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Original Article

The Effect of Robot-Assisted Training on Arm Function, Walking, Balance, and Activities of Daily Living After Stroke: A Systematic Review and Meta-Analysis

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HIGHLIGHTS

- We used a top-down approach to reduce the heterogeneity of the results of meta-analyses and used it to determine the methodology for literature selection and statistical analysis.
- In the results of meta-analysis, we found that RAAT had significant superiority over CT in improving arm function (standardized mean difference [SMD], 0.63; 95% confidence interval [CI], 0.37–0.88; $p < 0.001$; $I^2 = 84\%$) and ADL (SMD, 0.24; 95% CI, 0.05–0.43; $p = 0.010$; $I^2 = 27\%$).
- Through results of the meta-analysis, we found that RAGT, had a significant superiority over CT in improving balance (MD, 2.47; 95% CI, 0.41–4.53; $p = 0.020$; $I^2 = 50\%$), but no significant superiority was identified in improving gait function (SMD, 0.22; 95% CI, −0.07 to 0.52; p 0.140; $I^2 = 38\%$) and ADL (SMD, 0.17; 95% CI, −0.04 to 0.38; $p = 0.11$; $I^2 = 0\%$).

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The authors have no potential conflicts of interest to disclose.

Author Contributions
Conceptualization: Yoo SD, Lee HH; Data curation: Yoo SD, Lee HH; Formal analysis: Yoo SD, Lee HH; Investigation: Yoo SD, Lee HH; Methodology: Yoo SD, Lee HH; Project administration: Lee HH; Resources: Yoo SD,

ABSTRACT

This meta-analysis aimed to compare the effects of robot-assisted training (RAT) with those of conventional therapy (CT), considering the potential sources of heterogeneity in the previous studies. We searched three international electronic databases (MEDLINE, Embase, and the Cochrane Library) to identify relevant studies. Risk of bias assessment was performed using the Cochrane's Risk of Bias 1.0 tool. The certainty of the evidence was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluations method. The meta-analyses for each outcome of the respective domains were performed using 24 randomized controlled trials (RCTs) on robot-assisted arm training (RAAT) for arm function, 7 RCTs on RAAT for activities of daily living (ADL), 12 RCTs on robot-assisted gait training (RAGT) for balance, 6 RCTs on RAGT for walking, and 7 RCTs on RAGT for ADL. The random-effects model for the meta-analysis revealed that RAAT has significant superiority over CT in improving arm function, and ADL. We also showed that RAGT has significant superiority over CT in improving balance. Our study provides high-level evidence for the superiority of RAT over CT in terms of functional recovery after stroke. Therefore, physicians should consider RAT as a therapeutic option for facilitating functional recovery after stroke.

Keywords: Robotics; Upper Extremity; Lower Extremity; Recovery of Function; Stroke Rehabilitation

INTRODUCTION

Stroke is the primary cause of death and long-term disability worldwide in stroke survivors [1-3]. A significant proportion of stroke survivors have limited use of the affected upper and lower limbs. According to previous studies, upper limb deficits persist for 6 months after stroke onset in 30%–66% of patients with hemiplegia [4,5]. Cohort studies have revealed that 22% of patients with stroke do not regain walking ability [6]. Therefore, restoring the function of the affected upper and lower limbs after a stroke is of clinical importance.

Lee HH; Software: Lee HH; Supervision: Lee HH; Visualization: Lee HH; Writing - original draft: Lee HH; Writing - review & editing: Yoo SD, Lee HH.

Robot-assisted training (RAT) enables highly repetitive, adaptive, quantifiable, and task-specific training with feedback for enhancing brain neuroplasticity [7,8]. RAT may also have an advantage over conventional therapies (CTs) due to its potential to motivate patients [9]. Several previous meta-analyses have demonstrated that robot-assisted arm training (RAAT) is significantly more effective than nonrobotic therapy and therapist-mediated training in restoring upper extremity function, strength, and performance in activities of daily living (ADL) after stroke [10-12]. Previous studies demonstrated that robot-assisted gait training (RAGT) have positive effects on gait speed, gait independence, and balance recovery after stroke [13-15]. Therefore, RAT for restoring upper and lower limb motor deficits and subsequent functional decline following stroke has been applied worldwide in clinical settings [16]. In accordance with accumulated evidence of the therapeutic effectiveness of RAT, the Health Insurance Review and Assessment Service in South Korea has, as of February 2022, established a selective health benefit for RAGT in patients with stroke and gait disturbance above a certain level.

However, the results of the meta-analyses presented in the aforementioned studies exhibited a high level of heterogeneity [10,12-15,17], making it difficult to generalize the effect of RAT. Therefore, in this study, we aimed to compare the effects of RAAT and RAGT with those of CT through a meta-analysis, considering the potential sources of heterogeneity among studies that demonstrated the effectiveness of RAT.

MATERIALS AND METHODS

The protocol used in this study was determined before performing meta-analyses as a part of the development of the Clinical Practice Guideline for Stroke Rehabilitation in Korea. Part 1: Rehabilitation for Motor Function (2022) [18]. The protocol was not registered on a formal registration website.

Strategies to minimize the heterogeneity of meta-analysis results and draw generalized statements about the effectiveness of RAT

To reduce the heterogeneity in the results of meta-analyses that confirm the effectiveness of RAT, we propose the following conditions that the meta-analysis should meet: 1) RAT and CT should be dose-matched. 2) Exclude studies in which RAT was combined with interventions other than CT, such as interventions providing RAT in a virtual reality environment, were excluded, because the effectiveness of RAT alone could not be estimated by pooling the results of those studies. 3) Despite two Cochrane reviews confirming the effectiveness of RAT, including preliminary and pilot studies [14,17], we chose to include only randomized controlled trials (RCTs) because we assumed that including such studies could introduce heterogeneity into the results of the meta-analysis. Furthermore, since crossover RCTs may have potential drawbacks compared to parallel RCTs, such as carryover, period, and sequence effects and period-by-treatment interactions [19], we planned to select only parallel RCTs for the meta-analysis in this study. 4) As the form and technological level of robots evolve, older studies risk diluting the therapeutic effects of contemporary robots. Therefore, we conducted a meta-analysis of studies published after 2000.

To draw statements about the generalized effectiveness of robotic therapy from the results of the meta-analysis in this study, we considered the following: 1) inclusion of studies in which RAT was administered both alone and in conjunction with CT, 2) comprehensive inclusion of

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metrics for each of the following domains: arm function, balance, walking, and ADL, and 3) use of a random-effects model for the meta-analysis to deal with between-study variance [20] which reflects the heterogeneity of the environment in which the RAT is provided.

Literature selection

Search strategy

Utilizing previous meta-analyses and clinical practice guidelines [10-15,21,22], we identified and collected search terms presented elsewhere [18]. Six information search experts conducted a literature search using three overseas databases: the PubMed (https://pubmed.ncbi.nlm.nih.gov/), EMBASE (http://embase.com), and Cochrane Library (http://cochranelibrary.com). We conducted a comprehensive literature search for articles published before February 28, 2022. Literature selection was based on the preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement, which is presented in **Fig. 1**. The search was limited to articles published in English.

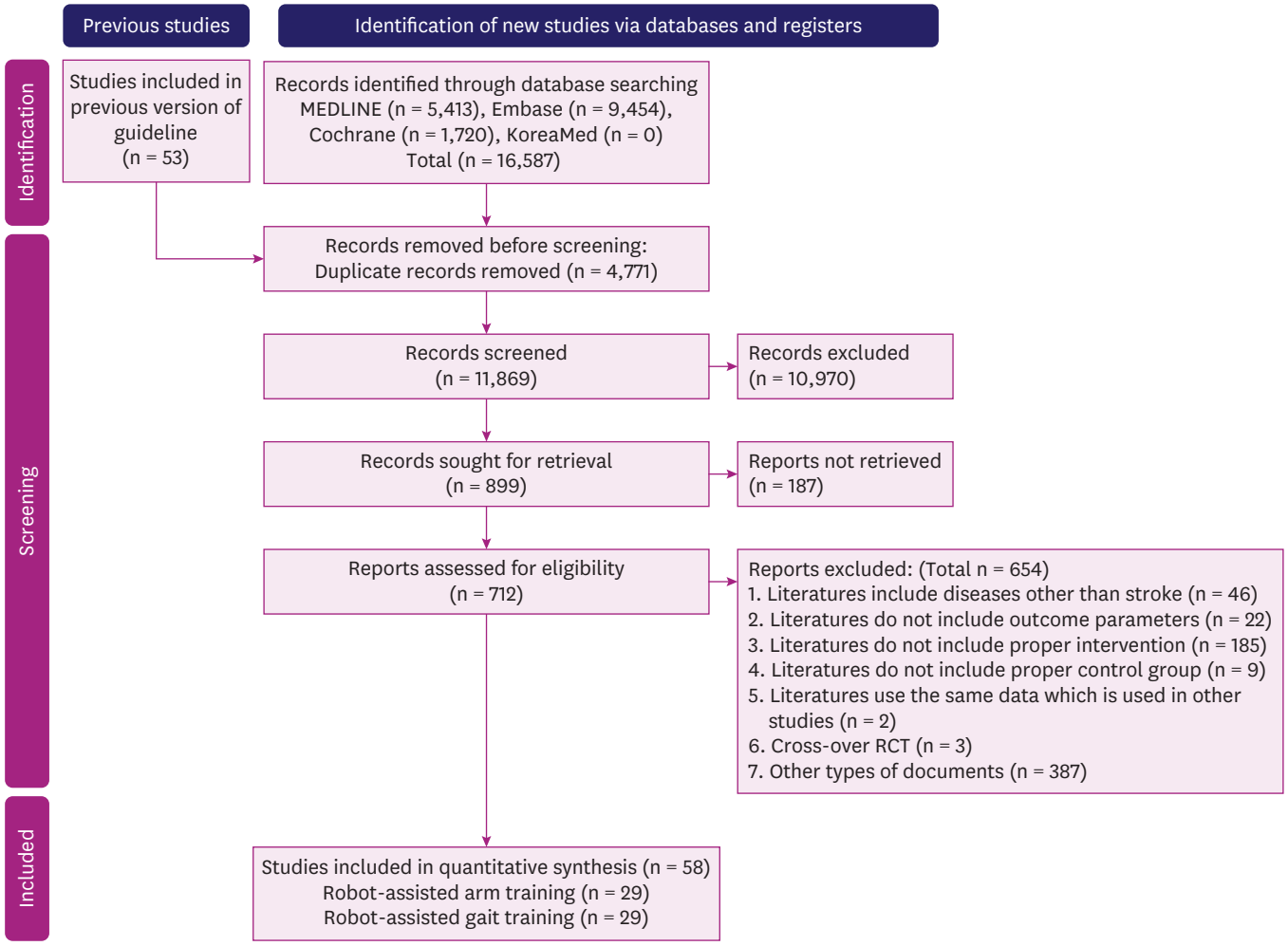

Fig. 1. PRISMA flow chart.

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Inclusion and exclusion criteria

Two reviewers (Y.S.D and L.H.H) independently reviewed the screened literature using our own Population, Intervention, Comparison, Outcomes and Study (PICOS) framework, which reflected the above strategies.

Population: We selected studies that enrolled patients with stroke onset age of 18 years and older and upper or lower limb dysfunction due to stroke.

Intervention: We defined RAT as "the application of electronic and computerized control systems to mechanical devices designed to assist human functions in rehabilitation," which was used in a previous study [10].

Comparison: RAT (add-on or alone) vs. CT

We set the conditions for comparability between interventions as follows: 1) the duration of therapy provided in the RAT and CT groups should be the same and 2) in studies where RAT is provided as an add-on therapy, treatments other than RAT in the experimental group must have the same form as those in the CT group, and the total duration of therapy in the RAT group should be the same as that in the CT group.

Outcome: We included studies that assessed each of the following domains using relevant endpoints: arm function, balance, walking, and ADL.

1) Arm function: Manual Function Test, Fugl-Meyer Assessment, Box and Block Test, Action Research Arm Test, Wolf Motor Function Test, and 9-Hole Peg Test
2) Balance: Berg Balance Scale
3) Walking: 10 Meter Walk Test, gait speed (average or maximum, m/s), 6 Minute Walk Test
4) ADL: Functional Independence Measure, Barthel Index, Modified Barthel Index, Korean version of the Modified Barthel Index, Frenchay Activities Index, Frenchay Arm Test, and Motor domain of Functional Independence Measure

We did not use outcomes obtained through patient-reported or subjective measures, which pose a potential risk of bias in the meta-analysis. Because numerous factors can influence the long-term effects of an intervention, we included studies with functional outcomes immediately after the intervention as the primary endpoint.

Study design: parallel RCT

As stated previously, we did not include studies that combined RAT with other interventions such as virtual reality and functional electrical stimulation. Two reviewers (Y.S.D, and L.H.H) independently screened potentially eligible studies by manually reviewing titles and abstracts, and assessed eligibility through full-text screening. Disagreements were resolved through discussion when necessary.

Risk of bias assessment

Two reviewers (Y.S.D and L.H.H) independently evaluated the methodological quality of the included RCTs using the Cochrane Risk of Bias 1.0 tool and resolved any disagreements by discussion.

Data extraction and transformation

If a study presented multiple outcomes for the same domain, we ranked the outcomes for each

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domain according to their order in the preceding list and used the highest-ranking outcome for the meta-analysis. The two reviewers reached mutual agreement on whether to use the post-intervention outcome or the difference in outcomes (calculated by subtracting the pre-intervention (baseline) outcome from the post-intervention outcome) for the respective domains (Y.S.D, and L.H.H). When the study did not directly provide the difference in outcome, we used the mean and standard deviation of both the post-intervention and pre-intervention (baseline) results to compute the mean and standard deviation of the outcome change, following the formula given in the Cochrane Handbook [23]. Studies with more than two intervention groups or if outcomes for continuous variables were not presented as means and standard deviations, they were converted to values to be pooled using a valid method, as described in the handbook. We excluded the studies in which no endpoints were obtainable for inclusion in the meta-analysis using the aforementioned procedure.

Assessment of certainty of evidence

The certainty of evidence was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) method [24] into high, moderate, low, or very low. We used five considerations (risk of bias, imprecision, inconsistency, indirectness, and publication bias) of the GRADE for the selected RCTs [24]. When evaluating the imprecision item in GRADE, we verified whether the total number of study participants in each domain met the criterion for optimal information size. Both authors independently performed the entire procedure and reached a consensus.

Statistical analysis

The previously outlined strategies were also embodied in our statistical analysis methodology. We conducted an intention-to-treat analysis in which all the participants who were initially randomized were included in the analyses according to the groups to which they were assigned. The effect of RAT on the outcomes of each functional domain was assessed using the pooled standardized mean difference (SMD). In cases in which a singular type of outcome was drawn for a particular domain, MD was used. To account for the variability between studies, we used a random-effects model to calculate the pooled SMD for the outcomes of each functional domain, along with their corresponding 95% confidence intervals. Defining an I^2 statistic ≥50 as statistical heterogeneity of the respective meta-analyses, following the same criteria as that of the previous study [10] and the Cochrane Handbook [23], we performed a subgroup analysis when the results of the meta-analysis showed statistical heterogeneity. We performed the subgroup analysis based on stroke chronicity, which was set at 3 months after onset, similar to the criterion in the Cochrane review [11,14]. While previous studies have performed subgroup analysis based on the type of robot and the part of the body trained [12], we did not perform further subgroup analysis to ensure the generalizability of the effects of the RAT and to avoid the risk of Type I error elevation due to multiple comparison. To evaluate the risk of publication bias in the results of the respective meta-analyses, we inspected the funnel plots for comparisons using more than 10 studies. The meta-analysis was performed using RevMan 5.2 (Nordic Cochrane Centre, Copenhagen, Denmark). The statistical significance was set at $p < 0.05$.

RESULTS

Based on the aforementioned criterion, we successfully identified 29 studies on the effectiveness of RAAT and RAGT. The results of the risk of bias assessment for the 58 studies

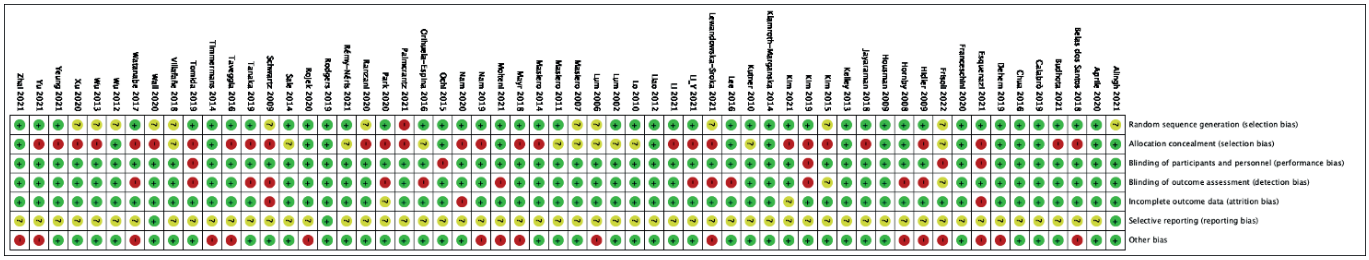

Fig. 2. Risk of bias summary for all selected literatures.

are presented in **Fig. 2**. We decided to use the changes in the arm function and ADL domain outcomes because we found significant differences in the baseline values of the outcomes between the two groups in the selected literature on RAAT. We also chose to use the change in outcome because there were notable differences in the baseline values for the balance and walking domains between the two groups in the selected literature on RAGT. The baseline values of the outcomes corresponding to the ADL domain were relatively homogeneous; therefore, we decided to use the post-intervention outcomes. After excluding studies that were rated as "high risk" in four or more domains of the risk of bias assessment and those that did not provide suitable endpoints for meta-analysis, we included 25 RAAT [25-49] and 16 RAGT [50-65] studies in the meta-analysis, which are detailed in **Supplementary Table 1**.

We found that RAAT had significant superiority over CT in improving arm function (SMD, 0.63; 95% confidence interval [CI], 0.37–0.88; $p < 0.001$; $I^2 = 84\%$) and ADL (SMD, 0.24; 95% CI, 0.05–0.43; $p = 0.010$; $I^2 = 27\%$) (**Figs. 3** and **4**). The meta-analysis of arm function showed a significant level of heterogeneity between studies, with an I^2 of 84%; therefore, we conducted a subgroup analysis based on the criterion of 3 months since stroke onset (**Fig. 5**). There were six studies that only recruited patients with stroke chronicity < 3 months, and the meta-analysis found a significant superiority (SMD, 0.41; 95% CI, 0.06–0.75; $p = 0.02$, $I^2 = 58\%$) of RAT over CT. There were 10 studies that only included patients with stroke chronicity > 3 months, and the meta-analysis also found a significant superiority of RAT over CT (SMD, 0.80; 95% CI, 0.26–1.33; $p = 0.004$, $I^2 = 84\%$), but the heterogeneity between studies was not resolved. In the meta-analysis of ADL, the heterogeneity between studies was low, with I^2 of 27%. The quality of evidence was judged to be 'high,' as there were no downgrades in the GRADE assessment for all outcome measures in each domain.

The meta-analysis revealed that RAGT had a significant superiority over CT in improving balance (MD, 2.47; 95% CI, 0.41–4.53; $p = 0.020$, $I^2 = 50\%$), but no significant superiority was identified in improving gait function (SMD, 0.22; 95% CI, -0.07 to 0.52; $p = 0.140$; $I^2 = 38\%$) and ADL (SMD, 0.17; 95% CI, -0.04 to 0.38; $p = 0.11$; $I^2 = 0\%$) (**Figs. 6**, **7**, and **8**). The I^2 of the meta-analysis for balance was 50%, showing some heterogeneity between studies; therefore, we performed a subgroup analysis based on the criterion of 3 months since stroke onset (**Fig. 9**). Three studies recruited patients with stroke chronicity < 3 months, and the meta-analysis of these studies had an I^2 of 7%, indicating a homogeneous selection of studies. The meta-analysis found a significant superiority (SMD, 5.75; 95% CI, 1.72–9.79; $p = 0.005$; $I^2 = 7\%$) of RAT over CT. Three studies recruited only patients with stroke chronicity >3 months, and the meta-analysis of these studies had an I^2 of 0%, implying a homogeneous selection of studies; however, there was no significant superiority of RAT over CT (SMD, -0.62; 95% CI, -2.55 to 1.34; $p = 0.51$; $I = 0\%$). The results of the meta-analysis of gait function and ADL showed relatively low heterogeneity between studies. The quality of evidence was judged to be 'high,' as there

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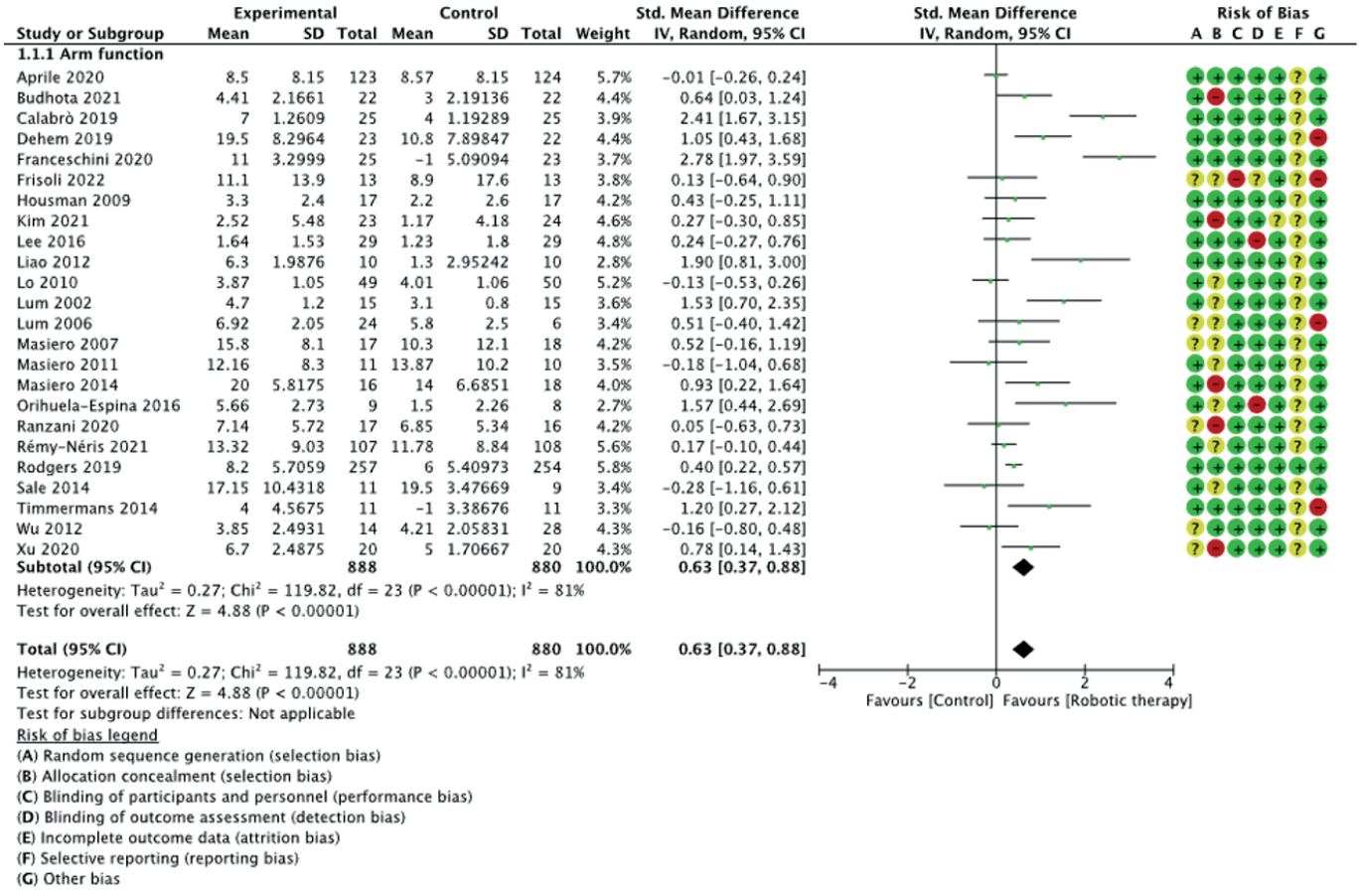

Fig. 3. Effect of robot-assisted arm training on arm function after stroke.
SD, standard deviation; CI, confidence interval.

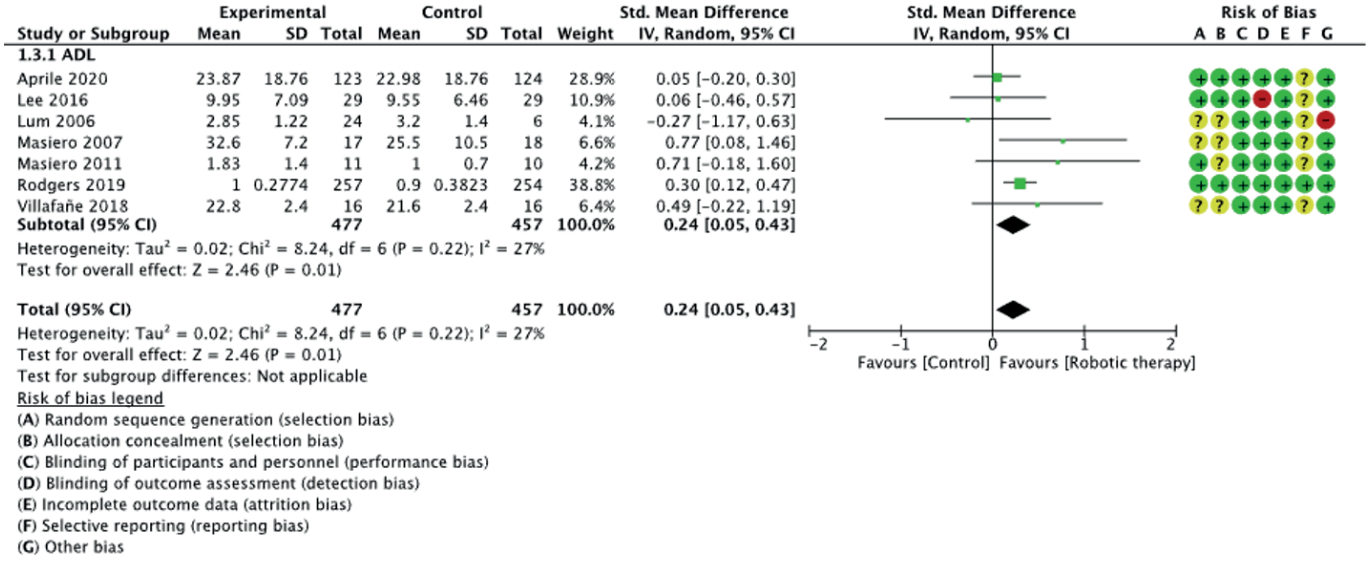

Fig. 4. Effect of robot-assisted arm training on activities of daily living after stroke.
SD, standard deviation; CI, confidence interval.

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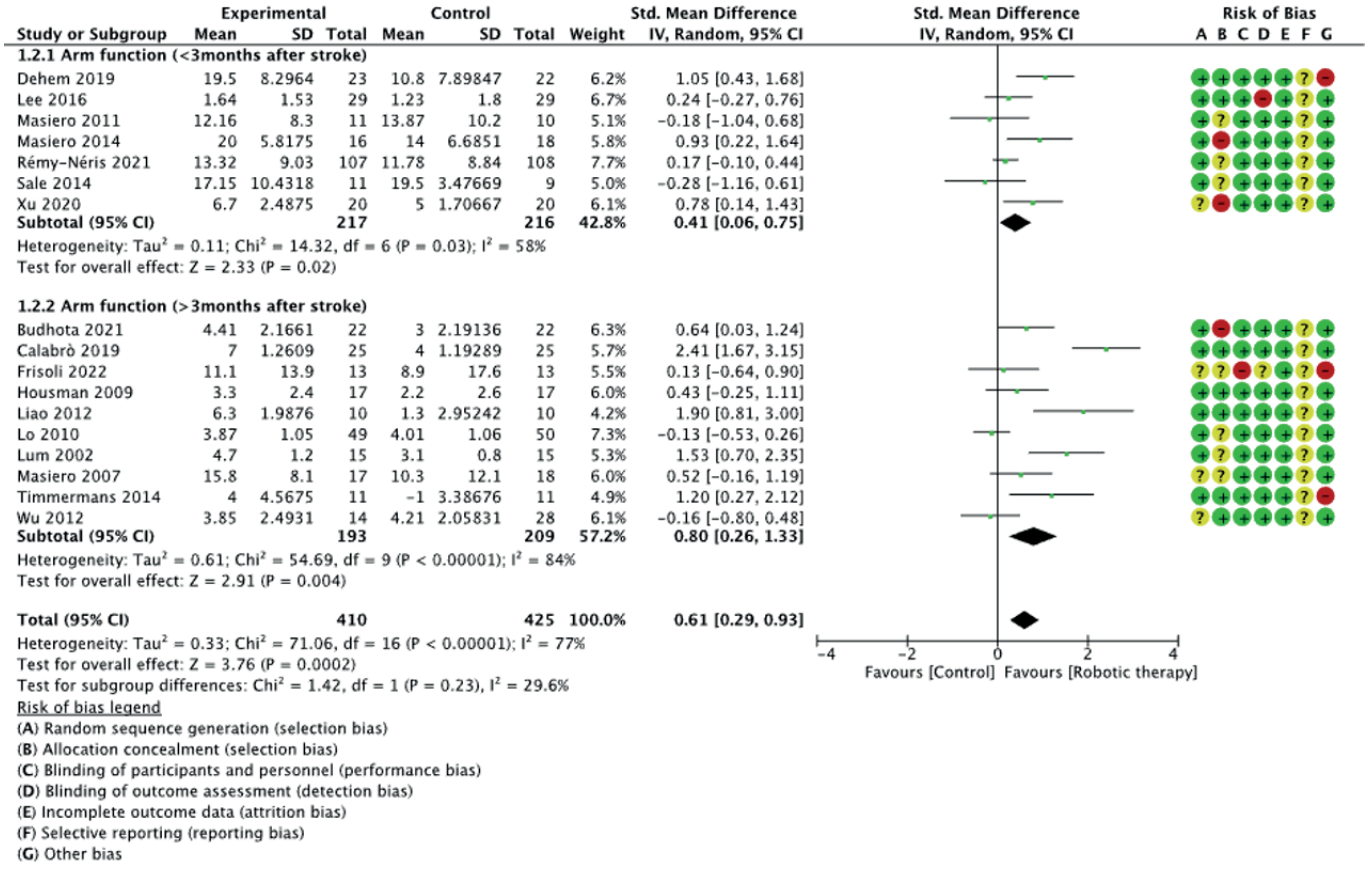

Fig. 5. Subgroup analysis results of robot-assisted arm training on arm function according to the chronicity of stroke.
SD, standard deviation; CI, confidence interval.

were no downgrades in the GRADE assessment for all outcome measures in the respective domains. We found no graphical evidence of publication bias in this meta-analysis (**Fig. 10**).

DISCUSSION

In the present study, we found that RAT was superior to CT in facilitating the recovery of several functional domains after stroke. The results of this meta-analysis are consistent with those of previous meta-analyses that found RAAT to be significantly superior to CT in restoring arm function and ADL performance after stroke [10,12,17,83]. The results of this meta-analysis are also consistent with those of previous meta-analyses showing a statistically significant superiority of RAGT over CT for balance [13,15], but are not consistent with those of previous meta-analyses showing a statistically significant superiority for gait [13,14]. The difference between the results may be attributed to the conditions proposed in this study to reduce the heterogeneity of the results of the meta-analysis and the additional conditions applied during the literature selection process. Mehrholz et al. [14] pooled the outcomes of gait independence, gait velocity, and walking capacity as the respective outcomes and found that RAT had an effect on the first two outcomes, but there was no significant effect on walking capacity. In contrast, in this study, we pooled all the results of these outcomes together in the walking domain.

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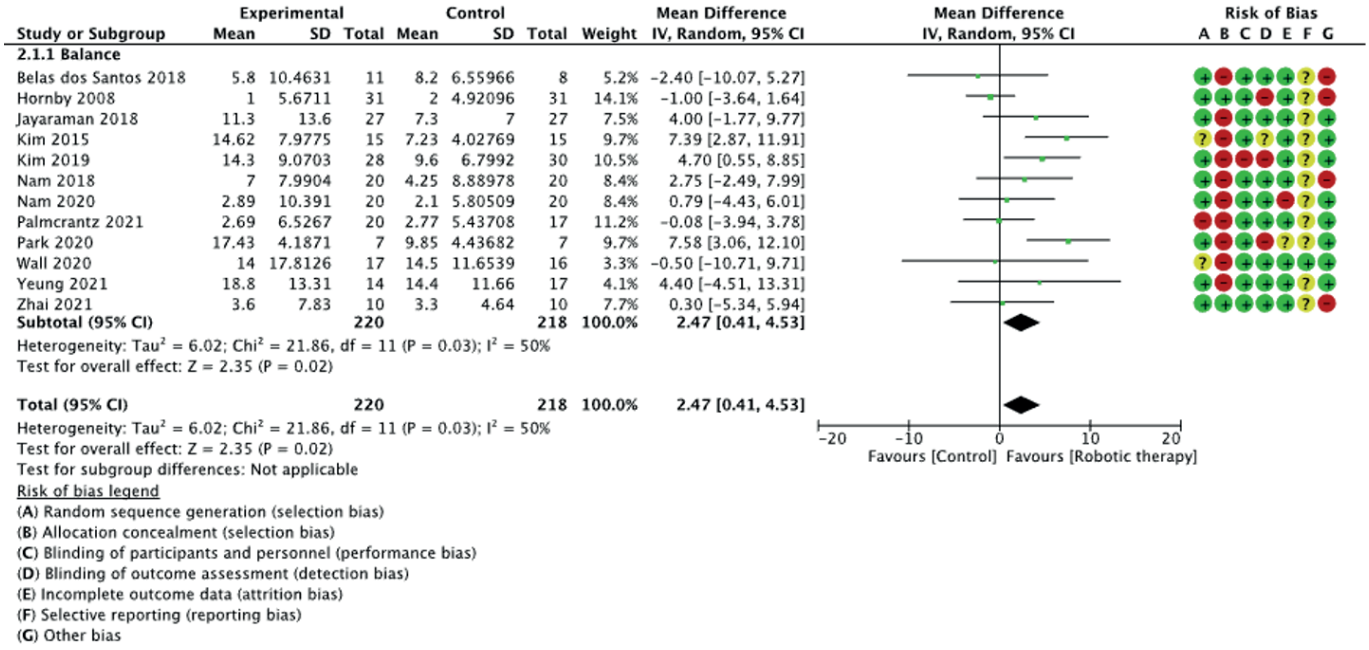

Fig. 6. Effect of robot-assisted gait training on balance after stroke.
SD, standard deviation; CI, confidence interval.

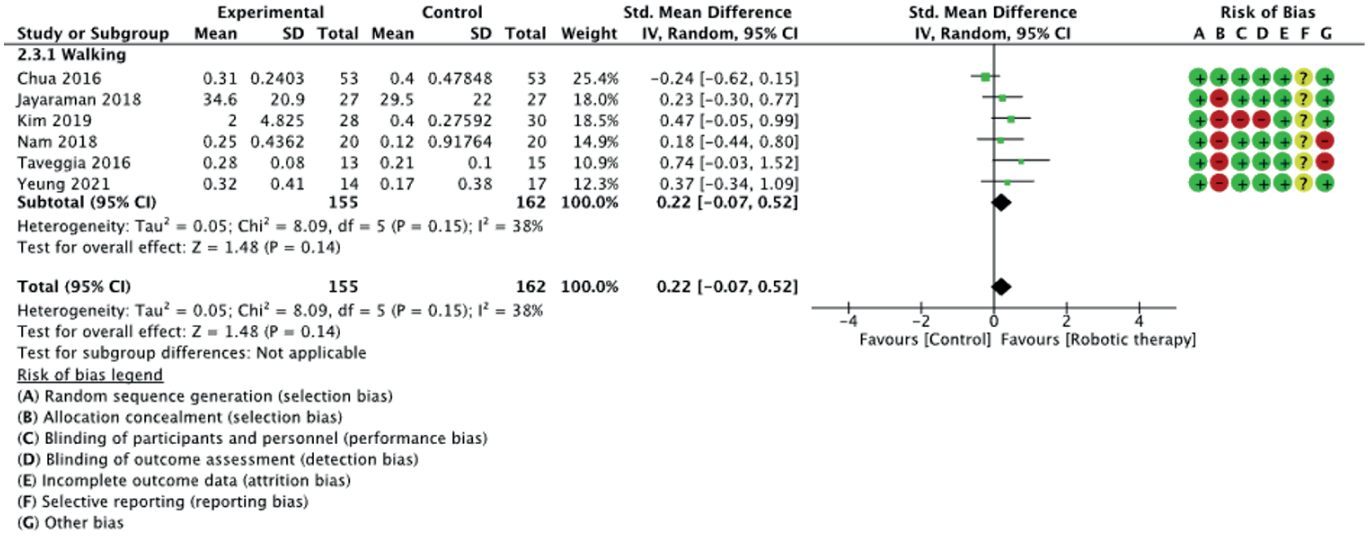

Fig. 7. Effect of robot-assisted gait training on walking after stroke.
SD, standard deviation; CI, confidence interval.

Subgroup analysis of arm function showed that RAAT was superior to CT regardless of chronicity, suggesting that RAAT can promote the recovery of arm function by providing repetitive and task-specific therapy, even in patients with chronic stroke. This is consistent with the results of a recent study that found a positive effect of RAAT over CT on arm function in the chronic phase over 3 months [83]. In the subgroup analysis of balance, the superior effect size of RAGT over CT was not statistically significant in the chronic phase of stroke. These results suggest that the degree to which RAGT affects balance is greater in the acute or subacute phase than in the chronic phase, which is consistent with previous research [15].

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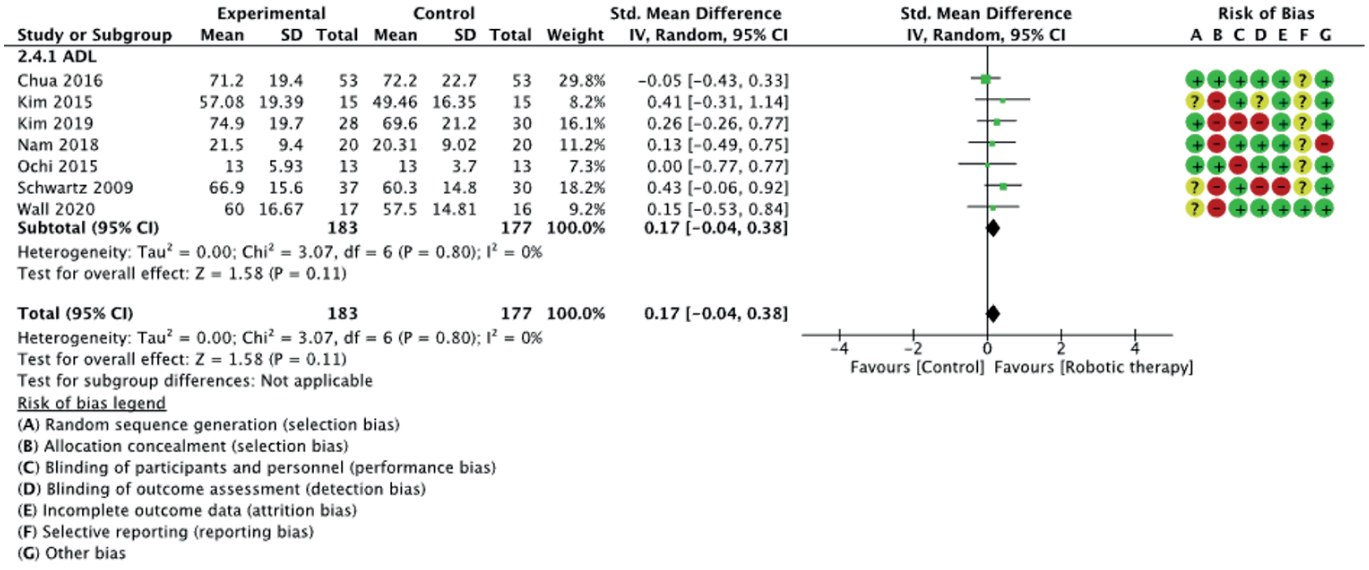

Fig. 8. Effect of robot-assisted gait training on activities of daily living after stroke.
SD, standard deviation; CI, confidence interval.

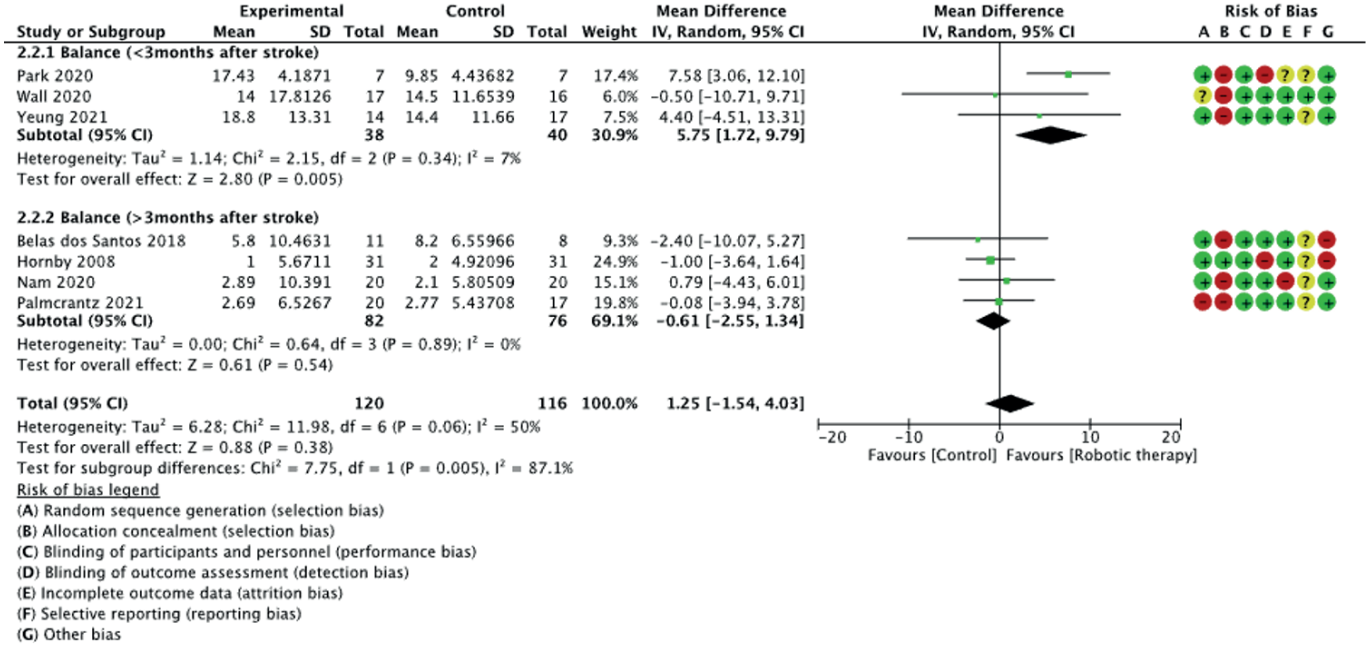

Fig. 9. Subgroup analysis results of robot-assisted gait training on balance according to the chronicity of stroke.
SD, standard deviation; CI, confidence interval.

The underlying mechanisms by which the effects of RAAT on the recovery of arm function and RAGT on the recovery of balance are affected differently by the chronicity of stroke should be confirmed in future studies.

We used a top-down approach to reduce the heterogeneity of the results of the meta-analyses and determine the methodology for literature selection and statistical analysis. However, we found a substantial heterogeneity in the results of this meta-analysis. Various factors

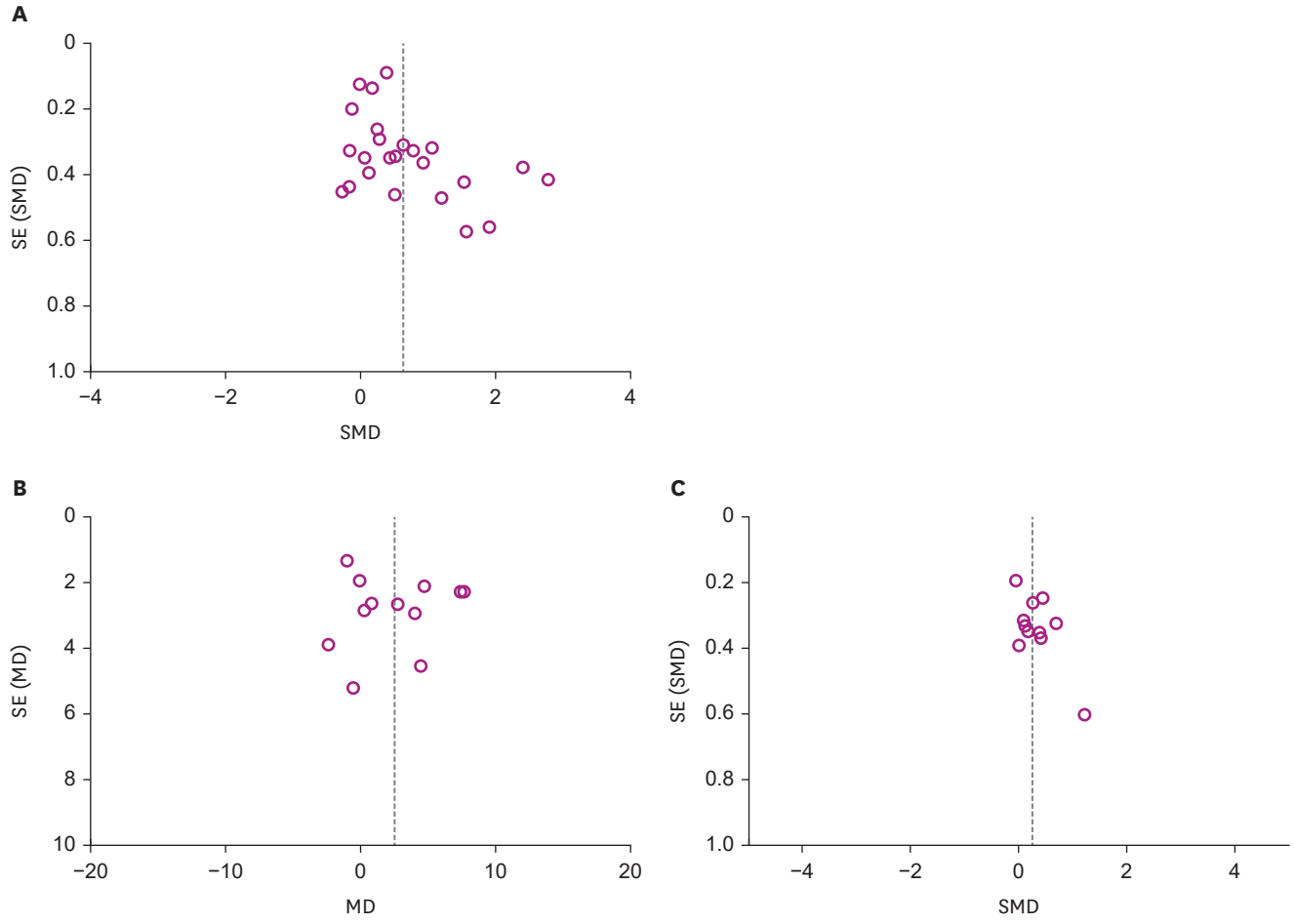

Fig. 10. Funnel plots of comparison using ≥ 10 studies.
SE, standard error; SMD, standardized mean difference; MD, mean difference.

may have contributed to the heterogeneity. First, the heterogeneity of the meta-analyses may be attributed to the heterogeneity of the interventions. The manner in which RAT is delivered varies depending on the trial design (add-on vs. alone), robot type (end-effector vs. exoskeleton), training part (proximal vs. distal vs. both), and laterality (unilateral vs. bilateral), making it difficult to control the intervention [12], which is a common feature of rehabilitative therapies [84]. We also did not distinguish between varying levels of RAT intensity and duration across studies. Second, heterogeneity may occur when the results from assessment tools with different levels of construct validity, reliability, and responsiveness are pooled [85]. In this study, we measured arm function, balance, walking, and ADL using a variety of clinical assessment tools according to the respective domain, which corresponds to the construct in the context of measurement [86]. Because the four constructs cannot be measured directly, it is necessary to secure the validity, reliability, and responsiveness of the assessment tools that indirectly measure each construct so that the construct can be meaningfully correlated with the number obtained by the assessment tool [85]. Even metrics that measure the same construct reflect it to varying degrees, since those have distinct degrees of construct validity. This could be a source of heterogeneity when combining clinical assessment tool outcomes. Reliability encompasses internal consistency and test-retest, inter-rater, and intra-rater reliabilities, which refers to the precision or accuracy of measurement procedures [85,87]. Even if the same construct is

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assessed using clinical assessment tools with the same level of construct validity, there will be heterogeneity in the outcomes if the reliability level of the measurement varies. Responsiveness refers to an instrument's ability to detect changes resulting from an intervention [87], including floor effects, ceiling effects, and minimal clinically important differences. When clinical assessment tools with varying levels of responsiveness to each construct are used, heterogeneity may occur during the pooling of outcomes, even when SMD is used. Additionally, the ceiling or floor effect of the instrument can result in skewed outcome distributions, which can lead to misleading results when the number of studies used for meta-analysis is small [23]. This may have been another source of heterogeneity. Third, in our review process, we did not distinguish between studies on first-ever stroke and those on recurrent stroke, which may be another source of heterogeneity in the meta-analyses. We should also consider that I^2, which indicates heterogeneity in the results of meta-analyses, has the risk of being a biased estimate in small meta-analyses [88].

Physicians should consider RAT as a therapeutic option to facilitate functional recovery after stroke, as high-level evidence supports the superiority of RAT over CT. Despite the significant heterogeneity, the generalizability of the effect sizes from the meta-analysis was still considered valid because the meta-analysis was conducted using a random-effects model. The results of this meta-analysis will be updated in future studies. We propose that future studies should consider the factors that may cause heterogeneity in the results of the meta-analysis more comprehensively. In addition, it is necessary to consider a valid methodology that accounts for the heterogeneity of interventions and outcome measures in rehabilitation medicine, which is a barrier to meta-analysis and must be overcome to determine the generalized effectiveness of rehabilitative therapies.

SUPPLEMENTARY MATERIAL

Supplementary Table 1
Characteristics of included studies

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