Robotic-Assisted Upper Limb Rehabilitation After Stroke Using the ReHand System: A Randomized Controlled Trial

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Introduction

Stroke remains one of the leading causes of disability and mortality worldwide. With an aging global population and the widespread prevalence of risk factors, the incidence of stroke continues to rise annually. A significant proportion of stroke survivors experience upper limb dysfunction, particularly impairments in fine motor skills, which substantially limit daily activities and reduce quality of life (1,2).

Traditional rehabilitation methods—such as physical therapy, occupational therapy, and mirror therapy—require substantial time and human resources and may not always provide sufficient intensity and repetition of movements (3,4). Robotic technologies offer a promising alternative by enabling precise, repetitive, and patient-tailored execution of movements (5).

Among these, soft wearable robotic devices—such as rehabilitative gloves—have shown potential for restoring fine motor function. These systems can be used in both clinical and home-based settings, which is particularly advantageous for long-term post-stroke rehabilitation (6,7).

This study aims to evaluate the effectiveness of the ReHand robotic system for upper limb recovery in post-stroke patients.

Study Design

This is a single-center, randomized, controlled trial with parallel groups and a single-blind design (blinded assessor and statistician). Participants are allocated in a 1:1 ratio to either the intervention group or the control group. Stratified block randomization is used based on age and baseline upper limb motor deficit.

Participants

Eligible participants are adults aged 18 years and older who have experienced an ischemic or hemorrhagic stroke within the past six months, present with upper limb motor impairment, and are capable of understanding instructions. Patients are excluded if they have severe somatic or cognitive impairments, acute medical conditions, or fail to provide informed consent.

Randomization and Allocation

A total of 120 participants will be randomized (60 per group). Stratified block randomization (based on age and Fugl-Meyer Assessment for Upper Extremity [FMA-UE] score) will be used, with the random sequence generated using Random Allocation Software. Allocation will be managed by an independent coordinator who is not involved in the intervention or assessment processes.

Blinding

Single blinding will be implemented: outcome assessors and the statistician will be blinded to group assignments. Patients will not be blinded due to ethical considerations and the nature of the intervention.

Interventions

The intervention group will receive robotic therapy using the ReHand system (five 45-minute sessions per week over eight weeks) in addition to standard rehabilitation. The control group will receive standard therapy only. The ReHand device employs a mirror-motion method and supports both active and passive hand training.

Outcome Measures

The primary outcome is the Fugl-Meyer Assessment of Upper Extremity (FMA-UE).
Secondary outcomes include the Functional Independence Measure (FIM), Wolf Motor Function Test (WMFT), National Institutes of Health Stroke Scale (NIHSS), Barthel Index (BI), Disabilities of the Arm, Shoulder and Hand Questionnaire (DASH), and the Hospital Anxiety and Depression Scale (HADS). Assessments will be conducted at two time points: baseline (T0) and post-intervention (T1).

Sample Size Calculation

The sample size will be calculated using G*Power software based on the analysis of the primary outcome measure (FMA-UE). According to published clinical data, the minimal clinically important difference (MCID) between groups will guide the expected mean difference and standard deviation, enabling the estimation of the anticipated effect size (Cohen's d).
To achieve the desired statistical power at the predefined significance level, the minimum number of participants per group will be determined. To account for potential dropout, the total sample size will be increased accordingly to maintain statistical power.

Statistical Analysis Plan

Software and Libraries:

All statistical analyses will be conducted using Python (version 3.11) in the Google Colab environment. The following libraries will be used:

- pandas (v2.2.2) – data structuring and management
- numpy (v1.26.4) – numerical computations
- scikit-learn (v1.4.2) – data preprocessing
- statsmodels (v0.14.2) – statistical testing and modeling

Data Preprocessing:

- Categorical variables (e.g., sex, stroke type, treatment group) will be encoded using one-hot encoding.
- Numerical variables (e.g., age, days post-stroke) will be standardized using StandardScaler.

Population and Analytical Approach:

All analyses will follow the intention-to-treat (ITT) principle, including all randomized participants regardless of protocol adherence or dropout.

Descriptive Statistics:

- The Shapiro–Wilk test will assess the normality of continuous variables.
- Non-normally distributed data will be summarized using medians and interquartile ranges (Q1–Q3).
- Categorical variables will be reported as absolute and relative frequencies (%) with 95% confidence intervals (CI).

Statistical Methods:

- The Wilcoxon signed-rank test will assess within-group changes (T0 vs. T1).
- The Mann–Whitney U test will compare between-group changes (Δ values).
- Pearson's chi-squared test with Yates' correction will compare categorical data.
- All tests will be two-sided with a significance threshold of $p < 0.05$.

Effect Size Estimation:

To evaluate the magnitude of between-group differences, Cliff's Delta will be calculated. This non-parametric measure is suitable for ordinal and non-normally distributed data.

Additional Analysis:

A sensitivity analysis using rank-based ANCOVA (Quade's test) will be performed with baseline scores as covariates. This will help adjust for initial differences and assess the robustness of the results.

References

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