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# Effectiveness of lower limb robotic rehabilitation on peak of oxygen uptake among patients with stroke: a systematic review and meta-analysis

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## ABSTRACT

**Objectives** To evaluate the effectiveness of lower limb robotic rehabilitation (LLRR) on cardiovascular health among individuals with stroke undergoing rehabilitation.
**Design** Systematic reviews and meta-analysis.
**Data sources** PubMed, Web of Science, Science Direct, Embase, China National Knowledge Infrastructure, Wangfang and VIP databases were searched from inception to 9 October 2023.
**Eligibility criteria** Randomised controlled trials (RCTs) involving LLRR among individuals with stroke were included. We considered the potential impact of LLRR on the resting heart rate (HRrest), peak of oxygen uptake ($VO_2$peak), peak of systolic blood pressure (SBPpeak) and peak of diastolic blood pressure (DBPpeak). Only studies published in Chinese or English were included.
**Data extraction and synthesis** Two reviewers independently extracted data and assessed the risk of bias. Results were reported as Hedges' g with 95% CIs. Meta-analyses were performed using a random effects model in STATA v17.0. The study was reported in compliance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.
**Results** Five RCTs with 179 patients were included in the meta-analysis. According to the Guideline Development Tool results, half of the evidence grades were moderate. The results of the meta-analysis showed that there were significant differences among robotic rehabilitation group than the control group in $VO_2$peak (standard mean difference (SMD): 0.71, 95% CI: (0.28, 1.13), p<0.001, $I^2$=45.61%), but insignificant difference found in HRrest (SMD: 0.30, 95% CI: (−0.12, 0.73), p=0.16, $I^2$=34.25%), SBPpeak (SMD: 0.04, 95% CI: (−0.44, 0.52), p=0.86, $I^2$=28.75%) and DBPpeak (SMD: 0.46, 95% CI: (−3.82, 4.73), p=0.83, $I^2$=0.00%). No significant heterogeneity was found among articles. The risk of bias assessment revealed that two studies showed low bias in most domains.
**Conclusion** Individuals undergoing stroke rehabilitation may benefit from LLRR with improved $VO_2$peak but insignificantly impacted HRrest, SBPpeak and DBPpeak.
**PROSPERO registration number** CRD42022382259.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The studies included in this systematic review and meta-analysis are randomised controlled trials (RCTs).
⇒ This study will be the first meta-analysis to evaluate the effectiveness of lower limb robotic rehabilitation on cardiopulmonary function among people with stroke.
⇒ Only five RCTs are included in this meta-analysis, all with a relatively small sample size.

## INTRODUCTION

Stroke causes high morbidity, mortality, disability and heavy disease burden worldwide.[1] According to the Global Burden of Disease report, there are an estimated 12.2 million patients with stroke all over the world, resulting in 143 million disability-adjusted life years and 6.55 million deaths.[2] Stroke is one of the leading causes of motor dysfunction,[3] especially lower limb dyskinesia. Lower limb dyskinesia is a common dysfunction in patients with stroke, which seriously affects their physical and mental health.[4] Traditional rehabilitation approaches, such as occupational therapy, physical therapy and other rehabilitation approaches, are well-known in the field of stroke rehabilitation.[5] Although traditional rehabilitation mostly depends on the clinical skill of a therapist. However, lower limb robotic rehabilitation (LLRR) opens up a new era in the field of post-stroke rehabilitation due to its wide application methods and success rate.[6 7]

The LLRR mainly focuses on improving post-stroke gait,[8] balance[9] and motor function.[10] Studies showed that patients with stroke who received early robot-assisted gait training got better at achieving independent walking than those who received only conventional gait training.[11] In addition to hemiplegia, patients with stroke are prone to decreased cardiovascular health and poor endurance. Based on the serious motor dysfunction of patients with stroke, how to improve the level of cardiovascular in patients is one of the urgent problems to be solved in clinical rehabilitation. Previous studies found that peak of oxygen uptake ($VO_2$peak) was lower in patients with stroke compared with age-matched healthy people.[12 13] However, peak exercise cardiac power output, cardiac output and the pressure-generating capacity of the heart are similar between stroke and healthy people.[14 15] A recent study has shown that robot training may have an effect on cardiopulmonary function in stroke patients.[16]

Although several studies focused on post-stroke robotic rehabilitation on cardiovascular health, no consistent conclusions have yet been drawn. For instance, Lee *et al*[17] suggested that robotic locomotor training was effective for improving cardiopulmonary function among patients with stroke, while another study showed that lower limb robot-assisted training just kept cardiopulmonary status stable without improving from pre-exercise states.[18] Furthermore, to our knowledge, no systematic review has been conducted to evaluate the effects of LLRR on cardiopulmonary function among people with stroke.

Therefore, the objective of this study is to evaluate the effectiveness of LLRR on cardiovascular parameters such as resting heart rate, peak oxygen uptake and blood pressure among patients with stroke.

## METHODS

This systematic review was reported following the Preferred Reporting Items for the Systematic Reviews and Meta-Analyses statement 2020.[19] This study was registered with the International Prospective Register of Systematic Reviews (PROSPERO) (CRD42022382259).

### Search strategy

We searched PubMed, Web of Science, Science Direct, Embase, China National Knowledge Infrastructure, Wanfang and VIP databases from inception to 9 October 2023 using the keywords 'stroke', 'robot' and 'randomised controlled trial'. Search terms were combined in each database using the Boolean operators 'AND' or 'OR'. In addition, the references list of the included studies was also hand-searched for inclusion. The search strategy is available in online supplemental material.

### Inclusion and exclusion criteria

The following inclusion selection criteria were used: (a) population: patients with stroke; (b) intervention: patients were treated by LLRR; (c) comparison: patients were treated by conventional rehabilitation therapy or other therapies except for the LLRR; (d) outcomes: the resting heart rate (HRrest, beats per minute), peak of oxygen uptake ($VO_2$peak, mL/kg/min), peak of systolic blood pressure (SBPpeak, mm Hg) and peak of diastolic blood pressure (DBPpeak, mm Hg); and (e) study design: randomised controlled trials (RCTs) to explore the effect of LLRR on cardiopulmonary function after stroke. The exclusion criteria were as follows: (a) letter, review, case report or comments; (b) studies with incomplete data that cannot be obtained from the authors; and (c) the language is not English or Chinese.

### Quality evaluation

Two reviewers independently assessed the methodological quality of the included RCTs[20] using the Cochrane Risk of Bias (RoB) Tool. Disagreements were resolved by discussion with a third reviewer. The RoB tool included seven aspects which were random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. Each of aspects was rated as having a low risk of bias, an unclear/some concern and high risk of bias. Additionally, the Grading of Recommendations, Assessment, Development and Evaluation Profile (GRADEpro) Guideline Development Tool (GDT) was used to assess the evidence grade.[21] This tool included five aspects: risk of bias, inconsistency, indirectness, imprecision and other considerations. The categories of recommendation level of evidence were as follows: (a) high: which means that further research is very unlikely to change our confidence in the effect estimate; (b) moderate: which means that further research is likely to play an important role in our confidence in the effect estimate and may change the estimate; (c) low: which means that further research is very likely to play an important role in our confidence in the effect estimate and to change the estimate; and (d) very low: which means that it is uncertain about any effect estimate. We used the online version of GRADEpro GDT[21] to complete evidence synthesis.

### Literature screening and data extraction

Two reviewers independently screened all of titles and abstracts and deleted duplicate and irrelevant studies. Two reviewers scanned the full text to determine whether the studies met the inclusion criteria. Two reviewers resolved disagreements about article inclusion through discussion with a third reviewer to reach a final consensus. Two reviewers completed the data extraction for the following characteristics of each study: author, publication year, sample size of patients in each group, mean age, intervention of each group and follow-up duration. The clinical outcomes included HRrest, SBPpeak, DBPpeak and $VO_2$peak. The effect size measure selected in this meta-analysis was the standard mean difference (Hedges' g).

### Statistical analysis

We used STATA v17.0 to perform meta-analysis using the random effect model. We calculated the Hedges' g and 95% CIs for continuous outcomes. The statistically significant value was a p value less than 0.05. If the $I^2$ value was more than 50%, the heterogeneity was large. It was necessary to perform sensitivity tests using residual monadic analysis to estimate the impact of the study results. A small $T^2$ value meant a small heterogeneity. Due to lack of required data and a small sample size, we did not analyse publication bias. Considering the non-uniform sample


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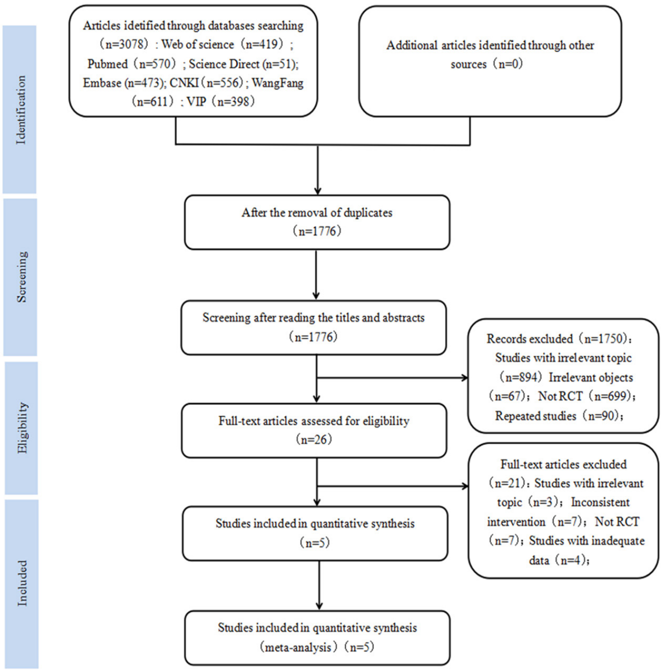


**Figure 1** Search results and the selection procedure.

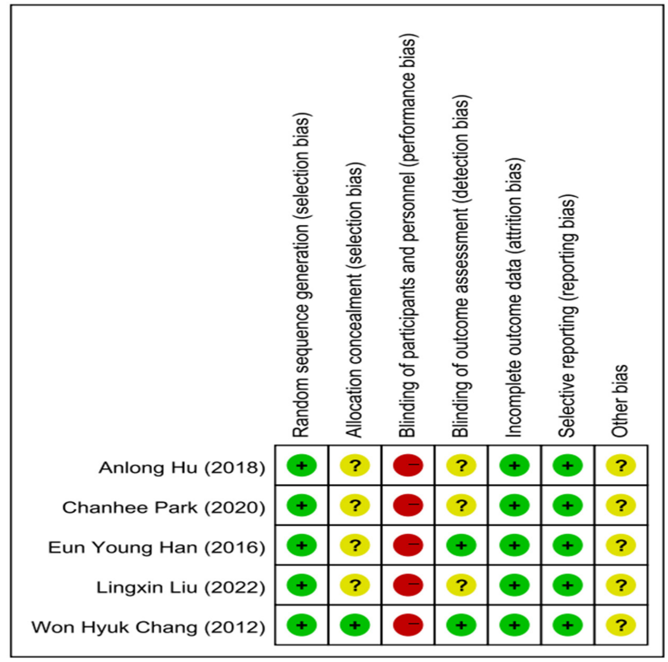


**Figure 2** Methodological quality of the randomised controlled trials.

size, the effects were pooled using a random effects model.

### Patient and public involvement

None.

## RESULTS

### Study characteristics

Of 3078 studies, five studies[22–26] met all inclusion criteria and were included in this systematic review (figure 1). Online supplemental table 1 summarises the main characteristics of all included studies. We calculated data from a total of 179 patients with stroke with mean age of 60.76, 111 (62.01%) male. The most common treatment programme was routine rehabilitation therapy in the conventional treatment group and routine rehabilitation therapy plus robot therapy in the intervention group. The conventional treatment group included sit-stand balance training, active transfer, sit-stand training, reinforcement exercises and so on. Lokomat,[25 26] GaitMotus,[22] Flexbot[24] and Walkbot[23] were used in the intervention group. Of five articles, four articles[23–26] compared the effectiveness of LLRR with conventional rehabilitation training, only one article[22] combined LLRR with respiratory training and conventional therapy and compared it with respiratory training alone as a control group. Four articles were reported on HRrest, four on $VO_2$Peak and two on blood pressure, with a follow-up period of 2 to 8 weeks.

### Risk of bias assessment

We assessed the quality of included RCTs according to the Cochrane RoB Tool (figure 2). According to RoB tools, five articles had a high risk of bias due to lacking blinding of patients and personnel, four articles had some concerns because of allocation concealment and blinding of outcome assessment, and five articles had a low risk in terms of random selection, incomplete outcome data and selection reporting (figure 3).

### Effect of LLRR on cardiovascular parameters in patients with stroke

From 139 patients with four RCTs,[23–26] we found that LLRR had no significant effect on HRrest improvement among patients with stroke (standard mean difference, SMD=0.30, 95% CI: −0.12 to 0.73, p=0.16, figure 4A.

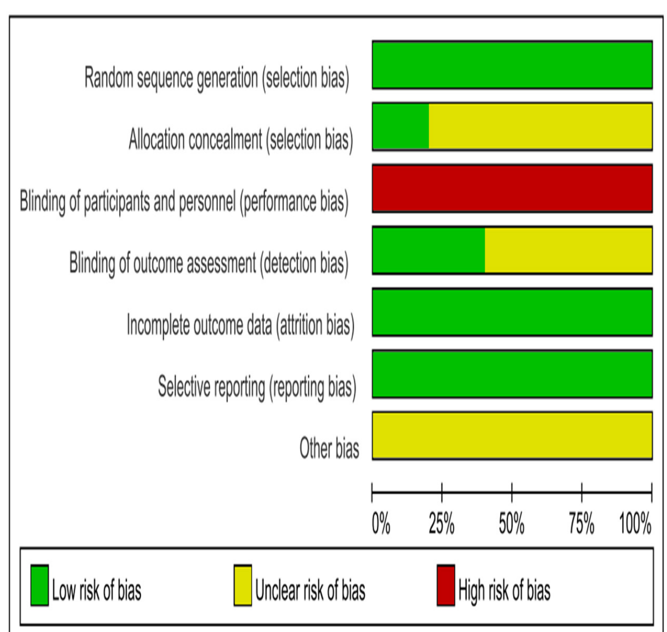


**Figure 3** Risk of bias.

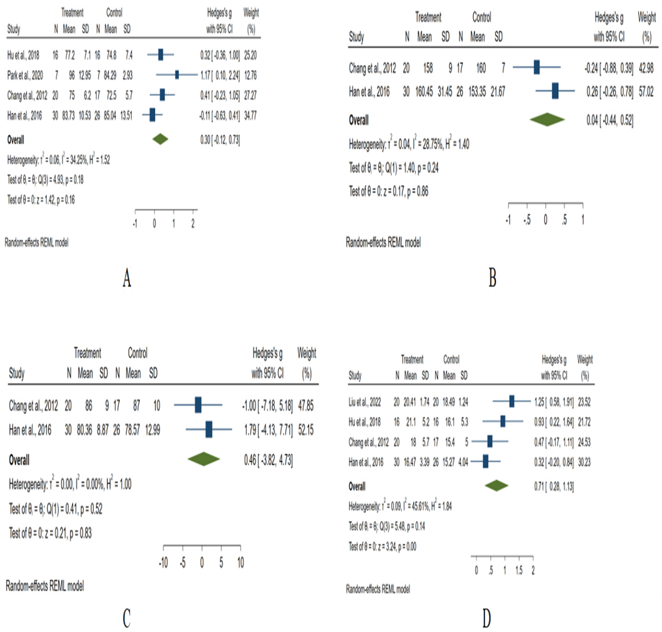


**Figure 4** Forest plot diagram showing HRrest (A), SBPpeak (B), DBPpeak (C) and VO2peak (D). DBPpeak, peak of diastolic blood pressure; HRrest, resting heart rate; SBPpeak, peak of systolic blood pressure; VO2peak, peak of oxygen uptake.

No significant heterogeneity was found among articles ($T^2$=0.06, $I^2$=34.25%, p=0.18).

Regarding SBPpeak of 93 patients from two articles,[25 26] we found that LLRR had no significant impact on the improvement of SBPpeak than the conventional treatment group (SMD=0.04, 95% CI: −0.44 to 0.52, p=0.86, figure 4B). No statistical heterogeneity was found among pooled studies ($T^2$=0.04, $I^2$=28.75%, p=0.24).

Two articles[25 26] investigating DBPpeak of 93 patients, among the LLRR group, there was not significant improvement in the control group (SMD=0.46, 95% CI: −3.82 to 4.73, p=0.83, figure 4C). There was no significant statistical heterogeneity ($T^2$=0.00, $I^2$=0.00%, p=0.52).

From 165 patients with four articles,[23–26] we found that LLRR significantly increased $VO_2$peak compared with the control group (SMD=0.71, 95% CI: 0.28 to 1.13, p<0.001, figure 4D), but no significant heterogeneity was found ($T^2$=0.09, $I^2$=45.61%, p=0.14) among studies.

### Evidence level and recommendation strengths

We evaluated the quality of evidence using GRADEpro GDT.[21] Considering the different LLRR used in the studies, the inconsistency of HRrest and $VO_2$peak was assessed as 'serious'. The results of the GDT showed that half of evidence grades were moderate due to the fact that the certainty assessment was not serious in terms of indirectness and imprecision. LLRR may have no significant effect on HRrest (SMD=0.30, 95% CI: −0.12 to 0.73), SBPpeak (SMD=0.04, 95% CI: −0.44 to 0.52) and DBPpeak (SMD=0.46, 95% CI: −3.82 to 4.73). The effect of LLRR on $VO_2$peak (SMD=0.71, 95% CI: 0.28 to 1.13) may be better than that of the conventional treatment group. Overall, the low or moderate level of evidence indicated that confidence in the effect estimate is likely to be changed by further research. Therefore, the result should be interpreted in clinical practice after a proper investigation of the patients' cardiovascular status and other vitals (online supplemental table 2).

## DISCUSSION

Regarding cardiopulmonary function after LLRR, insufficient evidence is a concern in clinical practice. Our study focused on some prime variables to assess cardiopulmonary function after LLRR, and we found that $VO_2$peak improved significantly, but HRrest, SBPpeak and DBPpeak remained unchanged. According to Pinna *et al*,[27] a change of more than 30% of between-subject standard deviation (SD-change) was considered the minimal clinically important difference. However, the results of this study found no minimal clinically important differences in $VO_2$peak (SD-change: 1.79% to 12.36%), HRrest (SD-change: 6.36% to 26.19%), SBPpeak (SD-change: 4.04% to 10.00%) and DBPpeak (SD-change: 0.11% to 18.18%) in the LLRR group. The $I^2$ of the pooled meta-analysis results of HRrest, SBPpeak, DBPpeak and VO2peak in this study was less than 50% and $T^2$ was small, indicating that the results of this meta-analysis were reliable.

LLRR had no significant effect on HRrest in patients with stroke (p>0.05), which was similar to the results of Qian Zhen *et al*.[28] LLRR improved patients' exercise endurance to a certain extent.[29] The improvement of exercise ability is conducive to the prognosis of stroke patients. Study has shown that HRrest (80~85 beats per minute) was associated with an increased risk of stroke and could also accelerate the progression of atherosclerosis by increasing vascular oxidative stress.[30] In future studies, it is recommended that the effect of LLRR in terms of HRrest be explored through high-quality RCTs in different stages of post-stroke patients.

The intervention of LLRR showed no significant effect in improving the SBPpeak (p>0.05) and DBPpeak (p>0.05). Another study[31] also showed similar results. One reason of our results could be that our study included two studies on SBPpeak and DBPpeak, and the number of studies was too small. It is suggested that a large sample and multicentre RCT study be carried out in the future to verify the effect of blood pressure further. Exercise makes the heart and vascular system work more efficiently, promoting blood circulation and increasing the tolerance and elasticity of the heart muscle, thereby improving blood pressure. We suspect that the reason the results are not significant may be that LLRR training is usually low to moderate intensity and is designed to gradually improve blood circulation[32] rather than drastically change blood pressure.

In this review, the intervention of LLRR increased $VO_2$peak in patients with stroke compared with controls (p<0.05). This finding supported the basic principle of


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conventional rehabilitation supplemented with LLRR training on cardiovascular and exercise endurance in patients with stroke.[22] The main reason is that LLRR promoted cardiomyocyte remodelling, which enhances diastolic function and improves blood pumping function in patients with stroke.[33] Another reason is that LLRR increases oxygen intake and lactate threshold,[34] which can improve the aerobic metabolism capacity of the body and increase the exercise endurance of patients with stroke. Hence, the LLRR is more likely to help patients with stroke to achieve better functional outcomes. Moreover, we found no minimal clinically important difference in $VO_2$peak, which may be related to the fact that the sample size was too small to find clinical significance. It is suggested that a large sample study should be conducted in the future to explore the minimal clinical important difference of $VO_2$peak.

### Limitations

Several study limitations need to be noted. First, only five RCTs were included in this meta-analysis, all with a relatively small sample size. Second, only English and Chinese studies were included, which may lead to possible publication bias. Third, this study did not include studies with enough information, which may have an impact on the results of the meta-analysis. Therefore, more and better studies are needed in the field to validate the conclusions further.

### Implications for future research

To the best of our knowledge, this is the first meta-analysis to explore the efficacy of LLRR on cardiovascular in patients with stroke. This study contributes to current knowledge by obtaining conclusions about the effectiveness of LLRR on $VO_2$peak in patients with stroke. In addition, this study recommends more and more research to pay attention to the influence of LLRR on cardiovascular, which is conducive to further improving cardiovascular health for patients with stroke.

## CONCLUSION

Individuals undergoing stroke rehabilitation may benefit from LLRR with improved $VO_2$peak but insignificantly impacted HRrest, SBPpeak and DBPpeak.

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**Contributors** YW drafted the protocol; YW and JL contributed in searching and extracted and analysed data; YW and MM wrote the manuscript. Supervision: JZ and SW. All authors reviewed and approved the final version. SW acted as guarantor.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** Not applicable.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** All data relevant to the study are included in the article or uploaded as supplementary information.



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