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REVIEW
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Efficacy of robot-assisted gait training on lower extremity function in subacute stroke patients: a systematic review and meta-analysis

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Abstract

Background Robot-Assisted Gait Training (RAGT) is a novel technology widely employed in the field of neurological rehabilitation for patients with subacute stroke. However, the effectiveness of RAGT compared to conventional gait training (CGT) in improving lower extremity function remains a topic of debate. This study aimed to investigate and compare the effects of RAGT and CGT on lower extremity movement in patients with subacute stroke.

Methods Comprehensive search was conducted across multiple databases, including PubMed, Web of Science, Cochrane Library, EBSCO, Embase, Scopus, China National Knowledge Infrastructure, Wan Fang, SinoMed and Vip Journal Integration Platform. The database retrieval was performed up until July 9, 2024. Meta-analysis was conducted using RevMan 5.4 software.

Results A total of 24 RCTs were included in the analysis. The results indicate that, compared with CGT, RAGT led to significant improvements in the Fugl-Meyer Assessment for Lower Extremity [MD = 2.10, 95%CI (0.62, 3.59), P = 0.005], Functional Ambulation Category[MD = 0.44, 95%CI (0.23, 0.65), P < 0.001], Berg Balance Scale [MD = 4.55, 95%CI (3.00, 6.11), P < 0.001], Timed Up and Go test [MD = −4.05, 95%CI (−5.12, −2.98), P < 0.001], and 6-Minute Walk Test [MD = 30.66, 95%CI (22.36, 38.97), P < 0.001] for patients with subacute stroke. However, it did not show a significant effect on the 10-Meter Walk Test [MD = 0.06, 95%CI (−0.01, 0.14), P = 0.08].

Conclusions This study provides evidence that RAGT can enhance lower extremity function, balance function, walking ability, and endurance levels compared to CGT. However, the quality of evidence for improvements in gait speed remains low.

Keywords Gait, Lower Extremity, Meta-analysis, Robotics, Stroke, Walking Speed

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Background

Stroke is a neurological disorder caused by either a rupture or blockage of cerebral blood vessels, resulting in high morbidity, disability, and a substantial social burden [1]. Globally, there were approximately 12.2 million incident cases of stroke, 101 million prevalent cases of stroke, and 6.55 million deaths attributed to stroke [2]. Stroke survivors usually experience physical dysfunction, notably affecting walking, which increases their risk of falling due to compromised gait and balance. This not only directly jeopardizes mobility and daily life, but also significantly diminishes their quality of life [3, 4]. Regaining the ability to walk is a critical milestone in the recovery of stroke survivors [5]. Physical rehabilitation plays a crucial role in improving motor function, mobility, and performance in daily life for stroke patients, particularly those with lingering movement disorders, and aiming to enhance their function, independence, and participation [6].

Conventional gait training (CGT) methods encompassing conventional floor gait training, stair gait training, and treadmill training, have been widely utilized in the rehabilitation of stroke survivors. CGT methods provided by therapists can improve gait speed and endurance, and other functional aspects for stroke survivors. Despite its benefits, CGT has several limitations, for example, the therapist ‘s physical limitations, vulnerable to interference from the outside environment, etc [5, 7]. Confronted with the huge rehabilitation needs of stroke patients, more effective treatment methods should be taken [8]. Robot-assisted gait training (RAGT) is widely used as a novel neurorehabilitation training technique. The robot equipment can include end-effector and exoskeleton systems [9], which are more effective in improving mobility than traditional therapy because they can provide a higher volume and more intensive treatment options [10]. These technologies are particularly effective in minimizing environmental disturbances during the rehabilitation process [11]. However, the efficacy of RAGT in the comprehensive rehabilitation of stroke survivors has yet to reach full satisfaction, indicating the need for further refinement and research in this area.

Existing studies point out that RAGT surpasses CGT in enhancing gait ability, balance function, and overall quality of life [12–14]. However, some studies challenge this view, suggesting that RAGT is not superior to traditional gait training in some respects [15, 16]. Amidst this backdrop, there are currently ongoing systematic evaluations or Meta-analyses with mixed results. For instance, Calafiore et al [17]. showed that robotic exoskeletons may have a potential role in walking ability recovery among subacute stroke patients. Conversely, Wang et al [18]. indicated that RAGT is an effective intervention to improve balance function in stroke survivors. Nedergård et al [19]. found no significant differences on step speed, treadmill frequency, stride length, and spatial asymmetries between the RAGT and the control group, leading to meta-analyses that also report no significant advantage of RAGT over CGT. The discrepancy in findings underscores the complexity of stroke rehabilitation and the variable effectiveness of RAGT. Therefore, this study aimed to delve into the effect of RAGT on the lower extremity function of subacute stroke patients through a Meta-analysis. By focusing on the subacute stage of stroke recovery, which is critical for rehabilitation, this study seeks to clarify the role of RAGT in enhancing the lower extremity function of stroke survivors, thereby offering valuable insights for clinical rehabilitation practices.

Method

The Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines were followed for the methodology of this study (See supplementary material 1). This study was registered on the international system evaluation registration platform PROSPERO (CRD42023453035).

Search strategy

A systematic search of the literature up to July 9, 2024, was conducted in languages limited to English and Chinese. Search databases included China National Knowledge Infrastructure (CNKI), Wan Fang Data Knowledge Service Platform, Vip Journal Integration Platform (VIP), SinoMed Database, Web of Science (WOS), PubMed, EBSCO, Embase, Cochrane Library, and Scopus databases. A combination of thematic and free-word searches was used, and supplemented by manual searches. The search terms were stroke, cerebrovascular accidents, CVA, cerebrovascular apoplexy, robot, robot assisted gait training, robot-assisted gait rehabilitation, randomly, trial, groups, etc. Detailed search strategies are described in Supplementary material 2. The relevant references in included studies and existing systematic reviews were searched manually.

Inclusion criteria and exclusion criteria

Inclusion criteria: [1] Population: Patients with a definite diagnosis of stroke, aged 18 years or older, with disease duration within 6 months, and stable vital signs and conscious; [2] Intervention: robot-assisted gait training; [3] Comparator: conventional gait training (physical therapy, exercise therapy, treadmill training, etc.); [4] Outcomes: Fugl-Meyer Assessment for lower extremity (FMA-LE), 10-Meter Walk Test (10MWT), 6-Minute Walking Test (6MWT), Berg Balance Scale (BBS), Timed Up and Go Test (TUG), Functional Ambulation Category scale (FAC); [5] Study design: Randomized controlled trials published in Chinese and English.

Exclusion criteria: [1] Lack of data on outcome metrics; [2] Duplicate studies and studies with incomplete data; [3] Abstracts, reviews, and conference reports; [4] Studies of too low quality.

Selection process

The retrieved studies were imported into Endnotes 20. Two researchers (MMH and SW) performed independent screening based on predetermined inclusion and exclusion criteria. Duplicate literature was first removed through Endnotes 20. The first screening was carried out according to the title and abstract, and the second screening was carried out after reading the full text. The two evaluators will cross-check the included studies. In the event of disagreement, a third researcher (KPL) will decide whether the study should be included or not.

Data extraction

Two researchers (MMH and SW) independently read the full text and have recorded the name of the first author, year of publication, country, duration of disease, age of patients, sample size, intervention, duration of intervention, type of robot, outcome indicators, and duration of follow-up. When differences arise, they must first be resolved through discussion, and if the disagreement persisted, the decision was made by a third researcher (LD). Articles with incomplete data were obtained by sending an e-mail to the authors.

Quality assessment

The quality assessment was conducted independently by two researchers (MMH and SW) using the Cochrane Risk of Bias Tool 2.0 (RoB2) [20]. The RoB2 sets out five domains of evaluation: bias in the randomization process; bias in deviating from established interventions; bias in missing outcome data; bias in outcome measurement and bias in selective reporting of outcomes. If all elements of the assessment are at low risk, this means that there is little or no risk of bias and the quality is A. If the assessment partially meets the low risk, this means that the risk of bias is medium and the quality is B. If none of the elements meet the low risk, this means that the risk of bias is very high and the quality is C. If there were differences, they were resolved through discussion with a third researcher (LD).

Statistical analyses

Data were combined and tested for statistical heterogeneity using RevMan 5.4 software. The mean difference (MD) and its 95% confidence interval (CI) were used for statistical analysis of effect values. If $P > 0.1$ and $I^2 \leq 50\%$, the heterogeneity was considered insignificant, and the fixed-effects model was used for meta-analysis. If $P < 0.1$ and $I^2 > 50\%$, the heterogeneity was considered significant, and the random-effects model was used for meta-analysis.

Subgroup analysis was conducted to assess the influence of the following factors on the estimated effect: (1) Duration of the intervention: two, three, four, and eight weeks. We selected these boundaries specifically because they were the most commonly used in the included studies. (2) The robot type: exoskeletons (e.g., Lokomat, BEAR-H1, Hybrid Assistive Limb, etc.) or end-effectors (e.g., Gait Trainer, Gait Master, Morning Walk, etc.).

Sensitivity analyses were used to identify sources of heterogeneity. Publication bias was assessed by using funnel plots and the Egger's test, with p-values less than 0.1 indicating the presence of potential publication bias. The significance level for all analyses was $P < 0.05$.

Results

Results of literature search

A total of 15,838 pieces of relevant literature were initially retrieved, including 1 piece of grey literature, and 4,502 pieces of duplicate literature were excluded. A total of 220 pieces of literature were included by reading the title and abstract. After further searching and reading the full text, the studies that did not meet the inclusion criteria, including issues related to the duration of disease, intervention group measures, control group measures, and research type were removed, resulting in the inclusion of 24 studies. The literature screening process and results are shown in Fig. 1.

Quality evaluation

According to the Cochrane risk assessment tool RoB2, the quality of the included 24 studies was evaluated, of which 21 were at some risk and 3 were at low risk. The specific evaluation indicators and results are shown in Fig. 2.

Basic characteristics of literature included in the analysis

The basic characteristics of the included studies are shown in Supplementary material 3. 24 studies were included [12, 21–43], with a total of 1103 cases, including 567 cases in the intervention group and 536 cases in the control group. The publication years of the included studies ranged from 2006 to 2024, the disease duration of patients ranged from 2 days to 6 months, the duration of interventions ranged from 2 to 8 weeks, 8 studies were followed up [21, 23, 26, 29, 33–35, 42], 15 studies used exoskeleton robots for interventions [12, 21, 22, 24, 25, 30, 33–37, 39, 40, 42, 43], 7 studies used end-effectors [23, 27–29, 32, 38, 41, 43], 2 studies used both exoskeletons and end-effectors[26, 31], 12 studies used random number tables[12, 21, 23, 28, 29, 32, 36–41], 7 studies had allocation concealment [12, 21–23, 35, 36, 40], and 12 studies had blinded to assessor [12, 21–23, 25, 26, 28, 31, 33, 34, 36, 41].

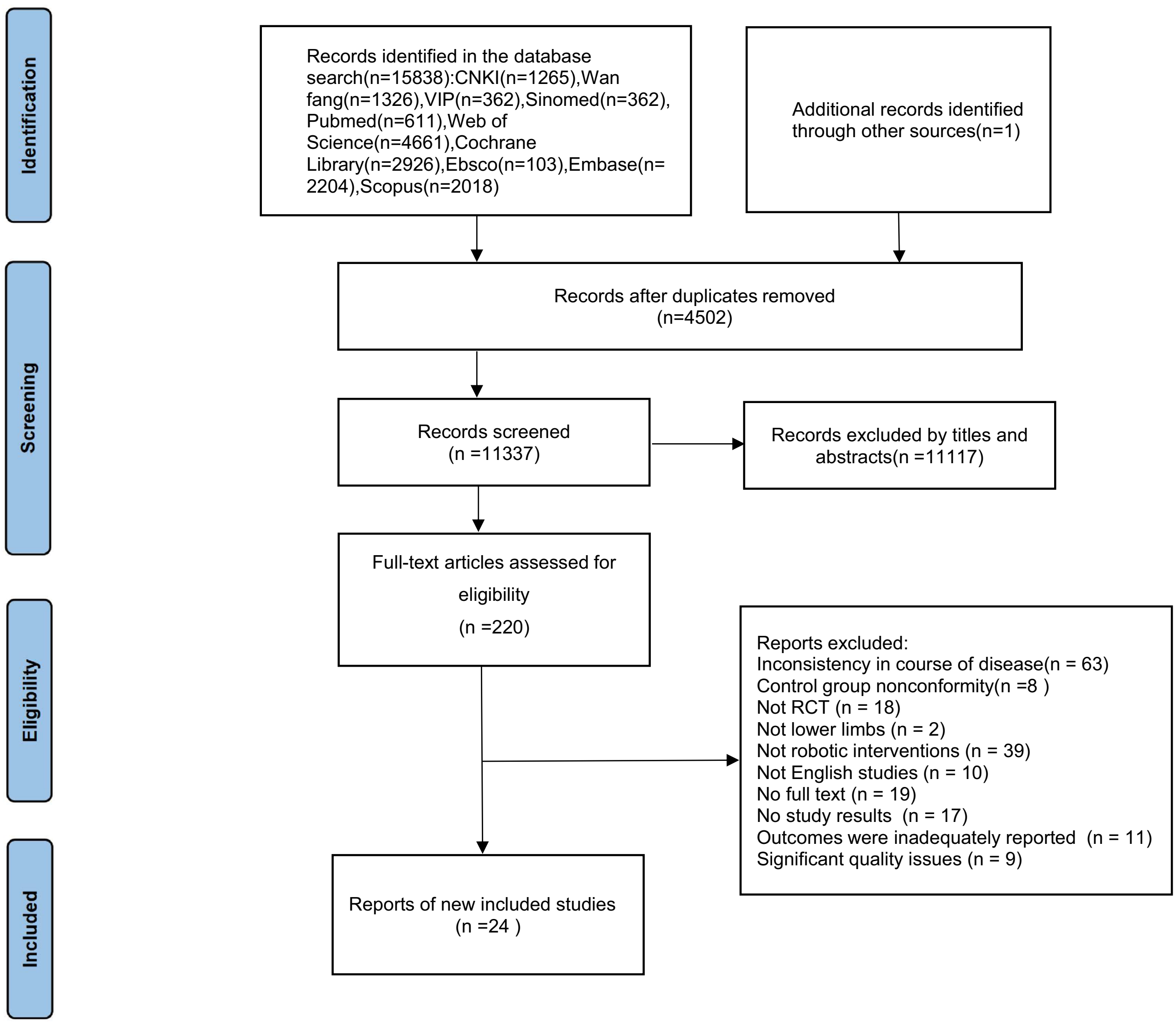

Fig. 1 Flow diagram of the study selection process

Results of meta-analysis

FMA-LE

Eight studies reported the effect of RAGT on FMA-LE, as shown in Fig. 3(a), which shows that there was no significant heterogeneity among the studies ($P=0.33$, $I^2=13\%$), and a fixed effect model was used. Meta-analysis showed that the difference was statistically significant [MD = 2.10, 95%CI (0.62, 3.59), $P=0.005$].

FAC

Sixteen studies reported the effect of RAGT on FAC, as shown in Fig. 3(b), which shows that the random effects model was used due to the large heterogeneity of the studies ($P=0.007$, $I^2=52\%$). Meta-analysis results showed that the difference was statistically significant [MD = 0.44, 95%CI (0.23, 0.65), $P<0.001$].

BBS

Ten studies reported the effect of RAGT on BBS, as shown in Fig. 3(c), which shows that there was no significant heterogeneity among the studies ($P=0.91$, $I^2=0\%$), and a fixed effect model was used. Meta-analysis showed that the difference was statistically significant [MD = 4.55, 95%CI (3.00, 6.11), $P<0.001$].

TUG

Seven studies reported the effect of RAGT on TUG. The study by Meng et al [12]. was not included in the analysis because the TUG test was combined with a dual-task walking test related to motor-cognitive interaction.

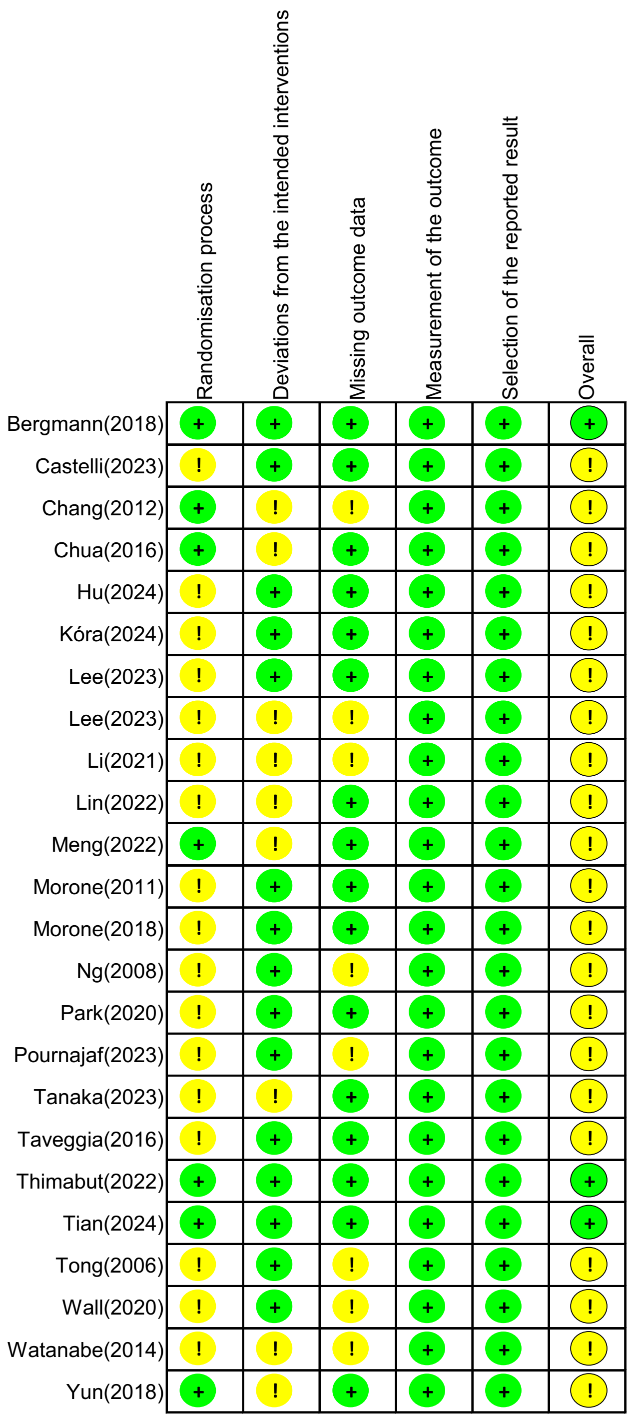

Fig. 2 Risk of bias assessment for included studies

as shown in Fig. 4(a), which shows that there was no significant heterogeneity among the studies (P = 0.37, I^2 = 7%), and a fixed effect model was used. Meta-analysis showed that the difference was statistically significant [MD = −4.05, 95%CI (−5.12, −2.98), P < 0.001].

6MWT

Ten studies reported the effect of RAGT on 6MWT, as shown in Fig. 4(b), which shows that there was no significant heterogeneity among the studies (P = 0.40, I^2 = 4%), and a fixed effect model was used. Meta-analysis showed that the difference was statistically significant [MD = 30.66, 95%CI (22.36, 38.97), P < 0.001].

10MWT

Eight studies reported the effect of RAGT on 10MWT, as shown in Fig. 4(c), which shows that there was no significant heterogeneity among the studies (P = 0.14, I^2 = 35%), and a fixed effect model was used. The results of the meta-analysis showed that the difference was not statistically significant [MD = 0.06, 95%CI (−0.01, 0.14), P = 0.08].

Subgroup analysis

Duration of intervention

Subgroup analysis of FMA-LE according to duration of intervention was performed, as shown in Fig. 5(a). The analysis showed that at 4 weeks of intervention, RAGT improved the FMA-LE level of patients better than CGT [MD = 2.39, 95%CI (0.41, 4.36), P = 0.02].

Subgroup analysis of FAC according to duration of intervention was performed, as shown in Fig. 5(b). The analysis showed that at 4 weeks of intervention, RAGT improved the FAC level of patients better than CGT [MD = 0.57, 95%CI (0.32, 0.82), P < 0.001]. It should be noted that in the study by Pournajaf et al [31], data from 20 intervention sessions could not be combined, and only descriptive analyses were performed, showing that 20 intervention sessions improved FAC levels in patients.

Robot type

Subgroup analysis of the 6MWT was performed according to robot type, see Fig. 6(a). The analysis showed that the exoskeleton RAGT improved the endurance level of patients better than the CGT [MD = 31.26, 95%CI (22.57, 39.95), P < 0.001].

Subgroup analysis of the 10MWT was performed according to robot type, see Fig. 6(b). The analysis showed that the exoskeleton RAGT improved the endurance level of patients better than the CGT [MD = 0.16, 95%CI (0.05, 0.27), P = 0.005].

Sensitivity analysis

Sensitivity analysis for the FAC was conducted, which eliminated one study due to its high heterogeneity.

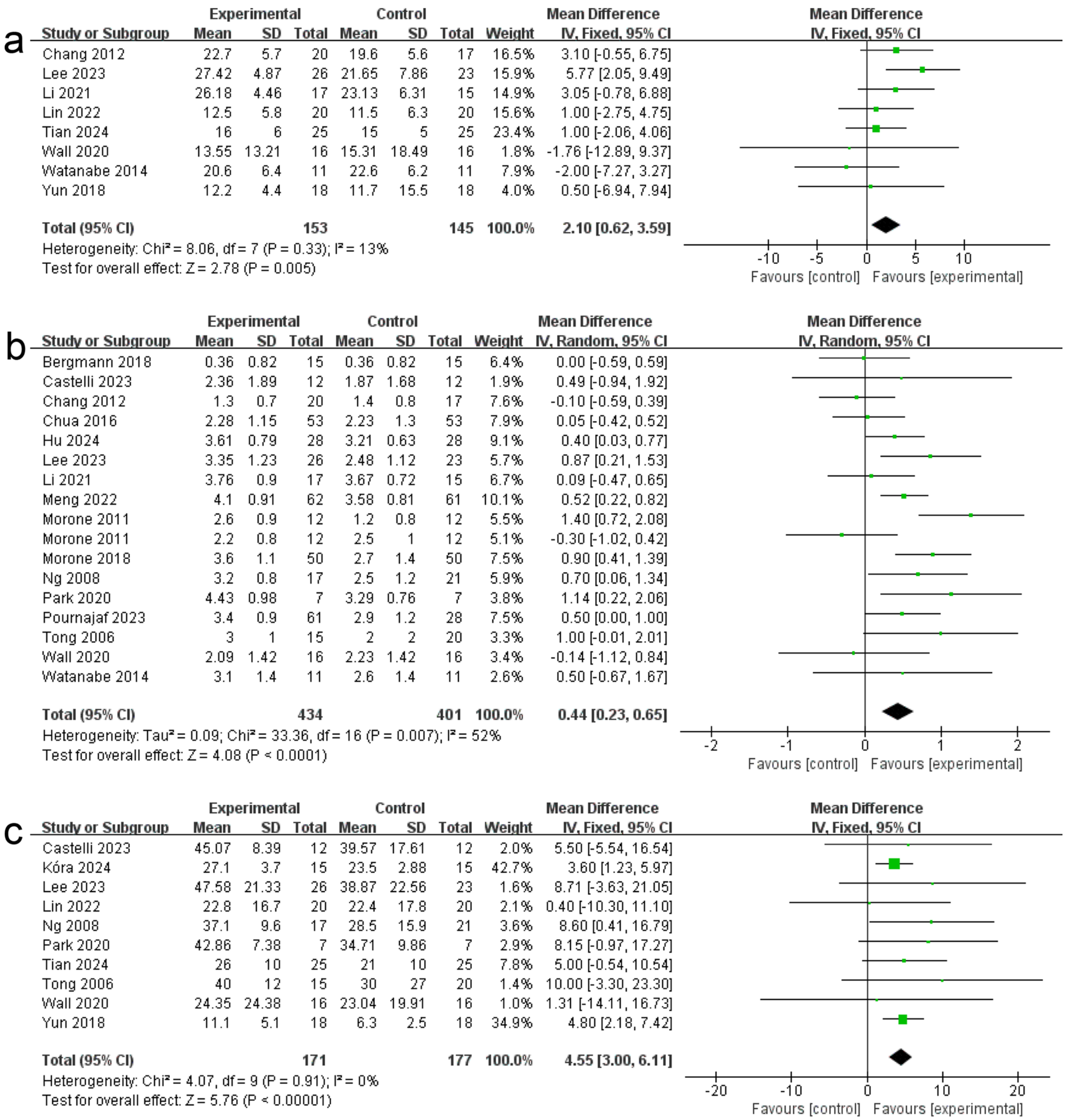

Fig. 3 The forest plot of Fugl-Meyer Assessment for Lower Extremity, Functional Ambulation Category Scale and Berg Balance Scale. Figure **a** shows the forest plot of Fugl-Meyer Assessment for Lower Extremity, Figure **b** shows the forest plot of Functional Ambulation Category Scale, Figure **c** shows the forest plot of Berg Balance Scale

After this, the analysis showed no significant heterogeneity (P = 0.09, $I^2 = 35\%$), and the fixed-effects model was used for the analysis. The meta-analysis results showed that the MD = 0.42, 95% CI (0.27, 0.56), P < 0.001, and the pooled results were not significantly changed, as shown in Fig. 7.

Publication bias analysis

There were at least 10 studies on FAC, BBS, and 6MWT in the literature, and to assess publication bias, we drew funnel plots of FAC, BBS, and 6MWT, as shown in Fig. 8. The results indicated symmetrical distribution of the data, with a smaller offset for published studies. Egger's

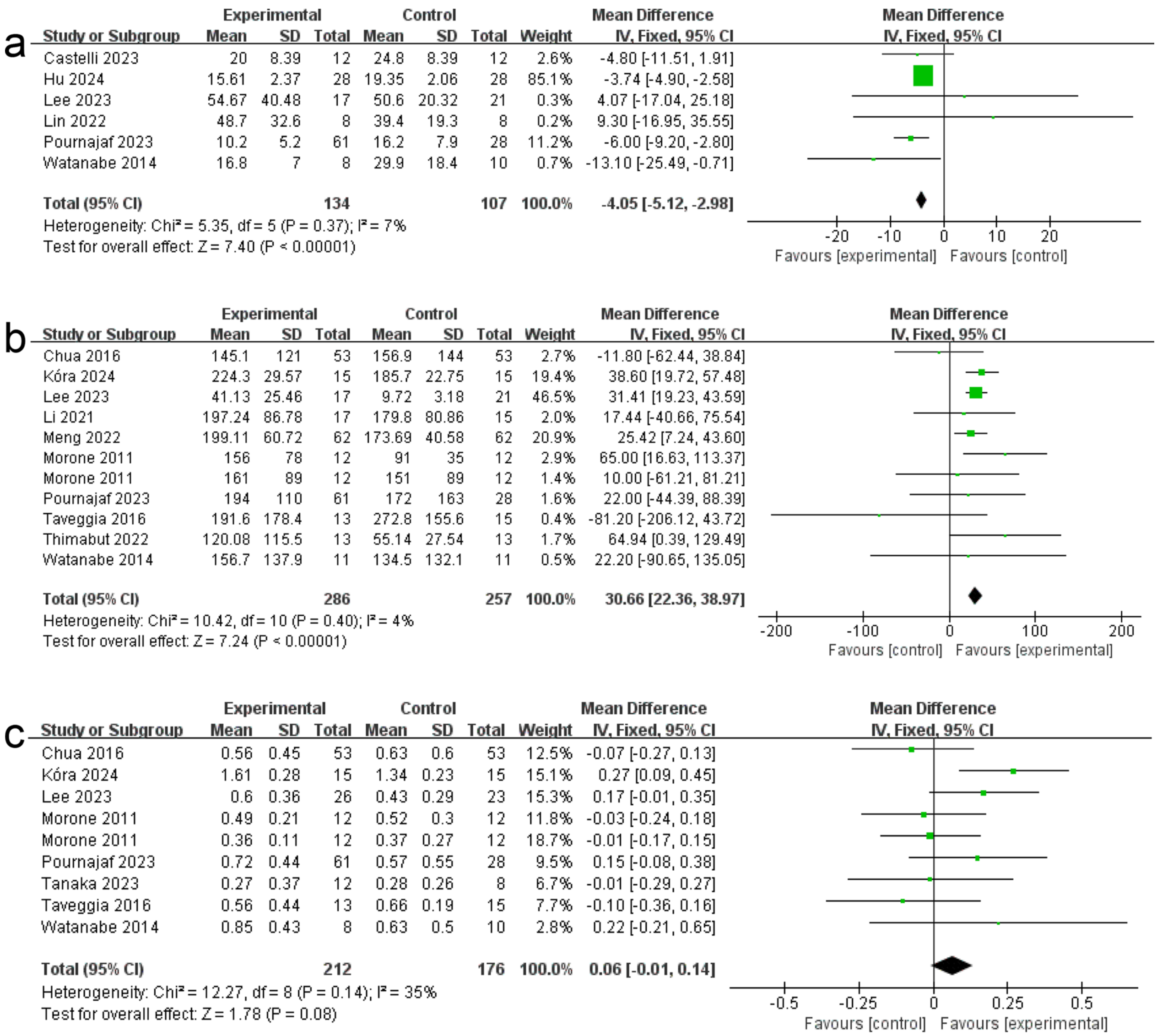

Fig. 4 The forest plot of Timed Up and Go Test, 6-Minute Walking Test and 10-Meter Walk Test. Figure **a** shows the forest plot of Timed Up and Go Test, Figure **b** shows the forest plot of 6-Minute Walking Test, Figure **c** shows the forest plot of 10-Meter Walk Test

test for publication bias yielded P values of 0.945 for FAC, 0.247 for BBS, and 0.250 for 6MWT.

Discussion

Lower extremity dysfunction and balance impairment are the key risk factors for accidental falls in stroke patients, severely limiting their mobility and daily activities [44]. Active physical rehabilitation is essential for enhancing their physical activity, facilitating the early recovery, and maximizing their reintegration into society and family life [45]. A retrospective longitudinal cohort study showed that functional improvement was significant within the first 6 months after stroke onset, so the first 6 months after stroke onset is the key to implementing rehabilitation [46]. Despite this, traditional rehabilitation treatments face numerous challenges and limitations. Considering the extensive rehabilitation needs of stroke survivors, there is a pressing demand for more efficacious rehabilitation strategies. RAGT can strengthen weak muscle groups and contribute to the recovery of the nervous system [46]. Furthermore, RAGT eliminates the need for manual placement of paralyzed extremities or assistance with trunk movement, significantly reducing the physical burden of therapists [47]. Nonetheless, the debate continues regarding the effectiveness of RAGT compared to CGT methods. According to the

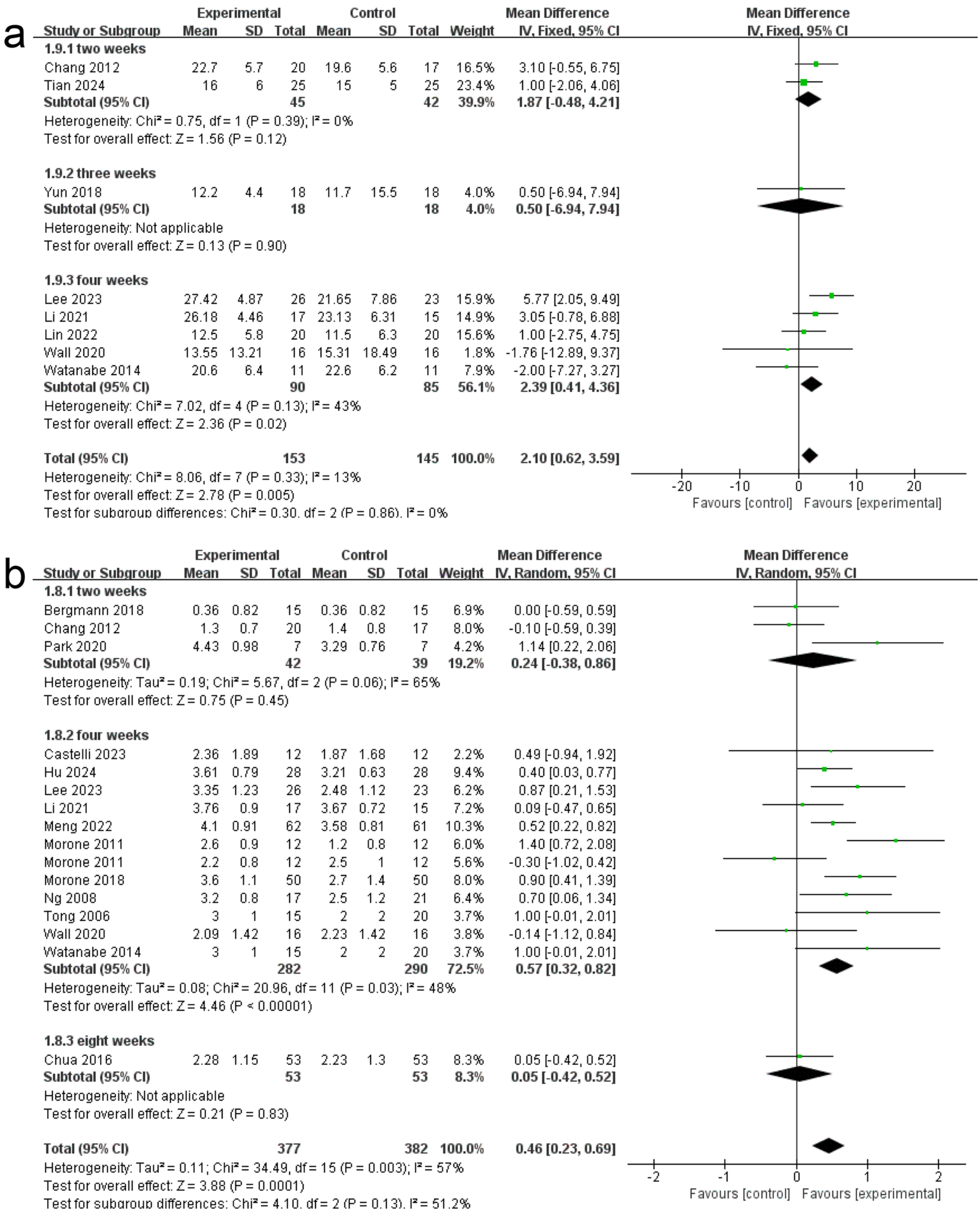

Fig. 5 The results of subgroup analysis based on the duration of intervention. Figure **a** shows subgroup analysis based on intervention time in Fugl-Meyer Assessment for Lower Extremity. Figure **b** shows subgroup analysis based on intervention time in Functional Ambulation Category Scale

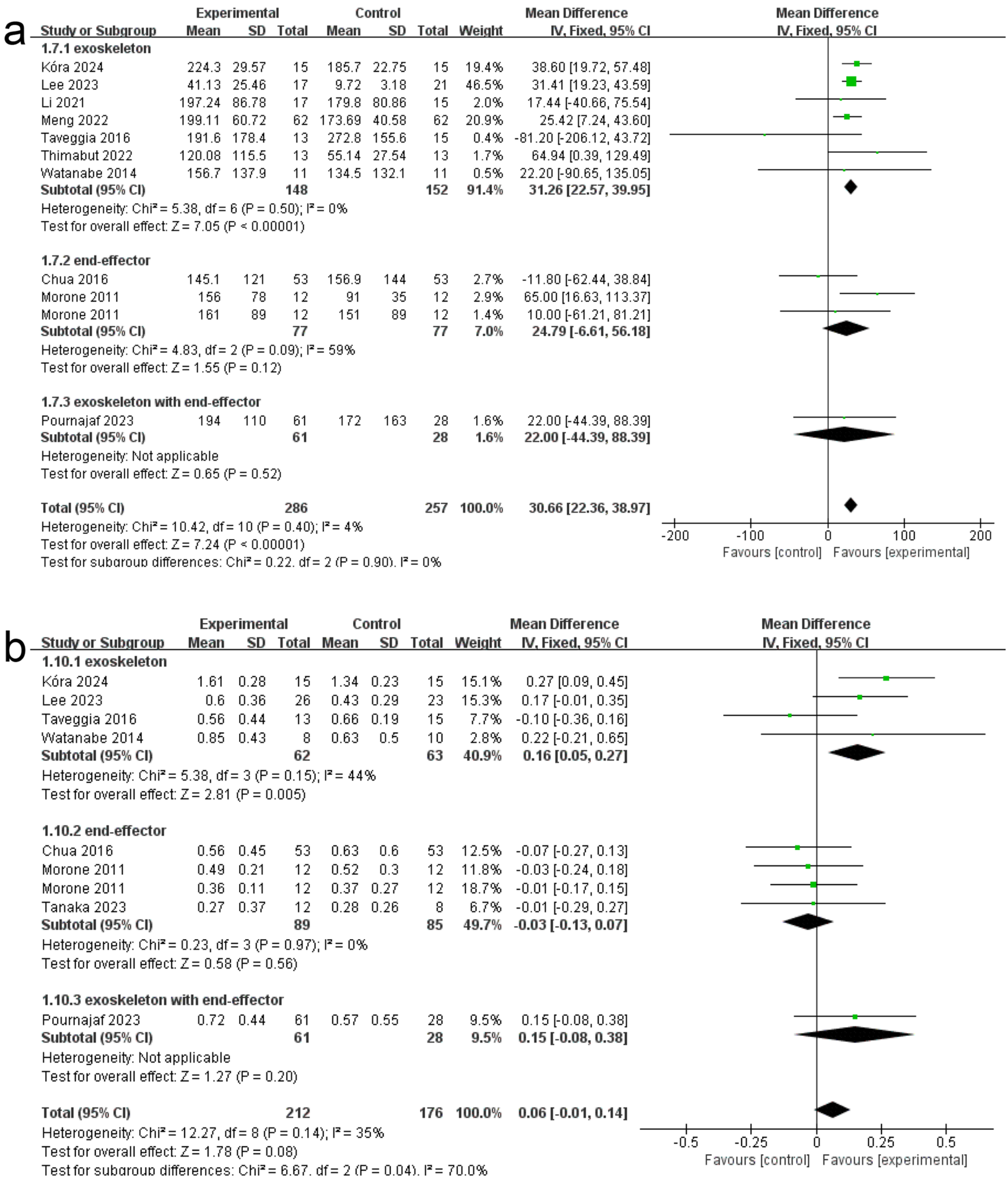

Fig. 6 The results of subgroup analysis based on the different robot types. Figure **a** shows subgroup analysis based on the different robot types in 6-Minute Walking Test. Figure **b** shows subgroup analysis based on the different robot types in 10-Meter Walk Test

2020 Canadian Stroke Best Practice recommendation states that RAGT devices may be considered for those who cannot walk. However, they should not replace CGT [48]. Additionally, a narrative review mentions RAGT as

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Fixed, 95% CI
Bergmann 2018	0.36	0.82	15	0.36	0.82	15	5.8%	0.00 [-0.59, 0.59]
Castelli 2023	2.36	1.89	12	1.87	1.68	12	1.0%	0.49 [-0.94, 1.92]
Chang 2012	1.3	0.7	20	1.4	0.8	17	8.4%	-0.10 [-0.59, 0.39]
Chua 2016	2.28	1.15	53	2.23	1.3	53	9.1%	0.05 [-0.42, 0.52]
Hu 2024	3.61	0.79	28	3.21	0.63	28	14.3%	0.40 [0.03, 0.77]
Lee 2023	3.35	1.23	26	2.48	1.12	23	4.6%	0.87 [0.21, 1.53]
Li 2021	3.76	0.9	17	3.67	0.72	15	6.3%	0.09 [-0.47, 0.65]
Meng 2022	4.1	0.91	62	3.58	0.81	61	21.6%	0.52 [0.22, 0.82]
Morone 2011	2.6	0.9	12	1.2	0.8	12	0.0%	1.40 [0.72, 2.08]
Morone 2011	2.2	0.8	12	2.5	1	12	0.0%	-0.30 [-1.02, 0.42]
Morone 2018	3.6	1.1	50	2.7	1.4	50	8.2%	0.90 [0.41, 1.39]
Ng 2008	3.2	0.8	17	2.5	1.2	21	4.9%	0.70 [0.06, 1.34]
Park 2020	4.43	0.98	7	3.29	0.76	7	2.4%	1.14 [0.22, 2.06]
Pournajaf 2023	3.4	0.9	61	2.9	1.2	28	8.0%	0.50 [0.00, 1.00]
Tong 2006	3	1	15	2	2	20	1.9%	1.00 [-0.01, 2.01]
Wall 2020	2.09	1.42	16	2.23	1.42	16	2.1%	-0.14 [-1.12, 0.84]
Watanabe 2014	3.1	1.4	11	2.6	1.4	11	1.5%	0.50 [-0.67, 1.67]
Total (95% CI)			**410**			**377**	**100.0%**	**0.42 [0.27, 0.56]**

Heterogeneity: Chi² = 21.63, df = 14 (P = 0.09); I² = 35%
Test for overall effect: Z = 5.76 (P < 0.00001)

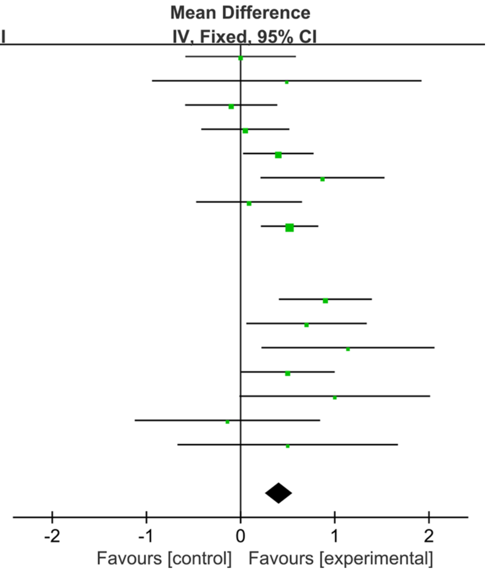

Fig. 7 Sensitivity analysis of Functional Ambulation Category Scale

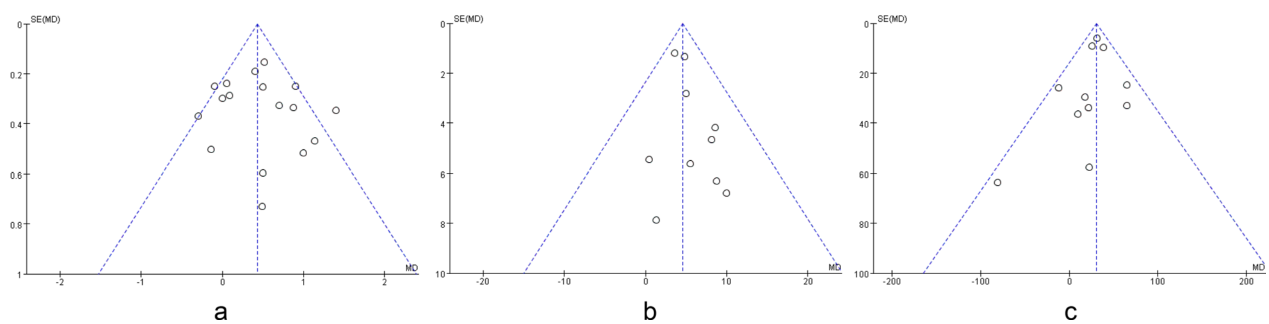

Fig. 8 Funnel plot. Figure **a** shows the funnel plot of Functional Ambulation Category Scale, Figure **b** show the funnel plot of Berg Balance Scale, Figure **c** shows the funnel plot of 6-Minute Walking Test

a promising alternative to conventional therapy by providing intensive, standardized care [49].

The current debate on the systematic evaluation of RAGT for lower extremity function in stroke patients is evolving, with an increasing number of original studies being published, highlighting the importance of incorporating the most recent findings into analysis [17, 19]. Therefore, this study has included randomized controlled trials with RAGT as the intervention group and CGT as the control group, and the disease course of subjects was within six months. RAGT can significantly improve outcomes measured by the FMA-LE, FAC, BBS, TUG, and 6MWT of patients with subacute stroke, but has no significant effect on 10MWT scores. These results suggest that while RAGT offers substantial benefits in certain aspects of lower extremity function and balance, its effects on specific walking speed may require further investigation.

Effect of RAGT on lower extremity function in subacute stroke patients

The results of the meta-analysis revealed that RAGT could effectively improve the FME-LE level in patients with subacute stroke compared with the CGT group, and the intervention that lasted for four weeks was the best. Our results showed some differences when compared to those of previous studies, which may be due to the inclusion of the latest randomized controlled trials in this study [50, 51]. This inclusion has increased the quality of evidence and provided a more thorough assessment of the effects of RAGT in patients with subacute stroke.

A study [52] has shown that postural stability can be significantly improved in the first two months after stroke, but it is not directly associated with the recovery of the most affected extremity. Instead, patients tend to utilize the less affected side for functional exercise. RAGT uniquely addresses this issue by encouraging patients to shift their center of gravity towards the more affected side without the fear of falling. Therefore, the patient can carry out rehabilitation treatment with sufficient intensity, thereby enhancing the plasticity of the nerve, and improving the function of the lower extremity [35, 53]. The emphasis on using the more affected side in RAGT helps to balance the rehabilitation focus, potentially offering a more holistic approach to improving the overall function of stroke survivors.

The heterogeneity of the study population, inconsistent training content, and differences in training volume and intensity may have contributed to the findings. A retrospective analysis by Chu et al [54]. identified that the timing of acute care rehabilitation is a predictor of post-stroke walking capability. The FMA-LE was reported in eight studies included in this study, two of which showed that RAGT was not superior to conventional gait training. The study by Wall et al [34]. indicated that the recovery rate of independent walking at 6 months after stroke was higher in younger patients than in older patients, and the association with intervention was not significant. This suggests that while RAGT has potential benefits, its efficacy in improving specific functional mobility measures such as FMA-LE may be affected by the details such as demographic factors. Furthermore, subgroup analysis in this study found that interventions lasting around four weeks showed the most pronounced effects in FMA-LE scores. However, these results still require further validation from higher-quality clinical research.

Effect of RAGT on balance function in subacute stroke patients

Meta-analysis revealed a significant difference in BBS scores between the two groups, with RAGT effectively improving the balance function of patients with subacute stroke [MD = 4.55, 95%CI (3.00, 6.11), $P < 0.001$]. Similarly, a meta-analysis by Wang et al [18], which included 13 RCTs, concluded that RAGT was beneficial in improving the balance function of patients. Furthermore, A scoped review [55] summarized seven categories of balance rehabilitation interventions in which RAGT can significantly improve trunk control and balance aspects in stroke patients. Baronchelli et al [56] showed inconsistent results, which may be due to the fact that their study population was primarily composed of patients with chronic stroke, and the study only included RCTs that utilized the Lokomat robot equipment for RAGT interventions. A retrospective cohort study [57] showed that recovery of balance during inpatient rehabilitation for subacute stroke was strongly associated with gait achievement without physical assistance at discharge. Patients with subacute stroke experience changes in muscle mass, affecting their balance and lower extremity function [58] Robotic devices can assist patients to complete high-intensity and repetitive gait training tasks and also experience vestibular and proprioceptive stimulation during training, which can improve neuroplasticity and functional recovery of patients [59] Therefore, RAGT is an effective rehabilitation method for patients with balance dysfunction.

Effects of RAGT on walking ability and endurance in subacute stroke patients

The results of the meta-analysis demonstrated that RAGT compared with the CGT can effectively improve patients with subacute stroke of FAC, TUG, 6 MWT, improve the walking ability of patients and endurance. This result is consistent with the results of a meta-analysis of chronic stroke patients conducted by Yang et al [60]. which highlighted that RAGT had a better effect on gait performance and physical endurance than the control group. Postol et al [61]. investigated the impact of lower extremity robotic exoskeletons on the 6MWT and TUG test in patients with acquired brain injuries, noting improvements not attributed to traditional gait interventions. However, their analysis was based on a limited set of five studies, not all focused on stroke-induced cerebral apoplexy. Yu et al [62]. matched two randomized controlled trials and found that there was no difference in the improvement of walking ability between high-intensity and low-intensity RAGT in patients over three months after stroke. This indicated that there may be no difference in the number of leg movement repetitions between the two groups within the same intervention time, which could imply the potential for a reduced gait training period. Nevertheless, because the study by Yu et al. was not a prospective study and the inclusion criteria of the two matched randomized controlled trials were also different, there was a certain deviation. Subgroup analysis within our study found that the best improvement in FAC scores was achieved when the intervention lasting for four weeks. The number of studies in the other two subgroups was small, necessitating further research to explore the optimal duration of robot-assisted gait intervention.

While innovative, the utilization of robotic equipment in rehabilitation is often challenged by its considerable size, complexity, high costs, and the requirement for multiple attendants during operation [53]. There is growing attention on the design of the robot, such as Wu et al [59]. designed a new type of 9 degrees of freedom redundant rehabilitation training robot compared with exoskeleton robots. This robot has the characteristics of lower cost and higher stability and can realize simulating multiple body movements more efficiently. The design incorporates a series–parallel hybrid structure, combining the high load-bearing capacity typical of parallel robots with the added benefit of a parallel guide rail sliding block mechanism for efficient force transmission. This feature facilitates the easier achievement of high-speed movements, addressing some of the limitations of previous designs.

This study encompassed RCTs of RAGT using exoskeletons and end-effectors. Subgroup analysis revealed that exoskeleton-type robots showed superior performance on patient endurance levels measured by the 6MWT. Therefore, if conditions permit, selecting a robotic device that aligns with the specific needs and conditions of the patient could optimize rehabilitation outcomes.

Effects of RAGT on gait speed in subacute stroke patients

The results of the meta-analysis revealed that RAGT could not effectively improve level of 10MWT in patients with subacute stroke compared with CGT, but the subgroup analysis found that the exoskeleton type robot was more effective in improving the walking speed than CGT. Nedergard et al [19]. analyzed the effect of RAGT on objective biomechanical measurements of human gait after stroke and found that RAGT did not have a significant effect compared with non-RAGT treatment, which may be related to the small number of included studies and the higher risk of bias. Similarly, the results of a systematic review [60] also showed that there was no statistically significant difference between the RAGT group and the control group in the 10MWT.

The relationship between leg muscle strength and walking speed is a critical factor in this context [32]. This study included in the two studies show that in the control group at baseline lower limb muscle strength higher than that of intervention group. The final results showed that the intervention group had greater improvement in gait speed, which has certain clinical significance [32, 33]. The minimal clinically important differences (MCID) can be used to interpret the clinical significance of clinical trial results [63]. Using MCID, researchers can judge the substantial improvement of patients' condition after treatment. According to a previous study, the MCID of 10MWT was 0.13 m/s [64]. The findings from the subgroup analysis of this study reveal that the exoskeleton-type robots have demonstrated a significant MD of 0.16 m/s in the 10MWT, surpassing the threshold of the MCID. This outcome underscores the clinical relevance of exoskeleton-type robots in enhancing the gait velocity of individuals recovering from subacute stroke conditions. Xie et al [65]. conducted soft robot exoskeleton intervention on stroke patients and found that the soft robot exoskeleton group was better than the conventional training group in all clinical scores, with the 10MWT and 6MWT values exceeding the MCID.

The meta-analysis of Hsu et al [66]. on the effect of wearable exoskeleton on gait after stroke showed that the exoskeleton training group was superior in gait speed and achieved the MCID. However, their subgroup analysis found that this conclusion was only applicable to chronic stroke patients, and no meaningful results were observed in subacute stroke patients. This differentiation may be explained that the use of external assistance might have an inhibitory effect on individual differences, slowing down the walking speed of patients with stronger walking ability and accelerating it for those with weaker ability. A systematic review [67] of the effects of soft robotic outerwear on the walking ability of stroke patients showed that the included studies all found an improvement in walking speed. Therefore, improvements in walking speed may be related to the characteristics of the participants or the type of robot.

Robot-assisted technology represents a significant advancement in rehabilitation, which can not only improve patients' lower extremity function through gait training but also enhance extremity function through other training methods. For instance, Li et al [68]. performed exoskeleton-assisted sit-to-stand training in patients with subacute stroke and found that this training method could improve lower extremity function after stroke by inducing changes in muscle synergy. Furthermore, robot-assisted technology allows for the customization of device parameters based on the patient's specific medical condition and muscle status, enhancing the personalization of rehabilitation efforts [69]. However, this customization also causes heterogeneity among various studies, and there is no consensus on the best intervention plan for RAGT. The results of an assessor-blinded RCT conducted by Talat et al [70]. showed that an additional three hours of gait training therapy per week during hospitalization for acute stroke achieved rehabilitation goals and was well-tolerated by patients. However, the sample size of this study was small, and more research is needed to explore the optimal intervention dose of RAGT. Zhang et al [71]. 's network meta-analysis found that combination of robot-assisted training with virtual reality yielded the best intervention for improve BBS and 10MWT scores. Therefore, RAGT combined with CGT or other rehabilitation techniques can be considered to enhance the rehabilitation effect when performing interventions for patients.

Limitations

This study acknowledges certain limitations that must be considered. Firstly, due to the use of the risk assessment tool RoB2 for strict quality evaluation in this study, only three studies were identified as low risk, which limits the robustness of our conclusions.

Secondly, this study found that the improvement of FMA-LE and FAC scores effect was greatest when the intervention lasted for four weeks, but the specific training duration per week was varied, and this result also needs to be verified. Thirdly, this study did not analyze the follow-up data of the patients, and it is possible that the effect of the robotic intervention is not immediate, which may influence the conclusions of this study. Future research directions could include exploring optimal parameter settings for robotic devices, investigating the intensity of training, and assessing the efficacy of combining RAGT with other treatment modalities. These endeavors will contribute to further advancements in the field of stroke rehabilitation.

Conclusion

This study highlights that Robot-assisted gait training exhibits promising potential for enhancing lower extremity function, balance function, walking ability, and endurance in patients with subacute stroke. However, the quality of evidence for improvements in gait speed remains low.

Supplementary Information

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Supplementary material 1.
Supplementary material 2.
Supplementary material 3.

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Author contributions
MMH: Conceptualization; Data Curation; Formal Analysis; Methodology; Software; Investigation; Validation; Visualization; Writing – Original Draft Preparation. SW: Conceptualization; Data Curation; Formal Analysis; Methodology; Software; Investigation; Validation; Visualization; Writing – Original Draft Preparation. CQW: Resources; Validation; Writing – Review & Editing. KPL: Resources; Validation; Writing – Review & Editing. ZHG: Resources; Funding Acquisition; Validation. GHX: Investigation; Methodology; Project Administration; Supervision; Validation; Funding Acquisition; Writing – Review & Editing. LD: Investigation; Methodology; Project Administration; Supervision; Validation; Funding Acquisition; Writing – Review & Editing. MMH and SW made equal contributions to this manuscript.

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Availability of data and materials
The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
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Competing interests
The authors declare no competing interests.

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