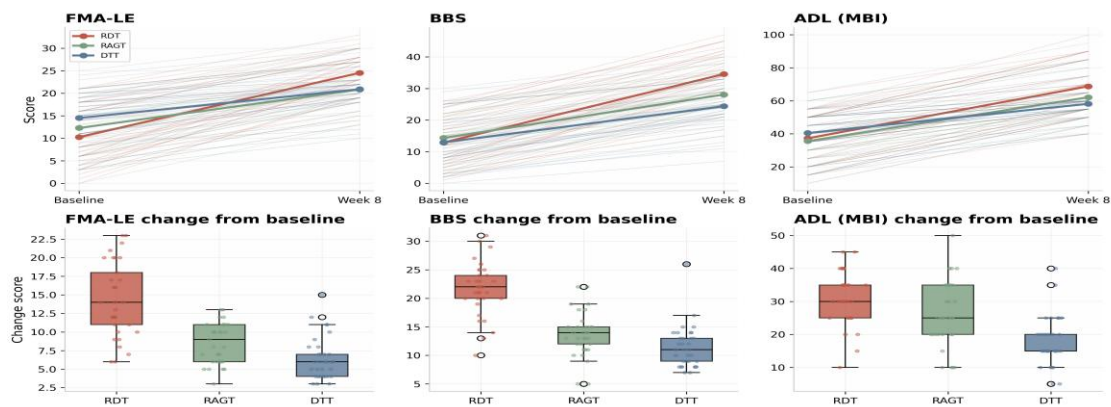


Figure 3

Figure 3. Individual participant trajectories and change scores. Spaghetti plots show individual baseline-to-week-8 trajectories, and scatter plots show the distribution of change-from-baseline values, for FMA-LE, BBS, and ADL in the RDT (n = 33), RAGT (n = 33), and DTT (n = 33) groups.

4 Discussion

4.1 Principal Findings

In this three-arm randomized controlled trial, all three interventions—robot-assisted gait training (RAGT), dual-task training (DTT), and synchronized robot-assisted dual-task training (RDT), each superimposed on conventional rehabilitation—produced significant within-group improvements in lower-limb motor function, balance, activities of daily living (ADL), and walking endurance after 8 weeks. The synchronized RDT group showed the largest gains on the primary outcome, with a mean FMA-LE improvement of 14.27 points, significantly greater than that of the RAGT ($\Delta 8.55$; pairwise ANCOVA $P = 1.1 \times 10^{-8}$; Cohen's $d = 1.43$) and DTT ($\Delta 6.39$; $P = 3.8 \times 10^{-10}$; $d = 1.94$) groups, and the RAGT group in turn improved more than the DTT group ($P = 0.009$; $d = 0.77$). Secondary outcomes followed the same consistent pattern of RDT superiority: the RDT group achieved the largest gains in BBS ($\Delta 21.67$) and ADL ($\Delta 31.52$) and the highest six-minute walk test (6MWT) category distribution at week 8 (66.7% of participants walking >300 m). For BBS, all pairwise comparisons were significant—RDT vs RAGT ($P = 5.0 \times 10^{-11}$; $d = 1.86$), RDT vs DTT ($P = 3.3 \times 10^{-15}$; $d = 2.43$), and RAGT vs DTT ($P = 0.005$; $d = 0.60$). For ADL, RDT was superior to DTT ($P = 1.1 \times 10^{-9}$; $d = 1.77$) and RAGT was superior to DTT ($P = 4.2 \times 10^{-4}$; $d = 1.00$); the RDT versus RAGT contrast, although modest, was also statistically significant in the completed sample ($P = 0.016$; $d = 0.55$), as well as in the sensitivity analysis excluding over-age participants ($P = 0.023$), but did not survive Bonferroni correction. Thus, RDT was superior to DTT on

4.2 Comparison with Previous Studies

Our findings align with the Cochrane review by Mehrholz et al., which concluded that electromechanical-assisted gait training combined with physiotherapy increases the odds of independent walking after stroke [5]; the RAGT arm here improved on every outcome, and the robot-based arms (RAGT and RDT) outperformed non-robotic DTT on the primary outcome. The results also speak to the lesson of the LEAPS trial, in which body-weight-supported treadmill training was not superior to a progressive home exercise programme, suggesting that device sophistication alone does not guarantee better outcomes [8]. In the present trial, adding attentionally demanding dual-task practice synchronously to robot-guided stepping converted robotic training into a markedly more effective intervention—FMA-LE gains rose from 8.55 (RAGT) to 14.27 (RDT) points—supporting the view that the content and cognitive engagement of training, rather than the technology per se, drive clinical benefit. Similarly, the improvements observed in the DTT arm are consistent with the randomized pilot trial by Liu et al., in which cognitive and motor dual-task gait training improved dual-task walking performance after stroke in a training-specific manner [12],

and with meta-analytic evidence that dual-task practice improves dual-task gait speed [13]. Direct randomized evidence for the synchronized combination is scarce; a network meta-analysis of combined physical and cognitive training in older adults found simultaneous (synchronous) combinations to be the most efficacious strategy, ranking above sequential combinations and single-domain training [23]; however, that evidence derives from older adults rather than patients with stroke, so its extrapolation to post-stroke rehabilitation should be made cautiously. It is nevertheless directionally consistent with the superiority of our synchronized RDT arm.

4.3 Possible Mechanisms

Several non-exclusive mechanisms may explain the synergistic benefit. First, the robot delivered high-repetition, task-specific stepping with graded body-weight support and progression, providing the practice dose thought necessary for experience-dependent neuroplasticity; structural connectivity of the corticospinal tract is a key determinant of motor recovery after stroke [16]. Second, walking itself recruits executive and attentional resources, and dual-task costs are exaggerated after stroke [9]; practising cognitive tasks synchronously during stepping may directly train the shared attentional control of gait, thereby improving walking automaticity—although, as noted below, dual-task outcomes were not measured in this dataset, so this mechanistic interpretation remains speculative. Third, functional near-infrared spectroscopy studies show that dual-task walking after stroke increases prefrontal cortical activation, reflecting compensatory attentional control of locomotion [22]; synchronized training may co-activate and recalibrate prefrontal-motor networks, coupling cognitive engagement with the afferent feedback of physiologically patterned stepping. Whether these behavioural gains are accompanied by measurable white-matter reorganization—for example, changes in corticospinal tract fractional anisotropy on diffusion tensor imaging (DTI) [16–18]—is being tested in the ongoing imaging component of this trial.

4.4 Plausibility of the Observed Effect Sizes

The effect sizes observed in this cohort (Cohen's d up to 2.43 for between-group contrasts, with within-group gains such as a 14-point mean FMA-LE improvement in the RDT arm) are larger than those reported in most comparable trials and meta-analyses of robot-assisted or dual-task gait training. Several factors likely contribute. First, participants were in the subacute phase, so spontaneous neurological recovery and the substantial dose of conventional rehabilitation (90 min/day) received by all three groups account for a considerable share of the absolute within-group gains; the large improvements in all three arms therefore cannot be attributed entirely to intervention-specific effects. Second, the within-group variability of change scores was small, which inflates standardized effect sizes relative to studies with more heterogeneous samples. Third, this was a single-center trial in a selected hospitalized inpatient population able to tolerate intensive training, which may yield larger and less variable responses than community-based or chronic-stroke samples. The between-group contrasts are the more informative estimates of intervention-specific benefit, and even these should be interpreted in light of these contextual factors.

4.5 Clinical Implications

The magnitude of improvement is clinically meaningful. The mean FMA-LE gain in the RDT group (14.27 points) is large relative to distribution-based estimates of meaningful change in lower-limb motor scores; importantly, no anchor-based minimal clinically important difference (MCID) has been established for the FMA-LE, so this interpretation should be made cautiously. BBS changes in all groups (11.45–21.67 points) exceed or approach the MCID range of 6.5–12.5 points reported for patients with acute stroke [21], and the graded 6MWT results—with 66.7% of RDT participants exceeding 300 m and none unable to complete the test—are encouraging; however, because the 6MWT was recorded as ordinal distance categories rather than exact metre values, it should be regarded as an exploratory outcome, and distance-based minimally clinically important difference thresholds cannot validly be applied to it. For rehabilitation services, the findings suggest that synchronized dual-task delivery during robot sessions—requiring no additional session time—may be a resource-efficient way to augment the value of existing robotic devices.

4.6 Limitations

Several limitations temper these conclusions. First, multiple pairwise comparisons were performed without formal correction for multiplicity; however, seven of the nine pairwise contrasts remained statistically significant even under a conservative Bonferroni correction ($\alpha = 0.05/9 \approx 0.0056$); the two exceptions—FMA-LE RAGT versus DTT ($P = 0.009$) and ADL RDT versus RAGT ($P = 0.016$)—were nominally significant and should be interpreted with particular caution. Second, the group $\times$ baseline interaction for FMA-LE was statistically significant ($P = 0.013$), indicating that the homogeneous-slopes assumption underlying ANCOVA was not fully met for the primary outcome; although an unadjusted ANOVA sensitivity analysis and a baseline-stratified analysis (RDT superior within all three baseline FMA-LE strata) yielded consistent conclusions, the adjusted effect sizes for FMA-LE should be interpreted with caution. Third, an earlier interim look at the data was conducted before enrolment was completed without a prespecified interim monitoring plan or formal stopping boundaries; such repeated looks at accumulating data can inflate the type I error rate, and the present final analysis at the planned sample of 99 participants should be read in that context. Fourth, participants could not be blinded to the intervention owing to its nature; although they were not informed of the study hypotheses or of any expected superiority among groups, performance bias cannot be excluded, particularly for effort-dependent outcomes such as the 6MWT. Fifth, 6MWT performance was recorded as distance categories rather than precise metre values; this entails information loss, precludes distance-based MCID comparisons, and relegates the 6MWT to an exploratory outcome, and participants unable to complete the test were assigned to the lowest category, which may further compress true between-group differences. Sixth, despite randomization, baseline FMA-LE differed among groups ($P = 0.022$), with the DTT group least impaired; although ANCOVA was used to adjust for baseline values, residual confounding by regression to the mean or differential room for improvement cannot be excluded. Seventh, during data cleaning one duplicate data-entry record was identified and removed; although this improved data integrity, the possibility of other undetected data-entry errors cannot be excluded. Eighth, this was a single-center trial in hospitalized

patients, which may restrict generalizability. Ninth, ADL was assessed with the Modified Barthel Index, but the exact scale version was not specified in the dataset and is reported here as the MBI; ceiling effects of the MBI may also have attenuated between-group contrasts in ADL. Tenth, no post-intervention follow-up data are available, so the durability of the gains is unknown. Eleventh, DTI data are still being collected and could not be linked to clinical outcomes here. Finally, thirteen enrolled participants exceeded the protocol-specified upper age limit of 75 years (RDT 4, RAGT 5, DTT 4); they were retained on clinical-judgment grounds, introducing a protocol deviation, although a sensitivity analysis excluding them ($n = 86$) left all conclusions unchanged, with all nine pairwise contrasts remaining statistically significant. In addition, several further limitations should be noted. Dual-task outcomes were not measured: because no dual-task cost (DTC) metrics were collected, the proposed gait-automaticity mechanism cannot be directly supported by the present data. Disease duration was not reported, although it is a key prognostic variable for post-stroke recovery. Stroke type was heterogeneous, including eight participants with mixed lesions, which may introduce pathophysiological heterogeneity. Finally, the actual dose of synchronous dual-task exposure in the RDT arm was not quantified; in particular, Phase 1 of the graded protocol involved no dual task, so the effective dual-task dose varied across participants and over time.

4.7 Future Directions

Incorporation of the ongoing DTI acquisitions to test whether clinical gains track corticospinal tract fractional anisotropy, and scheduled follow-up assessments to evaluate retention of benefits, are the immediate priorities. Future multicentre trials should compare synchronized against sequentially delivered robot and dual-task training, optimize dual-task load and progression algorithms, and include dual-task gait outcomes and fall incidence as endpoints.

5 Conclusions

In this single-center, three-arm randomized controlled trial in 99 patients with post-stroke walking dysfunction, synchronized dual-task training delivered during robot-assisted gait training (RDT), added to conventional rehabilitation, was associated with greater improvements than dual-task training (DTT) alone across all evaluated outcomes—lower-limb motor function, balance, activities of daily living, and walking endurance—and with greater improvements in lower-limb motor function, balance, and activities of daily living than robot-assisted gait training (RAGT) alone, although the ADL advantage over RAGT was modest and did not survive Bonferroni correction. These findings suggest that synchronously combining high-dose robotic stepping with attentionally demanding task practice may yield meaningful clinical benefit and offer a time-efficient rehabilitation strategy. Confirmation of the underlying neural mechanisms through the ongoing diffusion tensor imaging analyses and of the durability of benefit through longer-term follow-up is warranted before definitive recommendations can be made.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Jiangbei District Hospital of Traditional Chinese Medicine (approval number JZY-IRB-202526; approved 26 December 2025). The trial was registered in the Chinese Clinical Trial Registry (ChiCTR2500115695) and the National Medical Research Registration and Filing Information System (MR-50-25-090484). Written informed consent was obtained from all participants or their legal representatives before enrollment. The study was conducted in accordance with the Declaration of Helsinki.

Consent to participate

Written informed consent to participate was obtained from every participant (or their legal representative) before enrolment in the study.

Consent for publication

Not applicable.

Availability of data and materials

The de-identified participant datasets used and analyzed during the current study, together with the statistical analysis code, are available from the corresponding author on reasonable request.

Competing interests

Dong Qiu is an employee of Guiheng Rehabilitation Technology Co., Ltd., Jinhua, Zhejiang, China. The company had no role in study design, data collection, analysis, interpretation, manuscript writing, or the decision to submit for publication. The authors declare that they have no other competing interests.

Funding

This study was supported by the 2026 Chongqing Science and Health Joint Medical Research Project: “Multimodal Assessment of Walking Function after Stroke — A Clinical Study of Lower-Limb Robotics and Dual-Task Training Combined with Diffusion Tensor Imaging” (grant number 2026MSXM083). The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Authors' contributions

Conceptualization: Boyu Zhang. Project administration and supervision: Boyu Zhang, Pengcheng Li. Investigation and intervention delivery: Hang Chen (overall treatment execution and quality management), Yiyuan Zhao (dual-task training), Jing Li (robot-assisted training). Data curation and clinical assessment: Jing Wang. Formal analysis and

writing—original draft: Dong Qiu. Writing—review and editing: all authors. All authors read and approved the final manuscript.

Acknowledgements

Not applicable.

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