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The effect of lower limb rehabilitation robot on lower limb -motor function in stroke patients: a systematic review and meta-analysis

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Abstract

Background The assessment and enhancement of lower limb motor function in hemiplegic patients is of paramount importance. The emergence of lower limb rehabilitation robots offers a promising avenue for improving motor function in these patients, addressing the limitations associated with traditional rehabilitation therapies. However, a consensus regarding their clinical effectiveness remains elusive. Consequently, the objective of this study is to systematically review the rehabilitation efficacy of lower limb rehabilitation robots on motor function in post-stroke hemiplegic patients, thereby providing robust clinical evidence to support their promotion and utilization.

Methods Eight databases were examined between the start and April 2024. Patients with hemiplegia were included in randomized controlled trials to examine the effects of a lower limb rehabilitation robot on their motor function. Data extraction, risk of bias assessment, and study screening were carried out independently by two reviewers. Stata and Review Manager 5.3 were used for the meta-analysis. Sensitivity analysis was used to determine how reliable the findings were. To examine the origins of heterogeneity, meta-regression and subgroup analysis were employed.

Results This review comprised a total of 41 studies with 3279 participants. In one or more domains, the majority of the studies were rated as having a low or uncertain risk of bias. The study's findings demonstrated that the lower limb walking function, balance function, and ability to do activities of daily living improved more in the group receiving conventional rehabilitation (CR) + robot-assisted therapy (RT) than in the CR group. The Berg Balance Scale (BBS), which measures balance function, and the Fugl-Meyer scale (FMA), which measures lower limb motor function, were both better in the RT group than in the CR group. Sensitivity analysis proved that the findings were reliable. The sample size and publication years were found to be somewhat responsible for the heterogeneity, according to meta-regression analysis and subgroup analysis.

Conclusion In stroke patients with hemiplegia, the lower limb rehabilitation robot has demonstrated a certain level of clinical success in regaining lower limb function.

Keywords Stroke, Lower limb rehabilitation robot, Motor function, Systematic review, Meta-analysis

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Background

Stroke is one of the leading causes of disability worldwide and is a cerebrovascular accident brought on by disruption of the blood supply to the brain or rupture of a blood artery in the brain [1]. Following a stroke, 70% of patients frequently experience a slowed or hemiplegic gait [2]. Stroke patients are not only less independent due to this gait pattern, but they also run the risk of falling and developing secondary disability. Consequently, one of their most pressing demands is to become more adept at walking [3]. The main objective of rehabilitation is to restore the lower limbs' normal movement and balance, as these are necessary for normal walking ability [4, 5]. In conventional rehabilitation (CR), the therapist assists the patient in training using just their hands. However, in the early stages of hemiplegia, the patient lacks initiative, which requires a lot of labor and puts a significant strain on the therapist [6]. Lower limb rehabilitation robot technology is maturing along with rehabilitation therapy, which is fantastic news for patients as it helps restore function more effectively and eases the strain on therapists [7].

Based on the idea of central nervous system plasticity, the new robot-assisted training uses multi-parameter settings to accomplish multi-functional, physiological simulation, and sufficiently repetitive exercises. This is a practical, efficient, and secure form of rehabilitation therapy [5, 8, 9]. In a dynamic piece of technology for lower limb rehabilitation, the lower limb exoskeleton rehabilitation robot helps patients learn new skills like walking, balancing, and supported standing. The lower limb rehabilitation robot can efficiently maintain the patient's joint mobility and gradually enhance the patient's gait during rehabilitation training through active/passive motion, impedance motion, and mirror motion [10].

Hemiplegic patients' lower limb motor function and walking capacity can be considerably improved by lower limb rehabilitation robot training, which is active, resistant, repetitive, and weight reducing [11–13]. Through the correction of aberrant gait patterns during gait training, it offers the sensory input required to improve walking ability [14]. Due to individual factors including age, gender, experience, and strength, it can lessen the disparities in the effectiveness of rehabilitation therapists. The process of educating patients to walk can be made more efficient and effective by standardizing and proceduralizing it. Walking dysfunction is the most pressing issue facing stroke patients. Walking is a basic human ability that allows people to live regular lives and work freely.

Patients undergoing lower limb robotic rehabilitation training can meet their everyday needs and ensure patient safety by performing stable motions based on a normal gait. Additionally, despite the benefits of lower limb rehabilitation robots, such as guiding active movement, the majority of research subjects are paraplegic patients with spinal cord injuries [15, 16]. Huang et al. discovered that patients' motor and balance functions improved using lower limb rehabilitation robots following spinal cord injury [17]. Robotic lower limb therapy has not yet shown significant clinical evidence to improve lower limb walking abilities and balance in stroke survivors. Also, a variety of robot types are currently on the market. By being aware of these variations in robotic technology, medical professionals can better target patient treatment and selection, leading to more evidence-based medical evidence.

However, there are drawbacks to using robotic devices as well. For example, they can limit a patient's range of motion and direction of movement as well as partially impair their independence in terms of mobility [18]. According to multiple studies, stroke patients who combined CR with robot-assisted gait training improved more than those who only utilized CR in terms of walking capacities [19–21]. However, no difference in results between robotic and traditional therapy has been observed in other investigations. So, more research is required to determine whether using a lower limb rehabilitation robot to assist in the recovery of lower limb motor function following a stroke is advantageous [22, 23].

In order to make coherent conclusions, the aim of this study is to synthesize the findings of several investigations into the effect of lower limb rehabilitation robot on lower limb motor ability and walking ability of hemiplegic stroke patients. This will further improve the clinical evidence for the promotion and use of lower limb rehabilitation robots.

Method

This review was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) statement [24]. The protocol has been registered in International Prospective Register of Systematic Reviews (PROSPERO). The registration number is CRD42021272657. Further revisions and additions will be tracked in PROSPERO.

Eligibility criteria

Inclusion criteria

Studies were included if they met the following criteria:

1) the study design was a randomized controlled trial (RCT);
2) participants were aged 18 or older with unilateral limb hemiplegia due to a first-time stroke, with stable vital signs and clear consciousness;

3) the intervention was either a robot-assisted therapy (RT) alone or in combination with CR;
4) the control group received CR only;
5) at least one of the following outcomes was reported: Fugl-Meyer Assessment (FMA) was used to evaluate the patient's lower limb motor function, with higher scores indicating better motor function (total score 34 points).
   Berg Balance Scale (BBS) was used to evaluate the patient's balance ability, and higher scores indicated better balance ability (total score 56 points).
   Modified Barthel Index (MBI) was used to assess patients' activities of daily living. The higher the score, the stronger the subject's self-care ability and the better the ability to carry out daily living activities (total score 100 points).
   Both the Functional Ambulatory Classification (FAC) and the 6-minute walk test (6MWT) were used to evaluate the patient's walking ability, with higher scores representing better walking ability;
6) No limitation was imposed upon language, gender, age, country or race.

Exclusion criteria

The following exclusion criteria were applied: (1) participants with disabilities due to neurological diseases other than stroke; (2) reviews, case reports, conference abstracts, conference papers, or meta-analysis; (3) studies that were duplicates or lacked sufficient information to extract data.

Search methods

Electronic searches

We searched the PubMed, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), Wan Fang Database and China Science, and Technology Journal Database (VIP) from inception to April 2024. The search strategy utilized both Medical Subject Headings (MeSH) terms and free-text words to increase accuracy. The search terms were exhaustive and related to "stroke," "lower limb," "rehabilitation robot," and "randomized controlled trial." Detailed search strategy for PubMed can be found in Supplemental file, and similar strategies were applied to the other electronic databases.

Other sources

We additionally searched the gray literature, conference papers, reference lists of identified studies, www.chictr.org.cn, and ClinicalTrials.gov for eligible randomized control trials.

Studies' selection

All retrieved studies were managed using Endnote X9 and duplicate studies were filtered out. We screened studies based on titles and abstracts according to predefined inclusion and exclusion criteria. Subsequently, two authors (QH and JW) screened the full text and further reviewed them independently. Any discrepancies between the two authors were resolved by consulting a third author (TZ) to reach a consensus.

Data extraction

Two authors independently extracted data using preset Excel sheet, including the first author, title, publication year, country/region, participant characteristics (sample size, mean age, sex, and type of stroke), interventions, treatment period, control group measures, and study outcomes. The extracted data were recorded in PICO format. If necessary, the original authors were contacted to request missing data.

Quality assessment

Two authors independently assessed the risk of bias according to the recommendations of the Cochrane Collaboration [25]. The assessment covered seven domains: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other biases. Each domain was classified into three categories: low risk, unclear risk, and high risk. We used RevMan's built-in Cochrane risk of bias assessment tool to assess the quality of the included studies, namely ROB1.

Data synthesis

Statistical analysis was performed using Review Manager 5.3 (RevMan) and STATA software (version 15.0). Continuous outcomes were assessed using mean difference (MD). All data were reported with 95% confidence intervals (95% CI). Heterogeneity among the included studies was assessed using the Chi-squared test and the I^2 statistic. A fixed-effects model was used when $p > 0.05$ or $I^2 < 50\%$; otherwise, a random-effects model was applied. Intention-to-treat (ITT) analysis was used for missing data. Sensitivity analysis was used to determine how reliable the findings were. The sources of heterogeneity were investigated using meta-regression and subgroup analysis. Funnel plots and Egger's test were used to assess publication bias.

Results

Search results

A total of 464 studies remained after deduplication using Endnote X9, out of the 808 studies that were first found through database searching. A total of 103 papers needed to have entire texts evaluated after the titles and abstracts were screened. Ultimately, this meta-analysis and systematic review comprised 41 papers. Figure 1 illustrates the thorough screening procedure.

Description of included studies

The primary characteristics of the included studies is displayed in Table 1. A total of 41 studies with 3279 participants were included in this review, 34 [26–59] of which were published in Chinese and seven [2, 60–65] in English. There were 33 research [2, 26–48, 50, 51, 53–55, 58–60, 65] that chose the combination intervention of CR and lower limb rehabilitation robot, whereas eight studies [49, 52, 56, 57, 61–64] focused solely on the lower limb rehabilitation robot.

Thirty-seven studies [2, 26–37, 39–41, 43–54, 56–61, 63–65] used FMA to evaluate the patient's lower limb motor function. Twenty-six studies [26, 27, 29–31, 35, 36, 38, 40–42, 45–52, 55, 57–60, 62, 65] utilized the BBS to evaluate the patient's balance ability. Thirteen studies [26, 29, 30, 32, 37, 42, 43, 45, 53, 54, 59, 60, 62] used MBI to assess patients' activities of daily living. Ten studies [2, 26, 31, 36, 46, 50, 59, 60, 62, 64] used FAC, and 10 studies [2, 36, 40, 43, 44, 46, 50, 61, 63, 64] used 6MWT to evaluate the patient's walking ability.

Risk of bias in the included studies

Figures 2 and 3 indicate the risk of bias for 41 studies. Li et al. [28] study was judged to be at high risk of bias due to very small sample size. All other studies were judged to be low risk. Supplemental Table S1 displays the judgment's specifics.

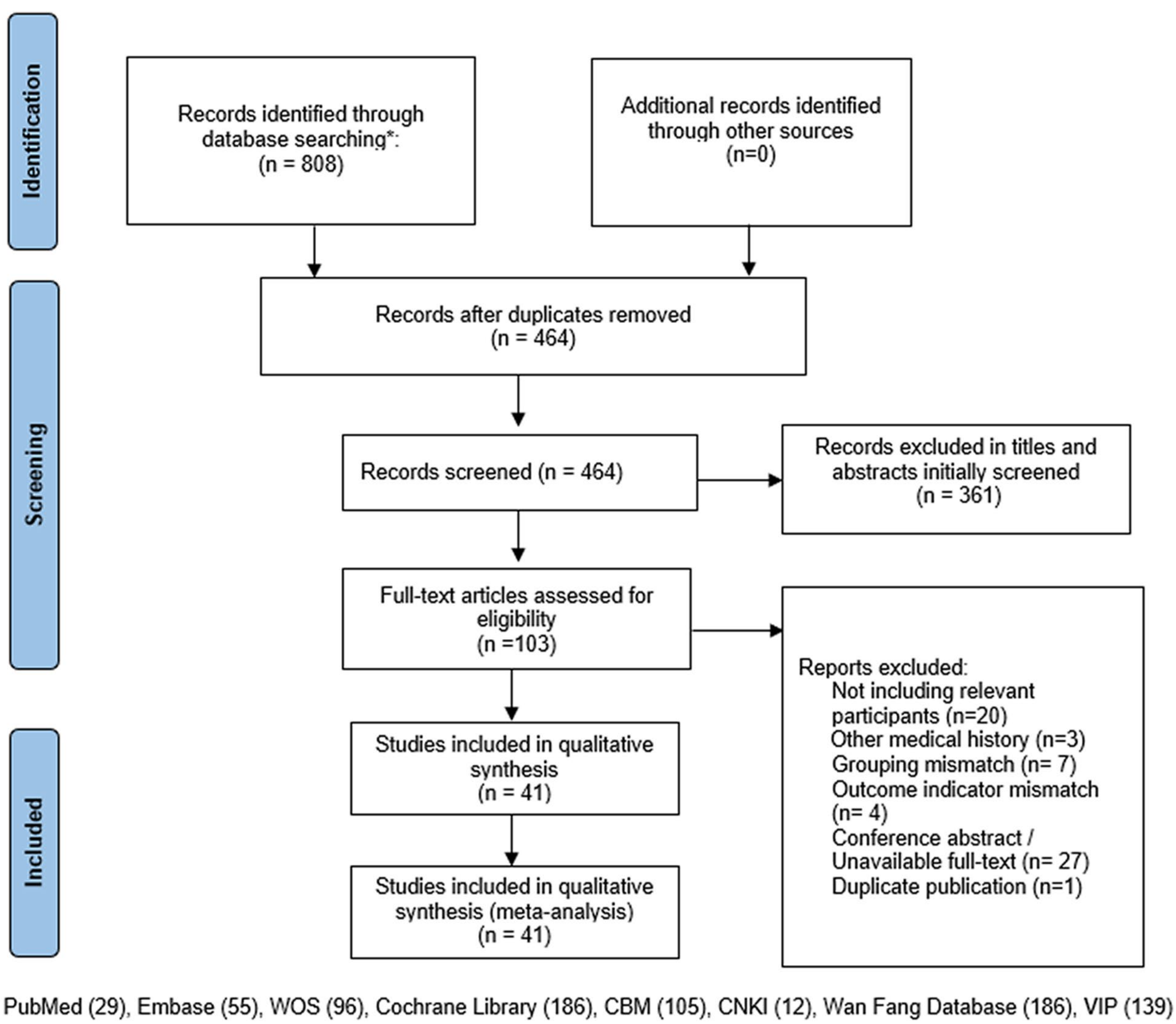

Fig. 1 PRISMA flow diagram

Table 1 Characteristics of included studies

Study	Year	Sample (E/C)	Age		Gender (Male/Female)		Intervention		Baseline Assessment Results (E/C)	Period
			E	C	E	C	E	Control		
Liu	2013	20/20	52.46 ± 8.04	53.22 ± 5.73	12/8	14/6	CR + rehabilitation robot	CR	BBS(20.5 ± 3.32/21.63 ± 2.98) FMA(20.7 ± 3.78/21.88 ± 2.57), MBI(28.3 ± 5.23/27.43 ± 3.65)	10w
Meng	2013	30/30	57.3 ± 10.2	56.5 ± 11.6	16/14	17/13	CR + rehabilitation robot	CR	FMA(15.0 ± 2.82/14.83 ± 3.10) BBS(27.8 ± 7.66/26.30 ± 5.93)	12w
Zhang	2013	17/17	55.65 ± 13.20	55.47 ± 13.61	10/7	12/5	CR + Lokohelp rehabilitation robot	CR	FMA(11.5 ± 5.39/11.64 ± 5.30) MBI(30.2 ± 6.17/31.24 ± 6.26)	4w
Zhao	2013	20/20	51.8 ± 10.1	57.6 ± 8.2	17/3	15/5	CR + Lokomat rehabilitation robot	CR	FMA(15.1 ± 2.1/14.9 ± 1.0)	10w
Gao	2014	30/30	50.6 ± 8.1	52.5 ± 7.3	18/12	20/10	CR + rehabilitation robot	CR	FMA(15.3 ± 7.12/15.18 ± 6.85) BBS(19.4 ± 5.78/18.92 ± 6.30)	8w
Ouyang	2014	50/50	56.5 ± 13.1	56.2 ± 13.5	27/23	24/26	CR + rehabilitation robot	CR	BBS(25.4 ± 4.3/24.3 ± 5.2) MBI(19.6 ± 6.7/19.2 ± 5.8)	8w
Bei	2015	40/40	61.7 ± 6.32	62.7 ± 6.48	34/6	29/11	CR + Lokomat rehabilitation robot	CR	FMA(9.95 ± 4.36/9.43 ± 3.64) FAC(0.82 ± 0.85/0.57 ± 0.81) BBS(7.38 ± 3.93/7.38 ± 3.87) BMI(29.6 ± 7.11/29.88 ± 7.80)	6w
Li	2015	38/38	62.3 ± 7.8	63.6 ± 6.7	20/18	22/16	CR + rehabilitation robot	CR	FMA(22.9 ± 4.19/24.14 ± 3.01)	NR
Luo	2015	20/20	66.43 ± 5.34	63.33 ± 6.30	10/10	12/8	CR + Lokohelp rehabilitation robot	CR	FMA(32.9 ± 5.71/32.53 ± 4.20)	24w
Wang	2015	30/30	43.6 ± 11.3	44.9 ± 12.7	17/13	15/15	CR + Lokomat rehabilitation robot	CR	FMA(18.1 ± 1.34/19.76 ± 0.94) BBS(16.2 ± 1.17/16.35 ± 1.21) 6MWT(211.31 ± 11.72/ 219.36 ± 13.19) FAC(2.71 ± 0.12/2.50 ± 0.31)	8w
Zhao	2015	30/30	57 ± 9	58 ± 8	13/17	14/16	CR + Lokomat rehabilitation robot	CR	FMA (13.6 ± 2.3/14.6 ± 2.8) BBS(19.8 ± 1.7/19.5 ± 1.9)	8w
Karla	2016	10/10	44.1 ± 12.55	64.1 ± 8.38	NR	NR	rehabilitation robot	CR	FMA (23.1 ± 6.37/20.1 ± 5.78) 6MWT(214.6 ± 118.46 /105.5 ± 95.51)	8w
Lu	2016	20/20	55.25 ± 10.88	59.15 ± 12.20	13/7	13/7	CR + rehabilitation robot	CR	FMA(18.40 ± 7.63 / 19.35 ± 8.29) MBI(45.50 ± 19.11 / 53.25 ± 24.56)	6w
Yao	2016	33/33	65.18 ± 5.27	64.27 ± 5.38	19/14	21/12	Lokohelp rehabilitation robot	CR	FMA(14.95 ± 1.6/14.85 ± 1.71) BBS(15.221.48/15.29 ± 1.52)	8w
Wang	2017	63/63	55.1 ± 3.13	54.3 ± 3.21	34/29	33/30	Lokomat rehabilitation robot	CR	FMA(15.3 ± 7.32/15.4 ± 7.07) BBS (18.7 ± 5.64/18.9 ± 6.01)	10w
Li	2018	3/3	60.7 ± 8.98	59.7 ± 9.01	NR	NR	CR + rehabilitation robot	CR	FMA(13.22 ± 7.02 / 13.13 ± 6/98)	10d

Table 1 (continued)

Study	Year	Sample (E/C)	Age		Gender (Male/Female)		Intervention		Baseline Assessment Results (E/C)	Period
			E	C	E	C	E	Control		
Liu	2018	30/30	54.18 ± 6.26	53.83 ± 6.21	17/13	19/11	CR + rehabilitation robot	CR	FMA(20.85 ± 3.62 / 21.73 ± 2.64) BBS(20.37 ± 3.13 / 21.55 ± 3.01) FAC(2.62 ± 0.11/2.56 ± 0.30) 6MWT(209.62 ± 12.06 /213.76 ± 13.24)	8w
Qian	2018	21/21	NR	NR	NR	NR	CR + rehabilitation robot	CR	FMA(13.47 ± 6.54 /12.18 ± 8.02) 6MWT(57.22 ± 15.41 /57.23 ± 20.10)	8w
Zhang	2018	34/34	57.08 ± 9.47	56.97 ± 8.73	22/12	20/14	CR + Lokomat rehabilitation robot	CR	FMA(18.79 ± 5.32 /19.07 ± 5.12) MBI(50.78 ± 16.02 / 48.73 ± 15.03)	8w
Zhao	2018	424/282	62. 0 ± 16. 37	62. 7 ± 14. 83	312/112	130/152	CR + rehabilitation robot	CR	BBS(9.08 ± 11.41/ 12.10 ± 19.98)	12w
Kim	2019	25/23	57.7 ± 12.9	60.4 ± 13.2	20/5	13/10	rehabilitation robot	CR	FAC(2.9 ± 1.2/2.9 ± 1.2) MBI(56.6 ± 21.5/54.0 ± 4.05) BBS(25.5 ± 16.3/26.9 ± 14.8)	3w
Hu	2019	40/40	55.53 ± 9.23	58.29 ± 9.01	23/17	23/17	CR + rehabilitation robot	CR	FMA(10.95 ± 1.85 /10.73 ± 2.03) BBS(6.43 ± 1.22 /6.65 ± 1.33) MBI(30.98 ± 3.13 /30.95 ± 3.15)	12w
Liao	2019	110/110	68.81 ± 3.54	68.10 ± 4.10	56/54	55/55	Lokomat rehabilitation robot	CR	FMA (15.42 ± 8.19 /15.11 ± 6.39)	3 m
Wen	2019	43/43	51.03 ± 9.93	50.82 ± 10.07	27/16	29/14	CR + Flexbot-B rehabilitation robot	CR	FMA(15.20 ± 5.88 /15.34 ± 5.06) BBS(19.24 ± 5.72 /18.96 ± 6.35)	10w
Yang	2019	45/45	58.65 ± 5.50	58.62 ± 5.47	28/17	26/19	CR + XYQ-8 rehabilitation robot	CR	FMA(18.26 ± 6.42 /18.23 ± 6.41) BBS(19.36 ± 5.24 /19.34 ± 5.26) FAC(1.35 ± 0.86/1.32 ± 0.87) 6MWT(200.65 ± 19.60 /200.61 ± 19.64)	6w

Table 1 (continued)

Study	Year	Sample (E/C)	Age		Gender (Male/Female)		Intervention		Baseline Assessment Results (E/C)	Period
			E	C	E	C	E	Control		
Min	2020	19/19	61.47 ± 11.15	56.36 ± 9.16	11/8	13/6	CR + rehabilitation robot	CR	FMA(21.47 ± 4.69 /18.36 ± 6.06) MBI(61.31 ± 17.59 /56.78 ± 20.59) FAC(3.21 ± 0.78/3.21 ± 0.71) BBS(33.21 ± 4.27 /37.89 ± 5.03)	4w
Gu	2020	20/20	54.5 ± 12.7	57.6 ± 10.3	13/7	14/6	CR + rehabilitation robot (Nutural gait I)	CR	FMA(12.4 ± 2.6/11.7 ± 2.9) BBS(29.3 ± 7.2/28.5 ± 6.4) MBI(53.3 ± 16.4/53.6 ± 14.2)	8w
Xie	2020	19/20	57.26 ± 12.00	54.00 ± 15.26	13/6	15/5	CR + rehabilitation robot	CR	FMA(21.89 ± 3.90 /23.94 ± 5.17) MBI(61.58 ± 17.16 /63.25 ± 26.37)	3w
Luo	2020	25/25	59.97 ± 9.32	60.74 ± 9.83	14/11	13/12	CR + A3 rehabilitation robot	CR	BBS(6.52 ± 1.05/6.47 ± 1.13)	8w
Shu	2020	30/30	57.43 ± 7.05	57.55 ± 7.02	15/15	16/14	CR + rehabilitation robot	CR	BBS(6.48 ± 1.28/6.67 ± 1.35) FMA(10.68 ± 2.01 /10.77 ± 2.10) MBI(51.86 ± 4.63 /50.55 ± 5.96)	8w
Wu	2020	60/60	52.64 ± 10.76	53.28 ± 10.91	35/25	32/28	CR + rehabilitation robot	CR	BBS(11.42 ± 5.33 /12.15 ± 5.46) FMA(15.16 ± 7.08 /15.83 ± 6.92)	8w
Li (1)	2021	17/15	50.53 ± 12.26	50.13 ± 9.49	15/2	14/1	CR + BEAR-H1 rehabilitation robot	CR	6MWT(107.88 ± 67.62 /137.80 ± 75.07) FAC(2.65 ± 0.86/2.93 ± 0.59) FMA(20.41 ± 5.33 /20.47 ± 5.69)	4w
Li (2)	2021	57/57	NR	NR	NR	NR	BEAR-H1 rehabilitation robot	CR	FMA 6MWT(NR)	4w
Jiang	2021	37/37	70.27 ± 5.12	69.94 ± 5.03	21/16	19/18	CR + rehabilitation robot	CR	FMA(13.05 ± 2.7/13.19 ± 2.68) BBS(37.17 ± 6.7/36.78 ± 6.17) FAC(1.31 ± 0.29/1.28 ± 0.31)	8w
Ma	2021	60/60	59.58 ± 2.66	59.73 ± 2.61	35/25	33/27	CR + A3 rehabilitation robot	CR	6MWT(158.42 ± 7.63 /158.75 ± 7.82) BBS(21.04 ± 1.72 /21.13 ± 1.65) FMA(18.89 ± 1.07 /18.75 ± 1.08)	8w

Table 1 (continued)

Study	Year	Sample (E/C)	Age		Gender (Male/Female)		Intervention		Baseline Assessment Results (E/C)	Period
			E	C	E	C	E	Control		
Pei	2021	21/21	54.13 ± 10. 17	57.28 ± 9.08	14/7	16/5	CR + A3 rehabilitation robot	CR	FMA(11.42 ± 6.54 /10.89 ± 6.87) 6MWT(30.47 ± 18.72 /31.21 ± 16.51) MBI(35.65 ± 7.22 /36.32 ± 7.53)	8w
Yao	2021	30/30	45.40 ± 13.05	43.17 ± 14.40	17/13	19/11	CR + rehabilitation robot	CR	FMA(22.07 ± 4.68 /21.23 ± 5.98) BBS(34.07 ± 6.94 /32.20 ± 6.18)	6w
Lin	2022	20/20	54.1 ± 8.6	56.5 ± 12.9	14/6	15/5	CR + rehabilitation robot	CR	FMA(8.1 ± 4.9/7.0 ± 4.7) BBS(8.8 ± 9.7/8.2 ± 8.4)	4w
He	2023	35/35	63.83 ± 5.74	63.31 ± 5.57	19/16	21/14	CR + rehabilitation robot	CR	FMA(15.97 ± 2.83 /16.20 ± 2.56) BBS(36.06 ± 5.87 /36.34 ± 6.07) FAC(1.37 ± 0.25/1.40 ± 0.27)	8w
Zhang	2023	18/16	56.88 ± 10.99	60.81 ± 9.61	14/4	13/3	rehabilitation robot	CR	FMA(20.69 ± 6.76 /17.31 ± 6.64) FAC(3.00 ± 1.00/3.00 ± 0.00) 6MWT(91.80 ± 141.00 /117.70 ± 71.41)	4w
Li	2023	19/19	57.52 ± 6.39	58.13 ± 6.46	9/10	7/12	CR + rehabilitation robot	CR	BBS(31.05 ± 6.10 /30.71 ± 5.89) FMA(9.07 ± 2.25/8.89 ± 2.31) FAC(1.31 ± 0.31/1.33 ± 0.29) MBI(38.92 ± 6.25 /39.88 ± 6.63)	4w

E/C Experimental group/control group, *CR* Conventional rehabilitation, *FMA* Fugl–Meyer Assessment scale, *MBI* Modified Barthel Index scale, *BBS* Berg Balance Scale, *FAC* Functional Ambulatory Classification, *6MWT* 6 min walk test, *NR* No report

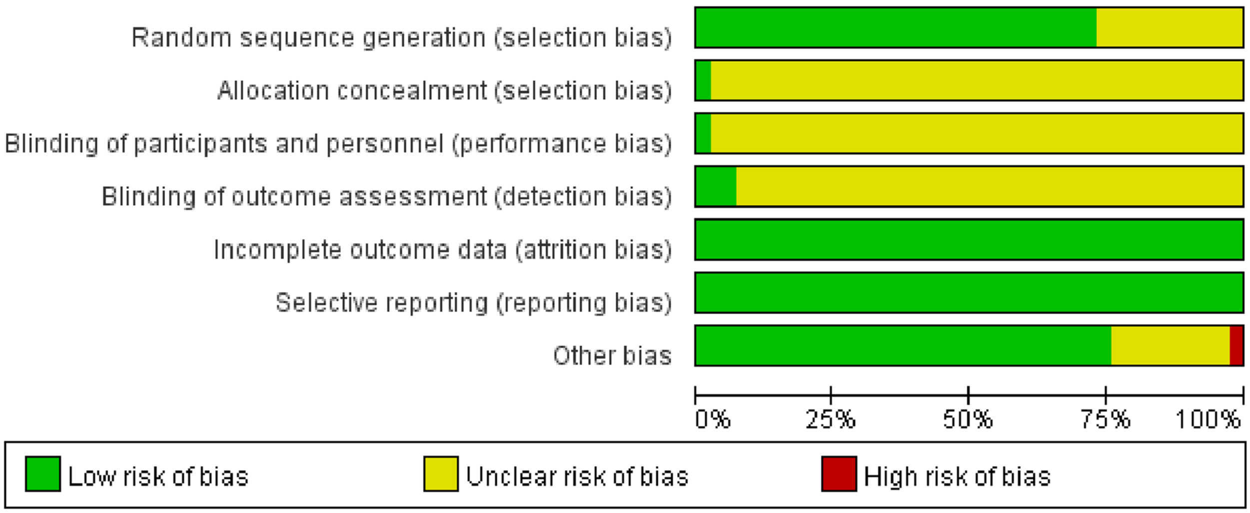

Fig. 2 Risk of bias graph

Meta-analysis results

Patient's lower limb motor function

FMA scores were reported in 37 studies [2, 26–37, 39–41, 43–54, 56–61, 63–65], assessing lower limb motor function in patients. Following treatment, lower limb function score of alone RT group was higher than CR group (MD = 5.44, 95% CI = 3.12 to 7.76, $P < 0.001$, $I^2 = 88\%$, 7 RCT, $n = 460$, Fig. 4); the CR plus RT group's lower limb function score was higher than the CR group (MD = 5.05, 95% CI = 3.90 to 6.20, $P < 0.001$, $I^2 = 92\%$, 30 RCT, $n = 1915$, Fig. 5). Owing to its significant variability, we opted for a random effects model.

Patient's ability to balance

BBS was employed in 26 studies [26, 27, 29–31, 35, 36, 38, 40–42, 45–52, 55, 57–60, 62, 65] to assess the patient's ability to balance. The alone RT group outperformed the CR group (MD = 12.22, 95% CI = 3.54 to 20.91, $P < 0.001$, $I^2 = 96\%$, 4 RCT, $n = 300$, Fig. 6); the CR plus RT group also outperformed the CR group (MD = 10.64, 95% CI = 8.04 to 13.25, $P < 0.001$, $I^2 = 97\%$, 22 RCT, $n = 2152$, Fig. 7).

Patients' activities of daily living

Thirteen studies [26, 29, 30, 32, 37, 42, 43, 45, 53, 54, 59, 60, 62] assessed the patient's activities of daily living (ADL) using MBI. Following treatment, the CR group and the alone RT group did not vary significantly (MD = 5.30, 95% CI = −6.31 to 16.91, $P = 0.37$, 1 RCT, $n = 48$, Fig. 8). The results of the CR plus RT group were superior to the CR group (MD = 15.44, 95% CI = 9.84 to 21.04, $P < 0.001$, $I^2 = 94\%$, 12 RCT, $n = 659$, Fig. 9).

Patient's walking ability

Ten studies [2, 26, 31, 36, 46, 50, 59, 60, 62, 64] used FAC to evaluate walking ability. When comparing the CR group to the RT group alone, there was no discernible difference (MD = 0.37, 95% CI = −0.14 to 0.89, $P = 0.15$, 2 RCT, $n = 82$, Fig. 10). The CR plus RT group's outcomes were more successful than those of the CR group (MD = 0.81, 95% CI = 0.48 to 1.13, $P < 0.001$, $I^2 = 89\%$, 8 RCT, $n = 472$, Fig. 11).

Ten studies [2, 36, 40, 43, 44, 46, 50, 61, 63, 64] disclosed the results of the 6MWT, assessing walking ability in patients. Comparing the results of the RT group alone to the CR group, there was no discernible difference (MD = 24.87, 95% CI = −45.99 to 95.73, $P = 0.49$, $I^2 = 67\%$, 3 RCT, $n = 168$, Fig. 12). The CR plus RT group outperformed the CR group (MD = 63.98, 95% CI = 35.50 to 92.45, $P < 0.001$, $I^2 = 99\%$, 7 RCT, $n = 446$, Fig. 13).

Sensitivity analysis

The total effect did not change significantly when we switched from the fixed-effects model to the random-effects model. The findings of the investigations were also proven to be stable by sensitivity analysis (metaninf) using STATA software. Figs. S1-3 displays the findings of the sensitivity analysis.

Meta-regression analysis and subgroup analyses

Patient's lower limb motor function (FMA)

A meta-regression study revealed that heterogeneity was significantly influenced by sample size and publication year ($P < 0.05$, see Table S1). The results of subgroup analysis are shown in Figs. S4-5, which can also prove the

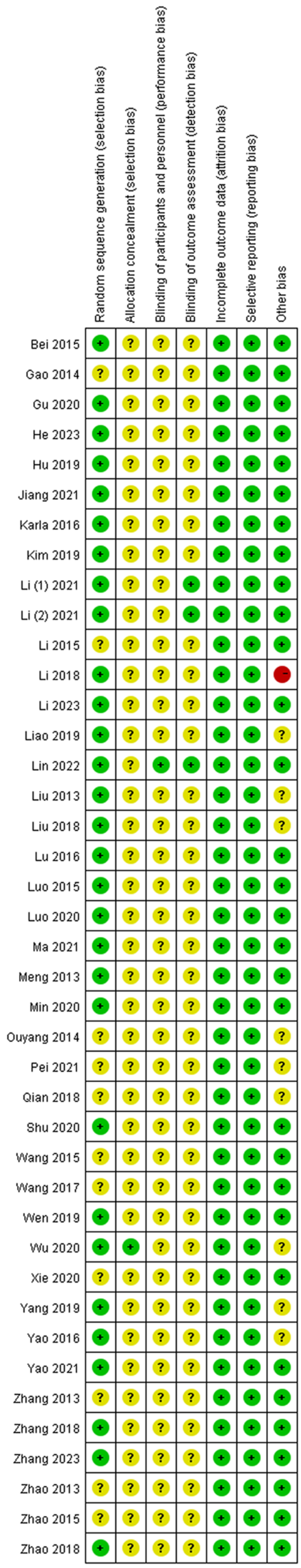

Fig. 3 Risk of bias summary

influence of sample size and publication years on result heterogeneity to a certain extent.

Patient's ability to balance (BBS)
The results of a meta-regression study showed that the treatment duration, sample size, and publication year had no bearing on heterogeneity.

Patients' activities of daily living (MBI)
The primary cause of heterogeneity, according to a meta-regression analysis, appeared to be the year of publication ($P<0.05$, see Table S1). But according to subgroup analysis, publication years did not significantly affect heterogeneity (Figs. S6-7). Our findings should therefore be interpreted cautiously.

Patient's walking ability (FAC)
We were unable to perform meta-regression to investigate the cause of heterogeneity since there were not enough studies ($n<10$).

Patient's walking ability (6WMT)
A meta-regression analysis was not conducted because there were not enough studies ($n<10$).

Publication bias

Patient's lower limb motor function (FMA)
The funnel plot is not completely symmetric. The Egger' test suggested that there may exist publication bias ($P=0.001$). The funnel plot is shown in Supplemental Fig. S8.

Patient's ability to balance (BBS)
The Egger' test suggested that there was no publication bias ($P=0.155$). Funnel plot is shown in Supplemental Fig. S9.

Patients' activities of daily living (MBI)
According to the Egger's test, there was no publication bias ($P=0.848$). Funnel plot is shown in Supplemental Fig. S10.

Patient's walking ability (FAC)
No publication bias was performed due to insufficient number of studies ($n<10$).

Patient's walking ability (6WMT)
No publication bias was performed due to insufficient number of studies ($n<10$).

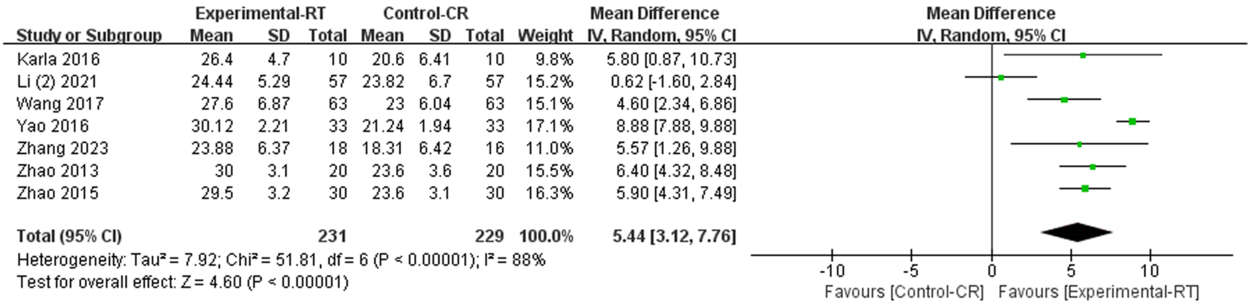

Fig. 4 Forest plot for FMA: alone RT vs. CR. (MD = 5.44, 95% CI = 3.12 to 7.76, $P < 0.001$, $I.^2 = 88\%$, 7 RCT, $n = 460$)

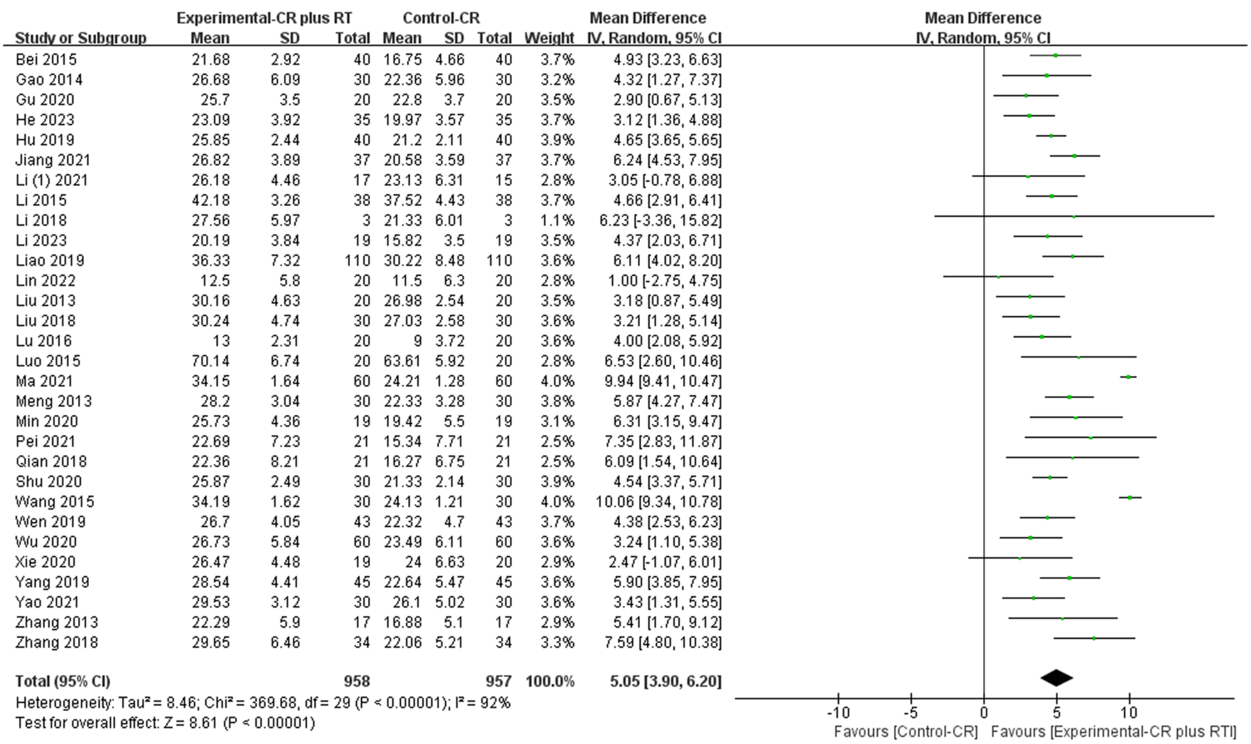

Fig. 5 Forest plot for FMA: CR plus RT vs. CR. (MD = 5.05, 95% CI = 3.90 to 6.20, $P < 0.001$, $I.^2 = 92\%$, 30 RCT, $n = 1915$)

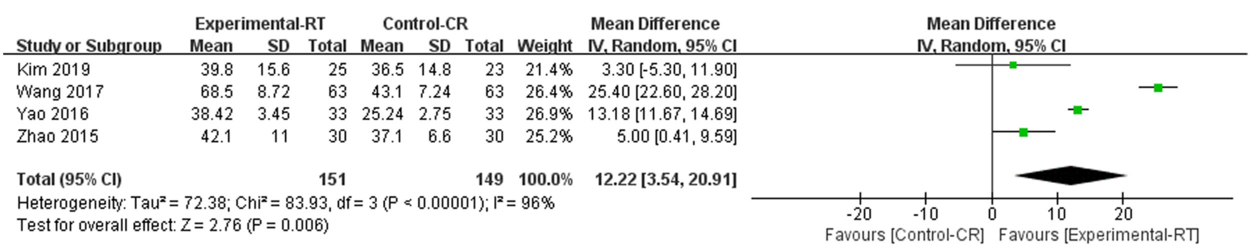

Fig. 6 Forest plot for BBS: alone RT vs. CR. (MD = 12.22, 95% CI = 3.54 to 20.91, $P < 0.001$, $I.^2 = 96\%$, 4 RCT, $n = 300$)

Discussion

This study extracts the mean difference and standard deviation of each study to analyze the rehabilitation effect of the lower limb rehabilitation robot to achieve consistent results. This systematic review and meta-analysis indicated that CR plus RT group had more significant improvements than CR group in lower limb motor function, balance ability, walking ability, and daily living

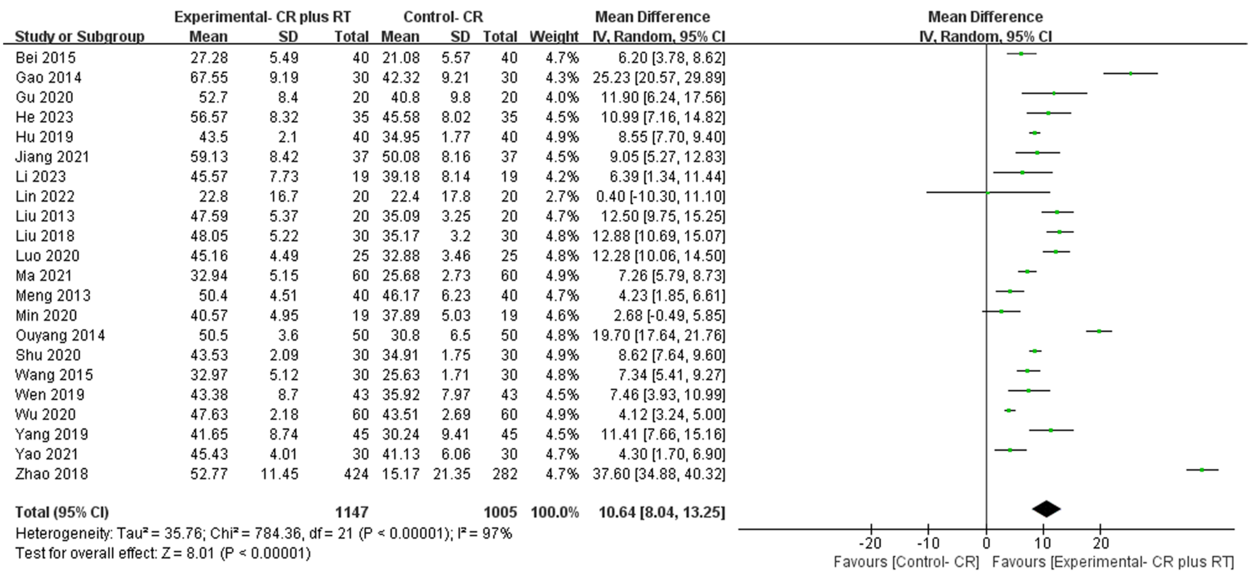

Fig. 7 Forest plot for BBS: CR plus RT vs. CR. (MD = 10.64, 95% CI = 8.04 to 13.25, $P < 0.001$, $I^2 = 97\%$, 22 RCT, $n = 2152$)

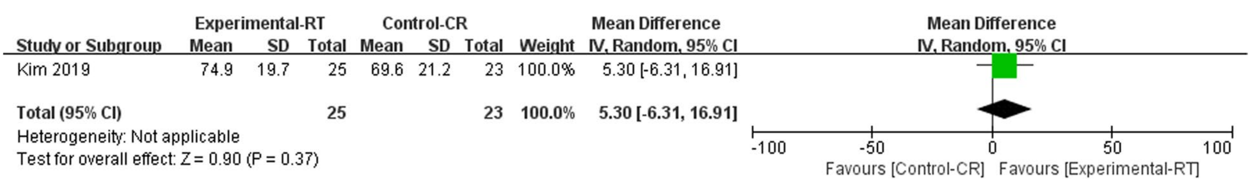

Fig. 8 Forest plot for MBI: alone RT vs. CR. (MD = 5.30, 95% CI = –6.31 to 16.91, $P = 0.37$, 1 RCT, $n = 48$)

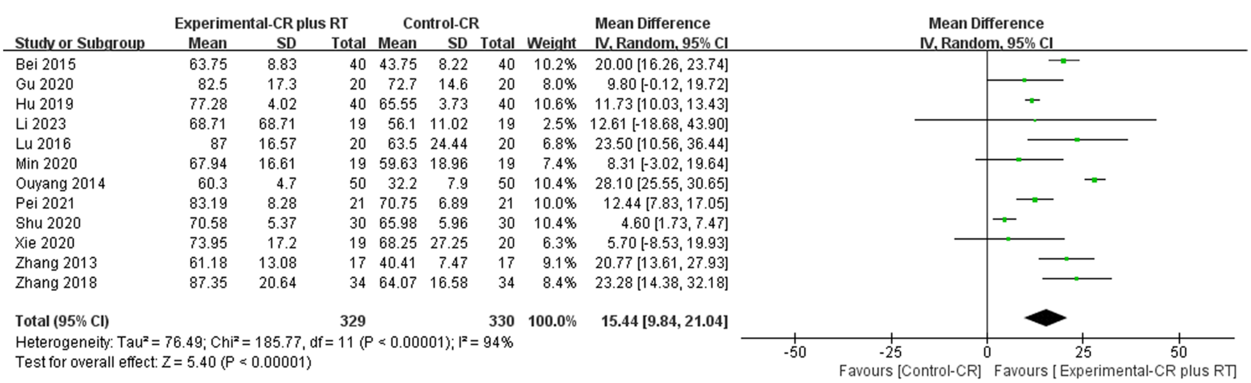

Fig. 9 Forest plot for MBI: CR plus RT vs. CR. (MD = 15.44, 95% CI = 9.84 to 21.04, $P < 0.001$, $I^2 = 94\%$, 12 RCT, $n = 659$)

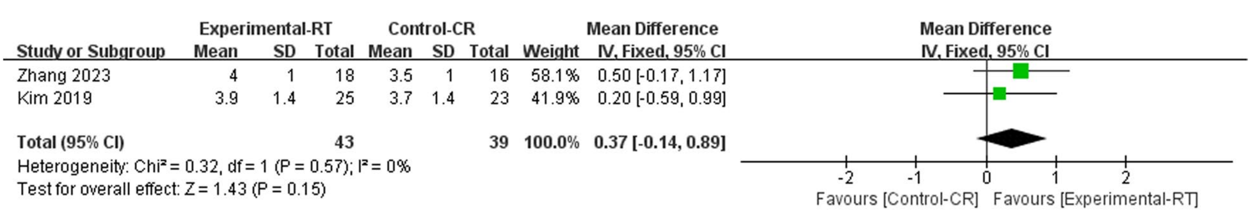

Fig. 10 Forest plot for FAC: alone RT vs. CR. (MD = 0.37, 95% CI = –0.14 to 0.89, $P = 0.15$, 2 RCT, $n = 82$)

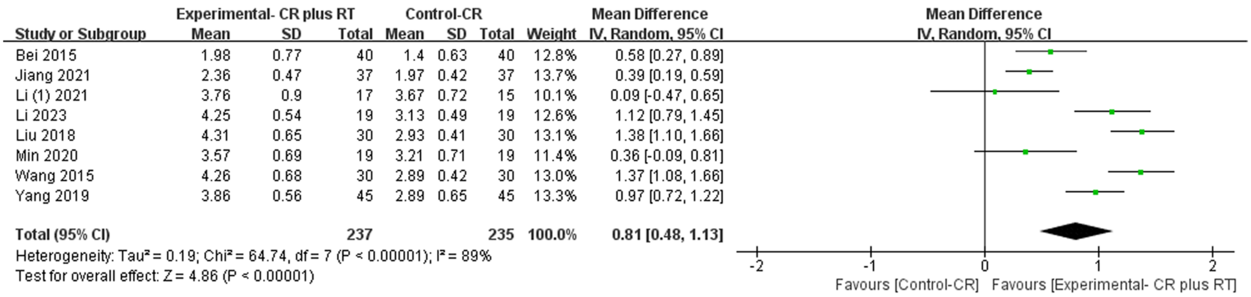

Fig. 11 Forest plot for FAC: CR plus RT vs. CR. (MD = 0.81, 95% CI = 0.48 to 1.13, $P < 0.001$, $I^2 = 89\%$, 8 RCT, $n = 472$)

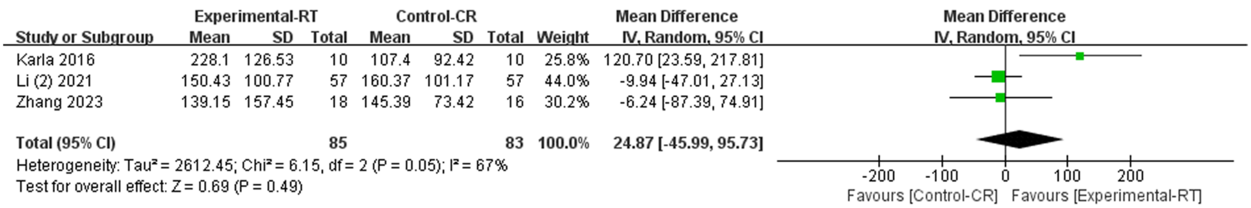

Fig. 12 Forest plot for 6MWT: alone RT vs. CR. (MD = 24.87, 95% CI = −45.99 to 95.73, $P = 0.49$, $I^2 = 67\%$, 3 RCT, $n = 168$)

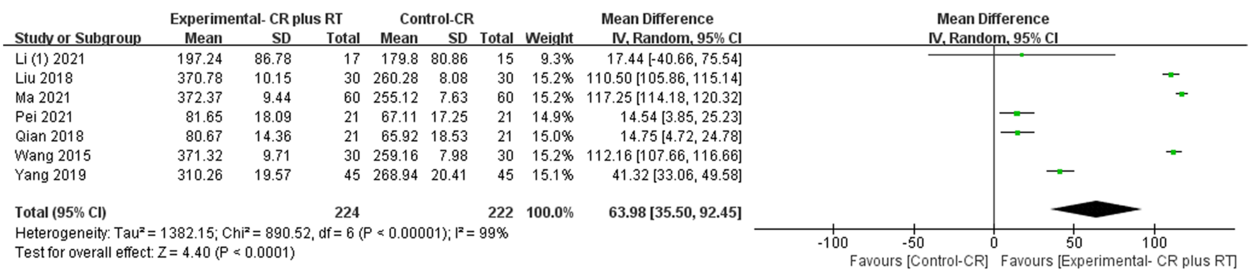

Fig. 13 Forest plot for 6MWT: CR plus RT vs. CR. (MD = 63.98, 95% CI = 35.50 to 92.45, $P < 0.001$, $I^2 = 99\%$, 7 RCT, $n = 446$). Note: alone RT vs. CR: experimental group= rehabilitation robot; control group= conventional rehabilitation. CR plus RT vs. CR: experimental group= CR+rehabilitation robot; control group=conventional rehabilitation

abilities. We discovered that while the FMA and BBS scores of RT group were higher than the CR group's, the scores of FAC, MBI, and 6MWT were not superior to the CR group. In summary, we found that the emergence of lower limb rehabilitation robots has had a positive impact on post-stroke hemiplegic patient, and CR combined with RT intervention is more conducive to the recovery of their motor functions.

Compared with previous studies [66, 67], this study searched more comprehensive and updated databases. Additionally, the research objectives and outcome indicators assessed were not entirely the same as before. Previous meta-analysis results have shown that lower limb exoskeleton robots can improve the primary outcome measures of lower limb rehabilitation in stroke patients—FMA and BBS scores and step frequency. However, the scores of FAC and 6MWT did not significantly improve [68]. This review used FMA, BBS, MBI, FAC and 6MWT as outcome indicators. This is because lower limb motor dysfunction is a primary problem in hemiplegic patients after stroke. Walking is a periodic coordinated movement between multiple joints and muscle groups in the human body, which requires sufficient weight-bearing capacity and balance function. Enhancing balance function is crucial for walking since it is directly linked to the capacity to carry out everyday tasks [69, 70]. The study's findings demonstrated that CR combined with RT training can promote and regain patients' motor function more effectively than training with RT by itself. Traditional rehabilitation training is effective, and combined with rehabilitation robot training can restore the patient's motor functions better and faster. Li et al. [71] revealed that FAC levels and walking test scores of patients in the observation group after intervention were significantly better than those in the CR group. This is consistent with our study results, suggesting that the combined use of

RT and CR therapy is more beneficial to the rehabilitation of patients with functional impairments. In addition, some researchers conducted exoskeleton robot training on stroke patients and found that the patients' walking speed and functional walking level were also significantly improved [72]. Similar results have been found in the rehabilitation of other neurological injuries. For example, Huang et al. [17] applied lower limb rehabilitation robotic technology to evaluate the motor function of patients after spinal cord injury. The results showed that the 6MWT, BBS, and FMA scores of the observation group after the intervention were better than those of the control group. However, the difference in MBI scores following the intervention was not significant, confirming its positive role in improving patients' walking function and balance function.

According to the results of meta-analysis, the heterogeneity of this study was large. We explore the possible reasons for the large heterogeneity from the perspective of PICO. First of all, in terms of subjects, the sample size included in the study is relatively small, and there may be bias; the subjects have different age, gender, and severity of onset, which may also have a certain impact on the results. Secondly, in terms of intervention measures, different manufacturers and types of lower limb robots used by different research societies, and differences in the intensity, frequency, and duration of treatment may also lead to heterogeneity in the results. As far as the control group is concerned, although conventional rehabilitation treatment is carried out, there are still differences in the implementation of rehabilitation treatment. Furthermore, different assessment tools are also a potential source of heterogeneity. We further verified the robustness of the research results through sensitivity analysis and found that although heterogeneity existed, the main conclusions were not significantly affected. Meta-regression analysis and subgroup analysis found that sample size and publication year might be the main sources of heterogeneity. Generally speaking, the larger the sample size, the more reliable the results and the more they demonstrate the efficacy of lower limb robotics for rehabilitation, and vice versa. However, most of the studies included in this review have relatively small sample sizes, and the results have certain limitations. The heterogeneity caused by the year of publication may be due to the fact that with the passage of time, lower limb rehabilitation robot technology has become increasingly mature, and patients' lower limb motor function and balance function have also improved significantly. We chose these two methods for the following reasons: meta-regression analyses could analyze the sources of heterogeneity of multiple factors at the same time. And subgroup analysis, by grouping these factors, allowed for a more intuitive comparison of the differences in effect values between subgroups, revealing the role of these factors under different conditions. The final results were also shown to be similar. The combination of these two methods is scientifically feasible and allows for a more comprehensive exploration of the sources of heterogeneity. In addition, these variables were selected based on the characteristics of the data from the included studies with reference to similar studies.

Lower limb rehabilitation robots come in different models and manufacturers, divided into end-effector robots and exoskeleton robots, but due to insufficient data, this study did not perform subgroup analysis on it. Lower extremity exoskeleton robots can provide support for strength-deficient patients during motion training and promote normal gait. Moreover, exoskeleton-based rehabilitation therapy can objectively and continuously monitor patient's performance and progress [73, 74]. End-effector robot training is effective in improving patient's lower limb strength, balance ability, and endurance [75]. In comparison, exoskeleton robots require more time for patients to wear [62]. Bertani et al. [76] found that compared to CR, end-effector robots seem to be more beneficial for improving post-stroke limb movement disorders. Previous studies investigated exoskeletons or end-effectors for stroke patients, indicating that robot-assisted gait training combined with physical therapy and body weight support training appears to be an effective intervention for post-stroke gait recovery [77]. This is consistent with our findings.

This review has several limitations. First, the quality of the included studies is generally low, and specific reasons need further analysis. Most studies did not explicitly describe randomization, blinding, or allocation concealment, so we could not accurately judge whether the authors performed these steps. Future clinical trial designs should be more rigorous, and the quality of research should be continuously improved. Second, meta-regression analysis and subgroup analysis found that sample size and publication year were possible sources of heterogeneity. However, some sources of high heterogeneity remain undiscovered. Moreover, since most studies did not accurately describe the time since onset and the authors could not be contacted, these factors were not included in the analysis. Finally, we included studies in Chinese or English, so the risk of missing data is inevitable.

In conclusion, lower limb rehabilitation robots represent a highly advanced rehabilitation treatment method and a new technology for improving clinical outcomes and reducing healthcare costs. Their repetitiveness and high intensity make the training more sustained [78]. The combination of lower limb robots with traditional rehabilitation therapy can further improve the lower limb motor function, balance, and ADL abilities of patients with post-stroke hemiplegia, thereby enhancing their quality of life. The promotion and use of lower limb robots provide a new option for the rehabilitation of lower limb dysfunction in hemiplegic patients.

Conclusion

The results of this study show that the use of RT combined with CR therapy can better improve the lower limb motor function of patients. However, methodological flaws in previous studies have led to the need for higher quality and larger studies to confirm its potential benefits for future rehabilitation of patients with hemiplegia.

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Patient and public involvement
No patient involved.

Authors' contributions
Conceptualization: TZ, ZL. Data curation: QH, JW. Formal analysis: QH, JW, YT. Funding acquisition: TZ. Investigation: QH, YT. Methodology: QH, JW. Project administration: TZ, ZL. Resources: QH, JW. Software: QH, JW. Supervision: TZ, ZL. Writing – original draft: QH. Writing – review & editing: MQ, JW, YT, TZ, ZL.

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Data availability
Not applicable.

Declarations

Ethics approval and consent to participate
Since this systematic review and meta-analysis are based on published studies, ethical approval and patient consent are not required.

Consent for publication
Not applicable.

Competing interest
The authors declare no conflict of interest.

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