Study Protocol

Effectiveness of Intelligent Rehabilitation Robot Training System Combined With Repetitive Facilitative Exercise on Upper Limb Motor Function After Stroke: a Randomized Control Trial

Registration number : NCT06435624

Proposed date : June 15, 2024

Study Start	June 15, 2024		
Primary Completion	August 31, 2024		
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Objective	To investigate the effectiveness of Intelligent robotic-assisted training (IRAT) combined with Repetitive facilitative exercise (RFE) on upper limb motor function in stroke patients		
Design	Randomized controlled trial		
Ethical Board	Medical Ethics Management Committee of Nanjing Mingzhou Rehabilitation Hospital		
Approval Number	NJKF202401001		
Location	Nanjing Mingzhou Rehabilitation Hospital, 102 Yaohua New Village, Qixia District, Nanjing, Jiangsu, China		
Randomization	Closed envelope method		
Masking	Single blind design (Outcomes assessor)		
Arms	IRAT group	RFE group	CT group
Enrollment	30	30	30
Interventions	IRAT (30min) + RFE (30min)	RFE (60min)	CT (60min)
Outcome Measures	Fugl-Meyer assessment for upper extremity Active participation proportion Trajectory deviation Trajectory tracking error		
Inclusion Criteria	Patients (18 to 74 years old) who suffered a first or Second unilateral stroke; Chronic stroke (over 6 months from the onset); Obvious upper limb movement disorders (FMA-UE scores from 25 to 42); Ability to understand and follow simple directions		
Exclusion Criteria	Pregnant or lactating; Upper extremity contracture, pain, or trauma; Perceptual, apraxic, or cognitive deficits that lead to inability to follow verbal instructions; Unable to maintain sitting posture; Cerebellar lesion; Clinically unstable medical disorders; Inability to provide informed consent		

Statistical analysis	Sample size calculation: G*power 3.1.9.7 software was used to calculate the sample size. Using the FMA-UE scores from a pilot study, we calculated the effect size f to be 0.374. With an alpha level of 0.05 and a power of 0.80, the total sample size was calculated to be 72. Statistical analysis method: SPSS 21.0 software was used to calculate the demographic and outcome measures. The Shapiro-Wilk test was used to assess the distribution of quantitative variables. Since all variables followed a normal distribution, a one-way analysis of variance was performed to compare the three groups. For post-hoc test, Bonferroni correction was applied when equal variances were assumed, and Tamhane's T2 was used when equal variances were not assumed. A paired samples t - test was used to compare data before and after the intervention. The chi-square test was used to compare qualitative variable. All significance tests were two-tailed, with p values <0.05 considered statistically significant.