STATISTICAL ANALYSIS PLAN (SAP)

Study Title: The Effect of Robot-Assisted Upper Extremity Rehabilitation on Motor Functions, Shoulder Pain, Cognitive Functions, and Glenohumeral Subluxation in Patients with Early Subacute Stroke

Document Date: July 1, 2026
NCT Number: [To be assigned]

1. Study Design and Sample Size

This study is a prospective, randomized, controlled trial with a parallel group design (1:1 allocation ratio). The total sample size consists of 36 participants, divided equally into two groups:

- **Intervention Group (Robotic Therapy Group):** n = 18
- **Control Group (Conventional Therapy Group):** n = 18

2. Blinding and Data Integrity

To maximize methodological rigor and eliminate evaluation bias, a single-blind model is utilized. The biostatistician performing the statistical analyses is completely blinded to the group assignments, intervention modalities, and clinical outcomes. Data will be fully de-identified before transfer to the statistical software to ensure complete anonymity.

3. Primary and Secondary Variables

- **Primary Outcome Measure:** Upper extremity motor function recovery assessed via the Fugl-Meyer Assessment for Upper Extremity (FMA-UE).
- **Secondary Outcome Measures:** Brunnstrom Motor Stages (Upper Extremity and Hand), Modified Ashworth Scale (MAS) for muscle tone, Brief Pain Inventory (BPI) for shoulder pain, Montreal Cognitive Assessment (MoCA) for cognitive status, Finger-Width Palpation Method for glenohumeral subluxation, and Functional Independence Measure (FIM) for activities of daily living.

4. Statistical Methodology

Statistical analyses will be performed using specialized statistical software (e.g., SPSS or R). The significance threshold for all hypothesis tests is set a priori at $p < 0.05$.

4.1. Descriptive Statistics

- Continuous variables (e.g., age, height, weight, BMI) will be presented as mean \(\pm \) standard deviation (SD) or median (interquartile range, IQR) based on distribution normality.
- Categorical variables (e.g., gender, dominant hand, hemiplegic side) will be presented as frequencies and percentages.

4.2. Normality Testing

The distribution of quantitative variables will be evaluated using visual methods (histograms, Q-Q plots) and analytical normality tests (Shapiro-Wilk test or Kolmogorov-Smirnov test) to determine whether parametric or non-parametric analysis paths are appropriate.

4.3. Within-Group Changes (Pre- vs. Post-Intervention)

- For normally distributed continuous data, the Paired Samples t-test will be used to compare baseline and post-treatment measures within each group.
- For non-parametrically distributed data or ordinal scales (such as MAS and Brunnstrom stages), the Wilcoxon Signed-Rank test will be applied.

4.4. Between-Group Comparisons

- To evaluate the superior efficacy of the interventions, post-treatment changes and scores will be compared between the Robotic Therapy Group and the Conventional Therapy Group.
- Parametric data will be analyzed using the Independent Samples t-test.
- Non-parametric data, continuous variables violating normality, and ordinal score differences (FMA-UE, Brunnstrom, MAS, MoCA, BPI, FIM, and subluxation grades) will be analyzed using the Mann-Whitney U test.
- Categorical demographic characteristics will be compared using the Chi-Square test or Fisher's Exact test.