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Assistive technology on upper extremity function for stroke patients: A systematic review with meta-analysis

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ABSTRACT

Background: In stroke rehabilitation, the selection of appropriate assistive devices is of paramount importance for patients. Specifically, the choice of device can significantly influence the functional recovery of the upper limb, impacting their overall activities or functional tasks.
Objectives: This review aimed to comprehensively analyze and summarize the clinical evidence from randomized controlled trials (RCTs) regarding the therapeutic effects of commonly used assistive devices on upper extremity function in patients with stroke.
Methods: To evaluate assistive devices for patients with stroke, we summarized qualitatively throughout synthesis of results, such as therapeutic intervention, intensity, outcome, and summary of results, and examined risk of bias, heterogeneity, mean difference, 95% confidence interval, and I-squared value. To analyze, we used RoB 2 and RevMan 5.4.
Results: The qualitative synthesis included 31 RCTs. The randomization process and the reporting of results showed minimal bias, but there were issues with bias from intended interventions, and missing outcome data presented some concerns. The quantitative synthesis included 16 RCTs. There was a significant difference in the Fugl-Meyer assessment-upper extremity functioning (FMA-UE) scores between the groups, with a total mean difference (95% confidence interval) of 2.40 (0.21, 4.60), heterogeneity values were $Tau^2 = 0.32$, chi-square = 8.22, degrees of freedom = 8 ($p = 0.41$), and $I^2 = 3\%$ for FMA-UE and the test for the overall effect produced $Z = 2.14$ ($p = 0.03$) in patients with chronic stroke. However, there was no significant difference in all other outcome measures.
Conclusions: Upper-limb robots did not demonstrate significant superiority over conventional treatments in improving function of upper limbs, with the exception of FMA-UE scores for patients with chronic stroke. The mean difference of FMA-UE was also lower than minimally important difference. Nonetheless, the usage of upper-limb robots may contribute to enhanced function for patients with stroke, as those devices support clinicians and enable a greater number of movement repetitions within specific time frames.
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Introduction

Stroke is associated with a high risk of death in adults and is relatively uncommon in individuals aged < 40 years.[1] Per data from the World Organization, each year sees around 15 million individuals globally undergoing the ordeal of a stroke.[2,3] Tragically, one-third of those cases result in death, while an equivalent number lead to enduring disabilities, inflicting not only the sufferers but also casting enduring impacts on their close ones and wider communities.[2,3] Rehabilitation following stroke is crucial for assisting stroke survivors in regaining independence and improving skills lost due to brain injury caused by stroke.[4,5] Assistive technology devices for the upper extremity (UE) can play a significant role in supporting patients with stroke; these devices can allow patients to regain or enhance their functional abilities.[6]

Assistive technology devices have been reported to have several positive effects on patients with stroke, including increased independence, improved functional abilities, enhanced safety,

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facilitated rehabilitation, psychological and emotional well-being, caregiver support, and adaptability.[4,5,7,8] These devices contribute to the functional recovery and overall well-being of patients with stroke. However, the effectiveness and suitability of assistive technology devices may vary depending on individuals and their specific needs.[9] The choice of the most beneficial assistive technology for the UE function at rehabilitation settings depends on the specific needs and capabilities of the individual with stroke.[4,7,10] Collaboration with health care professionals is crucial for identifying the most appropriate devices, providing proper training, and integrating them into the rehabilitation process to target various aspects of UE function and address an individual's specific impairments.[11,12] The primary purpose of this review was to meticulously present and estimate the clinical evidence pertaining to the most frequently utilized assistive devices that are integral in stroke rehabilitation, focusing specifically on their therapeutic effects on UE function for patients with stroke. The ultimate goal was to offer clinicians, researchers, and health care professionals a reliable reference that guides the selection and utilization of assistive devices, thereby facilitating more informed and effective rehabilitation strategies for improving UE functionality in patients with stroke.

Methods

Review design

This systematic review protocol was registered in PROSPERO (Registration Number: CRD42018096199). Two researchers (S.H. and C.-S.S.) independently searched and reviewed the selected studies. Subsequently, the results of the two researchers were compared. The remaining researchers completed the literature selection process when a difference was observed in the results between the two researchers.

Eligibility criteria

This review incorporated randomized controlled trials (RCTs) examining the effects of assistive devices on the UE functionality in individuals recovering from stroke. The selected studies contrasted the outcomes of these devices with therapeutic programs devoid of any assistive technology. Studies were deemed eligible if they met several criteria: focusing primarily on training involving assistive technology, exclusively enrolling patients with stroke aged between 18 and 85 years without additional neurologic conditions, categorizing patients into one to three recovery phases (acute, subacute, or chronic), employing standard outcome measures for UE functionality, presenting as RCTs, being drafted in English, and being available as complete reports. Meanwhile, studies were dismissed if they did not focus on assistive technology-based approaches, enrolled patients without stroke, did not emphasize either/both UE or/and lower extremity training, involved animal subjects, were not original articles (such as editorials, letters, comments, opinion pieces, reviews, notes, or news), or fell under the category of gray literature (such as dissertations, conference materials, or abstracts).

Information sources and search strategy

Records published up to December 31, 2022, were identified through searches in three electronic databases: MEDLINE, Embase, and ProQuest. The search strategy employed a combination of medical subject headings and related terms (see Appendix 1 for details). This review limited the systematic search to RCTs on human subjects, available in English. We excluded crossover RCTs lacking pretest and posttest data prior to the groups crossing over, as well as gray literature, which encompasses theses, materials from congresses or conferences, and research abstracts.

Screening and eligibility criteria of searched studies

Following the initial compilation of studies retrieved through our search, we eliminated duplicates through the use of a bibliographic management tool and by manually cross-checking the list of compiled studies. Our selection process unfolded in two main phases: first, by scanning titles and abstracts, we weeded out irrelevant reports. The second phase required a close examination of the full texts of the remaining papers to verify their compliance with our established inclusion criteria. During this meticulous review of full-text articles, we aimed to identify those that fit our inclusion criteria perfectly. Two reviewers, S.H. and C.-S.S., independently reviewed the eligibility of each study, providing their expert judgment to ascertain the relevance and appropriateness of each. This collaborative effort helped in making informed and unanimous decisions regarding the inclusion of studies, paving the way for the subsequent data gathering phase. The two researchers independently conducted searches with a focus on three pivotal elements: stroke, assistive technology, and upper extremities functionality. They individually evaluated the potential relevance of each identified study, initially screening through titles and abstracts, always keeping our inclusion criteria in mind. In instances where abstracts did not provide enough information for an informed decision, the full text of the article was retrieved and scrutinized. When there was ambiguity in the selection process, decisions were not left to the judgment of a single reviewer but were instead reached collaboratively. For a study to qualify for our meta-analysis, it had to present data in a manner that allowed for the computation of standard errors pertaining to the effect estimates associated with the use of assistive technology devices in patients with stroke. Those failing to meet this specific requirement were not considered further in our analysis.

Data extraction

For an accurate assessment of the empirical evidence supporting the use of assistive technology training for individuals recovering from a stroke, various details were extracted from each study. These details include the names of the authors, publication year, country of the study, participant population and their age ranges, specifics of the intervention implemented, types of devices utilized, intensity of therapy provided, comparison group details, the metrics used for outcome measurement, any additional therapies administered, and a summary of the main findings. Data extraction was executed independently by two reviewers, with any final decisions taken after consulting with a subject matter expert. This approach was taken to guarantee consistency and accuracy in the data extracted. In the event of divergences or conflicts between the two primary reviewers at any point during the review or extraction phases, a consensus-based resolution mechanism was activated. This involved reviewers deliberating, reassessing the contentious study, and working toward a joint agreement. For cases where discussions did not lead to an agreement, a third reviewer, K-C.M., was brought in to arbitrate and make the final decision.

Reporting bias assessment

The RoB2 is typically used to assess the risk of bias of RCTs. We analyzed five different risk of bias, including (1) bias arising from the randomization process, (2) bias due to deviations from intended interventions, (3) bias due to missing outcome data, (4) bias in measurement of the outcome, and (5) bias in selection of the reported results. Three reviewers engaged in discussion to assess the risk of bias in the included studies.[13]

Data analysis

Analysis of the reviews was conducted through the RevMan 5.4.1 software, accessed on May 19, 2021. To aggregate the effect estimates from the chosen RCTs, we amalgamated the mean and standard deviation (SD) values to compute the mean difference along with the 95% confidence interval (CI). The I^2 statistic was employed to evaluate heterogeneity, aiding precise interpretation and offering valuable insights for informed clinical decision-making processes.[14] Meta-analysis was executed with a random effects model when a minimum of two studies exhibited pertinent data, alongside adequate homogeneity concerning the population, interventions, and outcome measures. An I^2 value exceeding 40% was set as the criterion for identifying statistical heterogeneity, with random effects models applied under these circumstances. In scenarios where a study featured two experimental groups and one control group—and yielded identical results—data from the experimental groups were merged for synthesis purposes.[15]

Results

Literature search and characteristics of the included RCTs

Our initial search strategies yielded 1201 records from three databases: MEDLINE (280 entries), Embase (359 entries), and ProQuest (562 entries). We incorporated a total of 31 studies into our qualitative synthesis. These comprised four studies in the acute stage, 11 in the subacute stage, and 16 in the chronic stage of patient recovery periods, as delineated in Figure 1.

Qualitative synthesis of selected RCTs to review UE in stroke survivors

The review included four RCTs involving patients with acute stroke (Table 1). These studies comprised two that explored orthosis wearing[16,17] and two that examined robot-assisted training.[18,19] One study indicated that wearing orthosis led to greater improvements in UE function compared to conventional therapy.[17] In contrast, another study did not identify significant enhancements in UE function with orthosis-wearing relative to conventional therapy.[18] The two robot-assisted training studies involved 57 patients in total used either a neurorehabilitation robot[19] or a GloReha Professional glove.[20] While one study observed that robot-assisted training yielded more substantial improvement in UE function than passive movement,[20] the other study found no significant improvement in UE function with robot-assisted training compared to conventional therapy.[19]

This review included 11 RCTs encompassing a total of 708 patients (300 of whom were women) in the subacute phase of stroke.[20-30] All selected studies implemented robot-assisted training as the assistive technology. The specific devices utilized in these studies varied, ranging from end effectors such as the Armeo Spring[20,23] to sensor-based devices,[22] InMotion2,[24,28] ReHapticKnob,[28] and Reo therapy systems.[29,30] In all but one study, patients undergoing robot-assisted

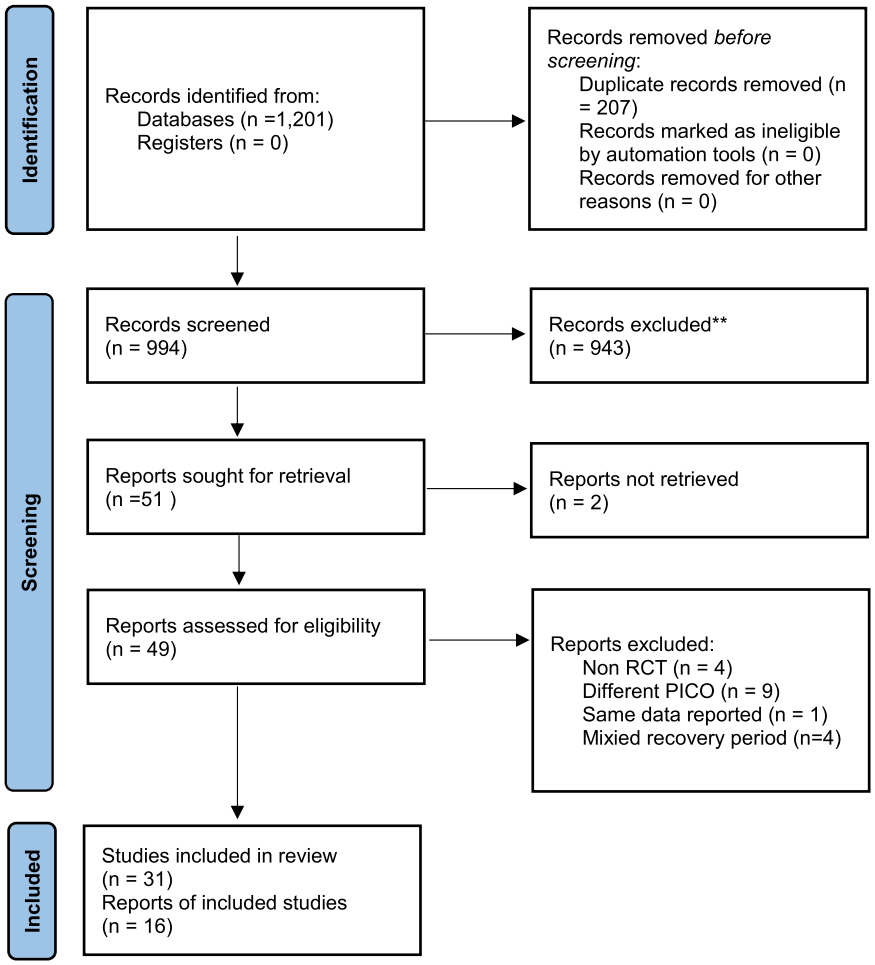

Fig. 1. The diagram of this systematic review.
Source: Page et al.[16]

Table 1
Qualitative synthesis of the selected randomized controlled trials showing assistive devices for the acute stage

Author, year	Participants, age	Intervention	Device type	Intensity	Comparison	Outcome	Additional therapy	Summary of findings	Journal quartiles
Hartwig, 2012[17]	41 (female, 18), EG: 64 ± 16, CG: 64 ± 13	Functional orthosis	Neuro-Lux	10 h/d 24 sessions	Usual care	SHSS, MRC scale, subluxation	Conventional care 30 min/d 24 sessions	EG > CG	SCIE (Q2)
Masiero, 2014[19]	30 (female, 10), EG: 65.60 ± 9.2, CG: 66.83 ± 7.9	Robotic-assisted training	NeuroRehabilitation-roBot	40 min/d 25 sessions	Conventional therapy with the assistance of a therapist	MRC, FMA, FIM, BBT, FAT, MAS	Conventional therapy 80 min/d	EG=CG	SCIE (Q1)
Morris, 2019[18]	43 (female, 19), EG: 67.2 ± 16.7, CG: 67.3 ± 10.1	Daily orthosis wear	Dynamic Lycra orthoses	8 h/d 56 sessions	Nondynamic lycra orthoses	9HPT, ARAT, MTS, MI, grip strength, MAL-14, EmNSA	Usual rehabilitation 45 min/d 40 sessions	EG=CG	SCIE (Q2)
Vanoglio, 2017[20]	27 analyzed, but offered at admission	Robotic-assisted training	Glove Gloreha professional	40 min/d 30 sessions	Passive movement	9HPT, MI, grip and pinch strength, QuickDASH	Basic rehabilitation	EG > CG	SCIE (Q2)

9HPT = nine-hole peg test; ARAT = action research arm test; BBT = Box and Block Test; CG = control group; EG = experimental group; EmNSA = Erasmus-modified Nottingham sensory assessment; FAT = Frenchay arm test; FIM = functional independence measure; FMA = Fugl-Meyer assessment; MAL = Motor Activity Log; MAS = modified Ashworth scale; MI = motricity index MRC = Medical Research Council; SCIE= Science Citation Index expanded; SHSS = shoulder-hand syndrome score.

training also received additional forms of therapy.[30] Of the 11 studies, five reported that robot-assisted training yielded positive benefits when compared to conventional therapy.[20,23,24,26,28] However, six studies found no statistically significant differences between the outcomes of robot-assisted training and those of conventional therapy[21,22,25,27,29,30] (Table 2).

Sixteen RCTs involving a total of 1192 patients with chronic stroke were selected for review. Four of those studies explored the use of splint/brace interventions, including dorsal and volar splints, electrobraces, and orthoses.[31-34] The remaining 12 studies employed robot-assisted training utilizing various assistive technology devices such as the HandTutor glove, Bi-Manu track, Rapael smart glove, ARM guide, IMU-based motion capture systems, myomo, Amadeo robotic device, and Massachusetts Institute of Technology-manus robotic gymnasium system.[35-46] Of the 16 studies, 10 reported that patients undergoing robot-assisted training experienced greater improvement in UE function compared to those undergoing comparison training,[32,34–36,38–40,42,43,45] whereas six studies did not observe significant benefits of robot-assisted training in enhancing UE function compared to comparison training[31,33,37,41,44,46] (Table 3).

Risk of bias in the RCTs

Thirty-one RCTs selected from all records were assessed for risk of bias. In terms of "bias arising from the randomization process," 23 studies exhibited a low risk of bias,[17–20,22,23,26,29,31–34,37–41,43–48] while eight studies presented "some concerns."[21,24,25,28,30,36,42,49] Regarding "bias due to deviations from intended interventions," nine studies showed a low risk,[21,24,25,29,36-38,40,44] and 22 studies raised some concerns.[17–19,22,23,30–34,39,41–43,45–47,49] For "bias due to missing outcome data," 16 studies raised a low risk,[17,21,24-27,29,30,36-38,40,42-44,46] whereas 15 studies had some concerns.[18-20,22,23,28,31-34,39,41,45,49] In terms of "bias in measurement of the outcome," 20 studies showed a low risk,[18,19,22,23,25,28-31,34,36,37,40,41,43-46,50] and nine studies raised some concerns.[20,21,24,26,32,39,42,47,49] And then two study showed a high risk at that bias.[17,33] All 31 studies analyzed for bias in the selection of the reported result displayed a low risk of bias (Appendix 3).

Effectiveness of assistive technology device for patients with subacute stroke in the RCTs

In patients with subacute stroke, seven RCTs involved a total of 375 patients to assess the Fugl-Meyer assessment-UE functioning (FMA-UE).[20,22-25,28,30] Additionally, the action research arm test (ARAT) was evaluated in two RCTs with 142 patients,[22,25] the Box and Block Test (BBT) was examined in two RCTs with 92 patients,[20,25] and the Wolf Motor Function Test (WMFT) was assessed in two RCTs with 148 patients.[22,30] There were no significant differences in scores between the experimental and control groups across those outcome measures. The total mean differences (95% CI) were −4.99 (−0.07, 10.05) for FMA-UE, −6.64 (−15.79, 2.50) for ARAT, −5.81 (−13.74, 2.12) for BBT, and −0.10 (−1.50, 1.30) for WMFT functional ability score. Due to significant heterogeneity, a random effects model was employed. The heterogeneity values were $Tau^2 = 15.93$, chi-square = 9.23, df = 6, and $I^2 = 35\%$ for FMA-UE; $Tau^2 = 0.00$, chi-square = 0.93, df = 1, and $I^2 = 0\%$ for ARAT; $Tau^2 = 0.00$, chi-square = 0.05, df = 1, and $I^2 = 0\%$ for BBT; and $Tau^2 = 0.00$, chi-sqaure = 0.15, df= 1, and $I^2 = 0\%$ for the WMFT functional ability scores. The overall effect test yielded $Z = 1.93$ ($p = 0.05$) for FMA-UE, $Z = 1.42$ ($p = 0.15$) for ARAT, $Z = 1.44$ ($p = 0.15$) for BBT, and $Z = 0.14$ ($p = 0.89$) for the WMFT functional ability score (Fig. 2).

Two RCTs involving 98 patients assessed the functional independence measure (FIM),[21,31] and two RCTs involving 109 patients evaluated the motricity index (MI)[28,30] to evaluate the effects of

Table 2
Qualitative synthesis of the selected randomized controlled trials showing assistive devices for the subacute stage

Author, year	Participants, age	Intervention	Device type	Intensity	Comparison	Outcome	Additional therapy	Summary of findings	Journal quartiles
Adomaviciene, 2019[21]	42 (female, 14), EG: 66 (60.5-70), CG: 62 (61-69)	Robot-assisted trainings + VR exergames	Armeo Spring	45 min/d 10 sessions	Kinect-based system training	ACE-R, BBT, FIM, modified FIM, FMA-UE, HAD, HTS, MAS, MMSE, ROM	Conventional therapy 3-4 h daily, 5 d/wk	EG > CG	SCIE(Q3)
Aprile, 2020[22]	224 (female, 97), EG: 69.5 ± 10.9, CG: 68.5 ± 11.5	Robot-assisted training	Robotic and sensor-based devices	45 min/d 30 sessions	Conventional therapy	FMA-UE, MI, MBI, MRC, FAT, ARAT, NRS, DN4, MAS, SF-36	Conventional rehabilitation focused on LE, 45 min/d 6 times/wk	EG=CG	SCIE(Q2)
Daunoraviciene, 2018[24]	34 (female, 12), EG: 65.88 ± 4.87, CG: 65.47 ± 4.05	Robot-assisted training + VR exergames	Armeo Spring	30 min/d 10 sessions	Conventional therapy 35-60 min/d, 10 sessions	ACE-R, FMA, modified FIM, HAD, MAS	Conventional therapy 30 min/d, 5 d/wk	EG > CG	SCIE(Q4)
Franceschini, 2020[25]	48 (female, 22), 72 y	Robot-assisted training	End-effector (InMotion2)	30 sessions	Traditional physical therapy	FMA-UE, MAS, ROM	Conventional therapy	EG > CG	ESCI(N/A)
Hesse, 2014[26]	50 (female, 22), EG: 71.4 ± 15.5, CG: 69.7 ± 16.6	Robot-assisted group therapy	Bi-Manu-Track, Reha-Digit, Reha-Slide, Reha-Slide duo	30 min/d 20 sessions	Individual arm therapy	ARAT, ASG, BBT, BI, FMA-UE, MRC	Individual arm therapy 30 min/d	EG=CG	SCIE(Q2)
Kim, 2019[27]	36 (female, 14), EG: 65.9 ± 9.4, CG: 64.7 ± 8.3	Robot-assisted therapy	Shoulder rehabilitation robot	30 min/d 20 sessions	N/A	K-SDQ, PROM, UG, VAS	Conventional therapy	EG > CG	SCIE(Q1)
Ranzani, 2020[28]	27 (female, 9), EG: 70.0 ± 12.79, CG: 67.46 ± 11.39	Robot-assisted neurocognitive therapy	ReHapticKnob	45 min/d 15 sessions	Conventional neurocognitive therapy without the robot	EmNSA, FAB, FMA-UE, MAS, MMSE	Conventional neurocognitive therapy 75 min/d	EG=CG	SCIE(Q1)
Sale, 2014[29]	53 (female, 22), EG: 67.7 ± 14.2, CG: 67.7 ± 14.2	Goal-directed planar reaching tasks with the robot	End-effector (InMotion2)	45 min/d 30 sessions	Conventional rehabilitative treatment	FMA-UE, MAS, MI, ROM	Physiotherapy 3 h/session	EG=CG after 30 sessions EG > CG after 15 sessions	SCIE(Q1)
Straudi, 2020[30]	39 (female, 15), EG: 68, CG: 68	Robot-assisted trainings (60 min) + FES (40 min)	End-effector (Reo therapy system)	100 min/d 30 sessions	Intensive conventional therapy	BBT, BI, FMA-UE, MAS, WMFT	None	EG=CG	SCIE(Q2)
Takahashi, 2016[31]	56 (female, 17), EG: 65.2 ± 10.9, CG: 64.6 ± 11.5	Robotic therapy	End-effector (ReoGo therapy system)	40 min/d 42 sessions	Self-guided therapy	FIM, FMA-UE, WMFT, MAL, MAS, MI, ROM, ST-EHF, VAS	Standard UE therapy 40 min/session	EG=CG	SCIE(Q1)
Wolf, 2015[23]	99 (female, 56), EG: 54.7 ± 12.2, CG: 59.1 ± 14.1	Robot-assisted training	Hand Mentor Pro	2 h/d 40 sessions	Home exercise program	ARAT, FMA-UE, WMFT	Home exercise program 1 h/d	EG=CG	SCIE(Q1)

ACE-R = Addenbrooke's cognitive examination-revised; ARAT = action research arm test; ASG = modified Ashworth sum score; BBT = Box and Block Test; BI = Barthel index; CG = control group; DN4 = douleur neuropathique 4; EG = experimental group; FAT = Frenchay arm test; FES = functional electrical stimulation; FIM = functional independence measure; FMA-UE = Fugl-Meyer assessment-upper extremity functioning; HAD = hospital anxiety and depression scale; HTS= hand tapping score test; K-SDQ = Korean version of the shoulder disability questionnaire; LE = lower extremity; MAL = Motor Activity Log; MAS = modified Ashworth scale; MBI = modified Barthel index; MI = motricity index; N/A = not available; MMSE = mini-mental state examination; MRC = medical research council; NRS = numerical rating scale; PROM = passive range of motion; ROM = range of motion; SCIE = science citation index expanded; SF-36 = 36-item short form health survey; ST-EHF, simple test for evaluating hand function; UG, ultrasonography grade; VAS, visual analogue scale; VR = virtual reality; WMFT = Wolf Motor Function Test.

Table 3
Qualitative synthesis of the selected randomized controlled trials showing assistive devices for the chronic stage

Author, year	Participants; age	Intervention; setting	Device type	Intensity	Comparison	Outcome	Additional therapy	Summary of findings	Journal Quartiles
Basaran, 2012[32]	39 (female, 16), EG1: 52.0 ± 11.2, EG2: 54.9 ± 12.3, CG: 59.9 ± 10.1	Dorsal splint Volar splint	Splint	10 h/d 5 wk	Conventional therapy	MAS, H-latency, H_{max}:M_{max} ratio, PROM	Home exercise program	EG=CG	SCIE (Q3)
Carmeli, 2011[36]	31 (female, 9), EG: 57.8, CG: 62.5	Robot-assisted therapy	HandTutor glove	20-30 min/d 15 sessions	Traditional hand therapy	BBT, FMA-UE, PA	Consecutive treatment 15 sessions	EG > CG	ESCI (N/A)
Hsieh, 2011[37]	18 (female, 4), EG1: 56.04 ± 13.74, EG2: 52.45 ± 1.98, CG: 54.00 ± 8.05	Robot-assisted therapy EG1: high intensity (twice by lower), EG2: low intensity	Bi-Manu Track	90-105 min/d 20 sessions	Conventional rehabilitation	FMA, MRC, MAL, ABILHAND, MFSI, 8-OHdG	N/A	EG1 > EG2=CG	SCIE (Q1)
Hsu, 2019[40]	43 (female, 23), EG: 53.1 ± 13.9, CG: 52.6 ± 12.5	Robotic-aided therapy used end-effector	Bi-Manu Track	40 min/d 12 sessions	Task-specific training	FMA, MAL, EMG	Sensorimotor stimulation 10 min/d	EG > CG	SCIE (Q3)
Jung, 2017[41]	13 (female, 12), 59-80	Robotic assistive game-mediated therapy	RAPAEL smart glove	30 min/d 15 sessions	Conventional therapy	AROM, WMFT	N/A	Some improvement in WMFT in EG	ESCI (N/A)
Kahn, 2006[42]	19 (female, 8), EG: 55.6 ± 12.2, CG: 55.9 ± 12.3	Robotic-guided active-assist training	ARM Guide	45 min/d 24 sessions	Free-reaching training	BE, FRE, FE	Voluntary reaching	EG=CG	SCIE (Q1)
Klamroth-Marganska, 2014[43]	73 (female, 27), 22-76	Robotic therapy	ARMin	60 min/d 24 sessions	Conventional therapy	FMA-UE, MAL, MAS, GAS, grip strength	N/A	EG > CG	SCIE (Q1)
Lee, 2018[44]	30 (female, 11), EG: 52.07 ± 14.07, CG: 50.27 ± 11.17	Robot-assisted therapy	REJOYCE robot	30 min/d 40 sessions	General occupational therapy	FMA, mBI	General occupational therapy 30 min/d	EG > CG	SCIE (Q4)
Lin, 2018[45]	18 patients, EG: 52.2 ± 10.2, CG: 62.6 ± 7.1	Robot-assisted therapy	IMU-based motion capture system	15 sessions	General rehabilitation treatments	AROM, FMA	N/A	EG=CG	SCIE (Q1)
NiJenhuis, 2016[33]	19 (female, 9), 48-70	Technology-supported training	SaeboMAS	30 min/d 36 sessions	Conventional exercises	ARAT, IMI, FMA, MAL, SIS participation, Grip strength	Hand exercises	EG > CG	SCIE (Q2)
Page, 2020[34]	34 (female, 14) 55.8	EG1: EMG brace + repetitive task-specific practice only EG2: EMG brace only	Myomo	60 min/d 24 sessions	Repetitive task-specific practice only	FMA, AMAT	N/A	EG1=EG2=CG	SCIE (Q1)
Park, 2021[46]	24 (female, 11), EG: 69.08 ± 4.71, CG: 71.58 ± 3.17	Robot-assisted hand training	Amadeo Robotic Device	30 min/d 20 sessions	Conventional treatments	Albert's test, LBT, CBS	N/A	EG > CG	SCIE (Q3)
Rodgers, 2019[47]	760 (female, 302), EG1: 59.9 ± 13.5, EG2: 59.4 ± 14.3, CG: 62.5 ± 12.5	EG1: robot-assisted training, EG2: enhanced UE therapy	MIT-Manus robotic gym system	45 min/d 36 sessions	Usual care	ARAT, FMA, BI, SIS, NRS	N/A	EG=CG	SCIE (Q1)
Susanto, 2015[38]	19 (female, 5), EG: 50.7 ± 9.0, CG: 55.1 ± 10.6	Robot-assisted therapy	Modified hand exoskeleton robot	60 min/d 20 sessions	Hand exercises with assistance from the therapy, sometimes	ARAT, WMFT, FMA, FII	N/A	EG=CG	SCIE (Q1)
Willigenburg, 2017[39]	12 (female)	Electro brace + repetitive task-specific practice	Myomo	45 min/d 24 sessions	Repetitive task-specific practice	SIS Reaching kinematics	N/A	EG > CG	SSCI (Q4)
Zheng, 2020[35]	40 (female, 9), EG: 55.2 ± 14.5, CG: 60.3 ± 9.8	3D-printed orthosis	Wearing orthosis	4-8 h/d	Low-temperature thermoplastic plate orthosis	MAS, PROM, FMA sensation, VAS, swelling score	Conventional therapy	EG > CG	SCIE (Q2)

8-OHdG = 8-hydroxy-2'-deoxyguanoxine; AMAT = arm motor activity test; ARAT = action research arm test; AROM = active range of motion; BE = biomechanical evaluation; BBT = Box and Block Test; BI = Barthel index; CBS = Catherine Bergego scale; CG = control group; EG = experimental group; EMG = electromyography; FIM = functional independence measure; FRE = free reachign evaluation; FE = functional evaluation; FII = finger individuation index; FMA-UE = Fugl-Meyer assessment-upper extremity functioning; GAS = goal attainment scale; IMI = intrinsic motivation inventory; IMU = Inertial Measurement Unit; LBT = line bisection test; MAL = Motor Activity Log; MAS = modified Ashworth scale; MFSI = multidimensional fatigue symptom inventory; mBI = modified Barthel index; MRC = Medical Research Council; N/A = not available; NRS = numerical rating scale; SIS = stroke impact scale; PROM = passive range of motion; UE = upper extremity; VAS = visual analogue scale; WMFT = Wolf Motor Function Test.

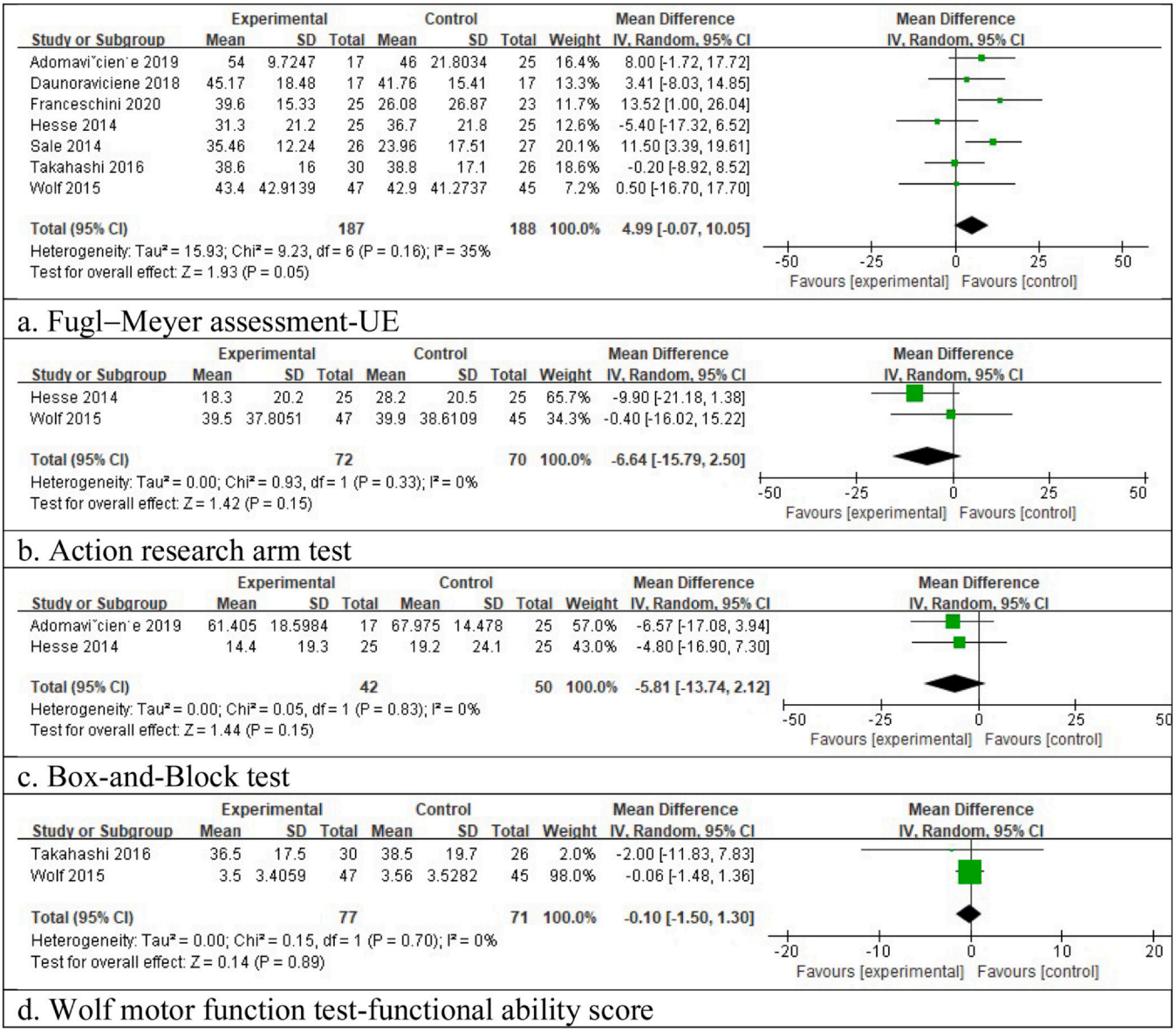

Fig. 2. Outcome of hand function to examine the assistive technology devices for subacute stroke. The size of the square is proportional to the weight of the study in relation to the pooled estimate, and the line in the middle of the square is the confidence interval for each study. The green color of the block means if the data are continuous. The placement of the center of the diamond on the x-axis represents the point estimate, and the width of the diamond represents the 95% CI around the point estimate of the pooled effect. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

assistive technology on the activities in subacute stroke. The scores for all the outcome measures did not show significant differences between the experimental and control groups. The total mean difference (95% CI) values were as follows: −0.49 (−5.84, 4.87) for FIM and 7.63 (−10.72, 25.97) for MI. The heterogeneity values were as follows: $Tau^2 = 0.00$, chi-square = 0.41, df = 1 ($p = 0.52$), and $I^2 = 0\%$ for FIM and $Tau^2 = 131.37$, chi-square = 3.83, df = 1 ($p = 0.05$), and $I^2 = 74\%$ for MI. The test for overall effect yielded Z = 0.18 ($p = 0.86$) for FIM and Z = 0.82 ($p = 0.42$) for MI (Fig. 3).

Effectiveness of assistive technology device for patients with chronic stroke in the RCTs

In patients with chronic stroke, nine RCTs involving 616 patients assessed the FMA-UE[32,33,35–37,39,43,44,46] and three records involving 444 patients assessed the ARAT[33,38,47] to evaluate the effects of assistive devices on UE function, while three RCTs with 80 patients evaluated the Motor Activity Log (MAL)[32,36,39] to evaluate the effects of assistive devices on activities. Furthermore, two records with 408 patients assessed the Stroke Impact Scale (SIS)[33,47] to evaluate the effects of assistive devices on participation. FMA-UE scores differed significantly between the experimental and control groups.

The total mean difference (95% CI) value was 2.40 (0.21, 4.60), and the heterogeneity values were $Tau^2 = 0.32$, chi-square = 8.22, df = 8 ($p = 0.41$), and $I^2 = 3\%$ for the FMA-UE. The test for the overall effect yielded $Z = 2.14$ ($p = 0.03$). However, other outcome measures did not differ significantly between the experimental and control groups. The total mean difference (95% CI) values were −0.29 (−0.92, 0.33) for the MAL-amount scale, −0.23 (−0.83, 0.38) for MAL-quality of movement, −2.59 (−7.31, 2.14) for SIS, and 0.92 (−2.47, 4.30) for ARAT. The heterogeneity values were as follows: $Tau^2 = 0.00$, chi-square = 0.20, df = 1 ($p = 0.91$), $I^2 = 0\%$ for the MAL-amount scale; $Tau^2 = 0.00$, chi-square = 0.48, df = 2 ($p = 0.79$), and $I^2 = 0\%$ for MAL-quality of

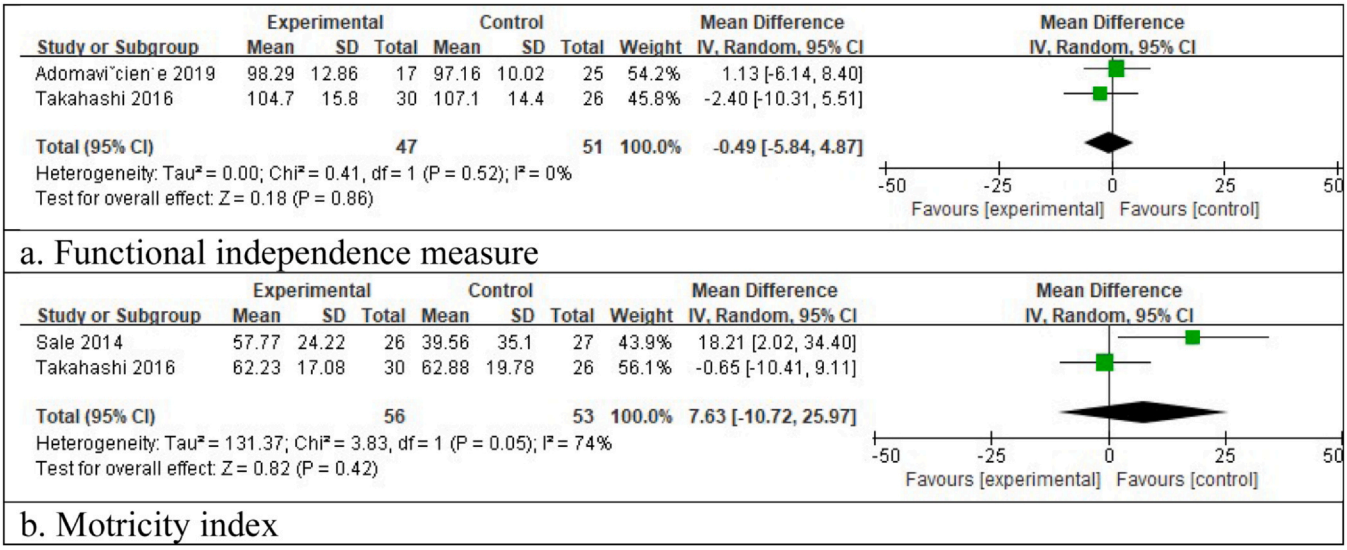

Fig. 3. Outcome of activity to examine the assistive technology for subacute stroke. Refer to Figure 3 for the meaning of the symbols.

movement; Tau^2 = 0.00, chi-square = 0.27, df = 1 (p = 0.60), and I^2 = 0% for SIS; and Tau^2 = 0.00, chi-square = 0.56, df = 2 (p = 0.76), and I^2 = 0% for ARAT. The test for overall effect yielded Z = 0.92 (p = 0.36) for the MAL-amount scale, Z = 0.74 (p = 0.46) for MAL-quality of movement, Z = 1.07 (p = 0.28) for SIS, and Z = 0.53 (p = 0.60) for ARAT (Fig. 4).

Summary of findings and grading the certainty of the evidence based in included RCTs

Based on GRADE, the certainty in cumulative evidence for the change in scores of FMA-UE,[21,23-26,29,31] ARAT,[23,26] BBT,[21,26] WMFT,[23,31] and FIM[21,31] was considered low in patients with subacute stroke. And the change of MI[29,31] after intervention was judged very low in patients with subacute stroke.

The certainty of the cumulative evidence for changes in the scores of FMA-UE[33,34,36–38,40,44,45,47] was considered moderate in patients with chronic stroke. Additionally, the change in the MAL-amount of use,[33,37,40] MAL-quality of movement,[33,37,40] SIS,[33,47] and ARAT[33,38,47] following intervention was judged to be low in patients with chronic stroke.

Discussion

While the randomization process and result reporting selection displayed a low risk of bias, deviations from intended interventions and missing outcome data presented concerns. The bias in outcome measurement, especially, requires careful consideration due to its high risk. Although our review found a significant result for the FMA-UE in patients with chronic stroke, the observed inconsistency in other outcomes and the minimally important difference for FMA-UE necessitate careful interpretation. One study by Page et al estimated a clinically important difference of FMA-UE scores ranging from 4.25 to 7.25 points in individuals with minimal to moderate impairment from chronic stroke.[51] Hiragami et al reported a minimally important difference of 12.4 for FMA-UE.[52] Considering these figures, our result for FMA-UE, although significant, warrants a cautious interpretation. The results of the meta-analysis revealed nonsignificant or highly heterogeneous measurement variables. To consider the risk of bias in the finding of the 31 included studies, this review employed the RoB2 tool.[13,53] Of the 31 studies, only four studies were judged as having a "low risk of bias" across all domains.[29,37,38,44] All studies exhibited a low risk concerning "bias in selection of the reported results." Specifically, the bias with the smallest number of low risk of bias was the "bias due to deviations from intended interventions," and the bias involving high risk was the "bias in measurement of the outcome." This bias emphasizes the need for careful interpretation of the study outcomes. However, in terms of bias from the selection of reported results, all studies displayed a low risk, suggesting a consistent and transparent approach by researchers. Although most studies showed a low risk of bias, certain domains raised significant concerns. Particularly, the bias in measurement of the outcome demands attention in future studies, as blinding evaluators and patients can be challenging or even impossible in clinical contexts.[54] These biases necessitate a cautious approach to result interpretation.

In our meta-analysis, we used the I^2 statistic to evaluate inconsistency across the included RCT studies. This statistic quantifies the proportion of total variation in study estimates due to heterogeneity rather than sampling error. An I^2 value of 0% indicates no observed heterogeneity, with higher values suggesting increasing levels.[14] For subacute patients, we assessed the I^2 in six outcome measures. While the ARAT, BBT, WMFT, and FIM showed no observed heterogeneity (I^2 values of 0%), the FMA-UE displayed moderate inconsistency (I^2 value of 35%), and the MI revealed a high inconsistency level (I^2 value of 74%). In patients with chronic stroke, the I^2 values were 3% for the FMA-UE (indicating minimal heterogeneity) and 0% for MAL, SIS, and ARAT, suggesting almost no heterogeneity. Despite this consistency, MAL, SIS, and ARAT showed no significant differences between assistive device training and control groups for patients with chronic stroke. Only the FMA-UE showed a positive effect, with other measures confirming no such effects.

This systematic review covers a diverse array of RCTs across different stroke recovery stages: acute (four studies), subacute (11 studies), and chronic (16 studies). Each stage introduces variability in therapeutic effects due to physiological and neurological differences and varying neuroplasticity levels.[55] The interventions in the studies displayed marked heterogeneity. In patients with acute stroke, both orthosis-wearing[16,17] and robot-assisted training[18,19] were explored, yielding mixed results. Differences in therapeutic intensity, types of comparisons (eg, usual care, nondynamic Lycra orthoses, conventional therapy, passive movement), and the specific devices used contribute to outcome variations. For patients with chronic stroke, interventions varied between splint treatments and various robot-assisted training devices, adding complexity.[35-46] Some studies reported improvements in UE functionality from robot-assisted training[32,34–36,38–40,42,43,45] or orthosis-wearing

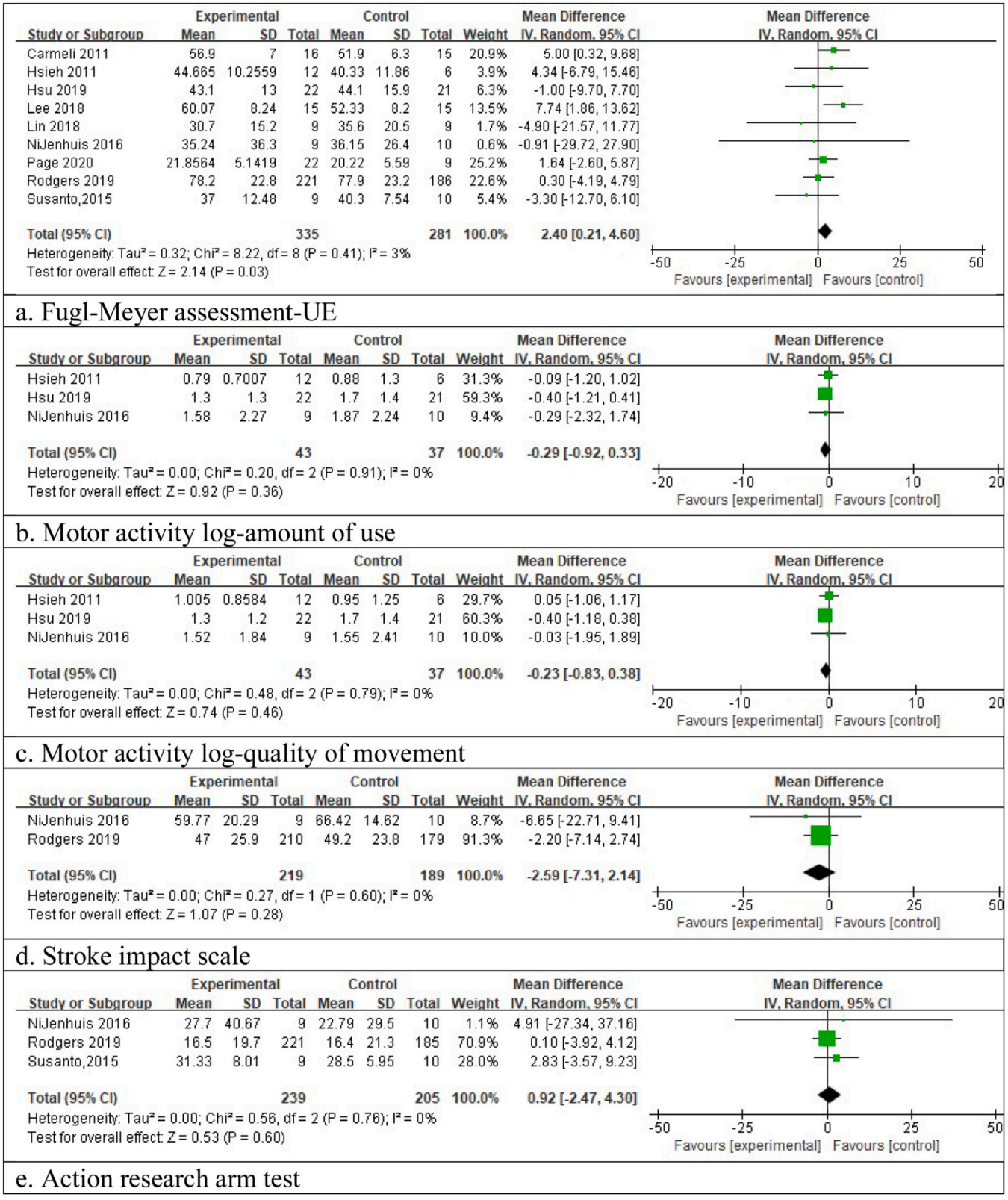

Fig. 4. Outcome to examine the effects of assistive technology for chronic stroke patients. Refer to Figure 3 for the meaning of the symbols.

compared to conventional or comparison training, while others found no benefits.[31,33,37,41,44,46] These discrepancies highlight the challenges of generalizations and underscore the need to consider intervention specifics, stroke recovery stages, and employed devices when interpreting results. Our review can pinpoint the imprecision of included RCT studies through CI, sparse data, or significant heterogeneity. Notably, the CIs, especially for FMA-UE and ARAT in patients with subacute stroke, were wide, suggesting potential

Table 4
Summary of findings and grading the certainty of the evidence for the subacute stage

Outcomes	Number of participants (studies)	Impact	I^2/95%CI	Certainty of the evidence (GRADE)
Change in score of Fugl-Meyer assessment-upper extremity	375 (7 RCTs)	No significant improvement of assistive devices on the function and activities of upper extremities	35%/−0.07, 10.05	⊕⊕○○Low[b,f]
Action research arm test	144 (2 RCTs)	No significant improvement of assistive devices on the activities of upper extremities	0%/−15.79, 2.50	⊕⊕○○Low[b,g]
Box and block test	92 (2 RCTs)	No significant improvement of assistive devices on the manual dexterity of upper extremities	0%/−13.74, 2.12	⊕⊕○○Low[b,g]
Wolf motor function test-functional ability score	148 (2 RCTs)	No significant improvement of assistive devices on the functional abilities of upper extremities	0%/−1.50, 1.30	⊕⊕○○Low[b,f,g]
Functional independence measure	98(2 RCTs)	No significant improvement of assistive devices on the functional activities of upper extremities	0%/−5.84, 4.87	⊕⊕○○Low[b,f,g]
Motricity index	109 (2 RCTs)	No significant improvement of assistive devices on the upper extremity function and functional mobility	74%/−10.72, 25.97	⊕○○○Very low[b,c,f,g]

CI = confidence interval; RCT = randomized controlled trial.
GRADE Working Group grades of evidence: high certainty, the authors have a lot of confidence that the true effect is similar to the estimated effect; moderate certainty, the true effect is probably close to the estimated effect; low certainty, the true effect might be markedly different from the estimated effect; very low certainty, the true effect is probably markedly different from the estimated effect. Explanations: (a) high risk of bias; (b) moderate risk of bias; (c) high methodological and statistical heterogeneity; (d) no standardization of intervention and therapeutic intervention; (e) the same authors or the same institution presented similar results; (f) funded by industry; and (g) only one or two small studies.

Table 5
Summary of findings and grading the certainty of the evidence for the chronic stage

Outcomes	Number of participants (Studies)	Impact	I^2/95%CI	Certainty of the evidence (GRADE)
Change in score of Fugl-Meyer assessment-upper extremity	616(9 RCTs)	Significant improvement of assistive devices on the function and activities of upper extremities	3%/0.21, 4.60	⊕⊕⊕○Moderate[b]
Motor activity log-amount of use	80 (3 RCTs)	No significant improvement of assistive devices on the activities of upper extremities	0%/−0.92, 0.33	⊕⊕○○Low[b]
Motor activity log-quality of movement	80 (2 RCTs)	No significant improvement of assistive devices on the activities of upper extremities	0%/−0.83, 0.38	⊕⊕○○Low[b,g]
Stroke impact scale	408 (3 RCTs)	No significant improvement of assistive devices on participation	0%/−7.31, 2.14	⊕⊕○○Low[a,f]
Action research arm test	444 (3 RCTs)	No significant improvement of assistive devices on the activities of upper extremities	0%/−2.47, 4.30	⊕⊕○○Low[a,f]

CI = confidence interval; RCT = randomized controlled trial.
Refer to Table 4 for the meaning of the symbols.

variability. While our central estimates indicate a specific effect, the true effect could range from clinically important to trivial.[14] A lack of statistical significance suggests uncertainty about the true efficacy of the assistive devices, even though the FMA-UE showed a significant *p*-value in patients with chronic stroke.

This study conducted a search targeting patients at all stages of disease progression without classifying them according to the course of the disease. The aim was to determine the most commonly used assistive devices for improving UE function in patients with stroke based on the progression of the disease. The study found that robotic assistive devices were the most frequently used in research settings. As previously mentioned, various robotic assistive devices have been employed to enhance UE function in patients with stroke. On the other hand, it was discovered that there is insufficient evidence to recommend that robotic assistive devices are effective in improving UE function in these patients. The review highlights that except for improvements noted in the FMA-UE score in patients with chronic stroke, robot-assisted training did not significantly outperform control group in enhancing UE function in patients with stroke. This observation is crucial and suggests that while robots are becoming prevalent, they are not necessarily superior to traditional therapies. Second, this review has also relied on the accurate reporting and methodological rigor of the included studies. Variability in the study designs, patient populations, or intervention types across the included studies could introduce heterogeneity, affecting the interpretation and generalizability of our findings. However, robot-assisted devices remain integral in UE rehabilitation, attributing to their numerous advantages in therapeutic training. For instance, they afford therapists the opportunity to provide consistent and precise assistance during therapy sessions.[56] This not only alleviates the physical burden on therapists but also enables them to concentrate on other pivotal aspects of patient care, such as personalized intervention planning and patient assessment.[27] It is imperative to consider that robots are not replacements but supplements to traditional therapeutic approaches in stroke rehabilitation. The role of therapists remains indispensable, as their guidance and expertise are fundamental to delivering comprehensive and individualized care to patients with stroke.

Limitations of the study

This study was not without limitations. The assistive devices used included RCTs did not consist of a series of joints, each with specific and distinct functions, and the measurement of effects of assistive devices were not evaluated on each joint individually. This is believed to be because although the anatomic characteristics of the upper extremities' series of joints are different, they work in concert to produce upper limb function. On the other hand, the findings of

this study may have limitations in providing evidence for identifying and addressing specific joint issues to enhance UE function. The RCTs in this review varied in sample size, which can influence each study's contribution to the meta-analysis. This variability can influence the weight each RCT contributes to the meta-analysis, potentially skewing results based on the size and outcomes of the larger studies.[14] We predominantly included published studies, possibly overlooking unpublished studies or gray literature, and we did not analyze a funnel plot. The statistical methodology, although robust, might not account perfectly for the diverse contexts of the individual studies, possibly affecting our estimated effect sizes. We also acknowledge potential errors from estimation methods for studies that lacked means and SDs, especially when sample sizes were small.

We noted inconsistencies in the baseline demographic and clinical characteristics reported across studies, with some showing variations in patient numbers at baseline and posttraining. This discrepancy hampers the appropriate interpretation and generalization of study findings, underscoring the necessity for future studies to provide detailed participant characteristics for those completing the study. Additionally, our meta-analysis included studies that might not have provided means and SDs, relying instead on estimations from medians and quartile CIs. This approach could introduce errors, particularly when the study sample size is small. Future research should address these limitations by employing rigorous methodologies and providing comprehensive reporting to facilitate more accurate and reliable analysis and interpretation of findings. The search strategy may have missed relevant studies due to the restriction to specific databases, keywords used, or inclusion and exclusion criteria, potentially leading to selection bias. Given these limitations, caution must be exercised when interpreting the findings of this review. Future research endeavors should aim to mitigate these limitations for a more accurate and comprehensive understanding of the impact of assistive devices on UE function in patients with stroke.

Conclusions

This study provides a nuanced understanding of the utility and effectiveness of various assistive technology devices in stroke rehabilitation, with a specific focus on robot-assisted training for UE function. The results of our review indicated that the most frequently employed assistive device for patients with stroke is a rehabilitative robot for the UEs. However, upper-limb robots are not significantly more effective than conventional treatments for improving upper-limb functionality for patients with stroke. Nevertheless, the use of upper-limb robots to enhance upper-limb functionality for patients with stroke may be attributed to their ability to assist experts and facilitate a higher number of movement repetitions within a given time frame.

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Declaration of competing interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

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Data availability

The data presented in this study are available on request from the corresponding author.

Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.jht.2023.12.014.

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JHT Read for Credit
JHT 37 # 4 Quiz: # B07

Record your answers on the Return Answer Form found on the tear-out coupon at the back of this issue. There is only one best answer for each question.

#1. The study design was
a. RCTs
b. systematic review
c. prospective cohort
d. case series

#2. The only measure which showed a significant difference was the
a. PUA-UE
b. PMA-UE
c. FUM-UE
d. FMA-UE

#3. According to the WHO, _____people suffer a stroke each year
a. 15 hundred
b. 15 thousand
c. 15 million
d. 25 million

#4. The authors are referring primarily to _____ when they say assistive devices/technology
a. prosthetics
b. robots
c. both of the above
d. none of the above

#5. The assistive devices did not appear to provide superior outcomes to more traditional interventions
a. true
b. false