Ref#: INU/REHAB/XC45 **Date: 12/05/2026**

1. Protocol Summary

Study Type: Observational (Retrospective) **Design:** Single-center, retrospective cohort study
Objective: To evaluate the cognitive effectiveness of combined somatotherapy and occupational therapy in post-stroke patients using Montreal Cognitive Assessment (MoCA) scores.
Enrollment: 50 participants **Study Period:** Data from patients treated between 2018–2019

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2. Background and Rationale

Stroke is a major cause of cognitive impairment worldwide. Cognitive deficits significantly affect functional independence and quality of life. Somatotherapy (structured sensorimotor therapy) combined with occupational therapy (task-oriented ADL training) is commonly used in stroke rehabilitation. This retrospective study aims to assess the cognitive benefits of this combined approach.

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3. Objectives

Primary Objective: To determine the change in cognitive function (measured by MoCA total score) before and after 4 weeks of combined somatotherapy and occupational therapy.

Secondary Objectives:

- To evaluate changes in individual MoCA cognitive domains.
- To determine the proportion of patients achieving MoCA score ≥26 after intervention.

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4. Study Design

- Retrospective observational study
- Single arm (no control group)
- Data collected from medical records of King Hospital, Swat, Pakistan (2018–2019)

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5. Study Population

Inclusion Criteria:

- Adults (≥30 years) diagnosed with ischemic or hemorrhagic stroke (first or recurrent)
- Referred for cognitive rehabilitation
- Received at least 4 weeks of somatotherapy + occupational therapy
- Had pre- and post-therapy MoCA assessment

Exclusion Criteria:

- Severe aphasia or speech impairment preventing MoCA testing
- Significant visual or hearing impairment interfering with testing
- Incomplete medical records

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6. Intervention / Exposure

Combined Somatotherapy and Occupational Therapy

- Duration: 4 weeks
- Frequency: 5 sessions per week
- Session length: 35 minutes
- Somatotherapy: Sensorimotor training, balance, coordination, and movement therapy
- Occupational Therapy: Patient-specific ADL training with cognitive integration
- Equipment: Adjustable tables/chairs, wheelchairs, splints, and assistive devices

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7. Outcome Measures

Primary Outcome: Change in MoCA Total Score (0–30) from baseline to 4 weeks.

Secondary Outcomes:

- Changes in MoCA subdomain scores (Visuospatial/Executive, Naming, Attention, Language, Abstraction, Delayed Recall, Orientation)
- Percentage of patients with MoCA ≥26 (normal range)

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8. Statistical Analysis Plan (SAP)

8.1 General Principles

- Software: SPSS version 23.0
- Significance level: $p < 0.05$ (two-tailed)
- Handling of missing data: Complete case analysis (only patients with both pre and post MoCA scores included)

8.2 Descriptive Statistics

- Continuous variables: Mean ± SD or Median (IQR) as appropriate
- Categorical variables: Frequency and percentages

8.3 Inferential Statistics

- **Primary Analysis:** Wilcoxon Signed-Rank Test to compare pre- and post-intervention MoCA total scores (non-parametric test for paired data).
- **Secondary Analysis:**
  - Spearman Rank Correlation between baseline and final MoCA scores.
  - Wilcoxon Signed-Rank Test for individual MoCA domains.
  - McNemar's test for proportion of patients with MoCA ≥26 before vs after intervention.

8.4 Subgroup Analysis (Exploratory)

- By age, gender, and stroke type (ischemic vs hemorrhagic), if sample size permits.

8.5 Significance Results will be considered statistically significant at $p < 0.05$.

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9. Data Management and Ethics

- Data were collected retrospectively from hospital records.
- Patient confidentiality and privacy maintained (anonymized data).
- No individual patient data will be shared publicly.

Ethical Considerations: This study was conducted in accordance with the Declaration of Helsinki. Being retrospective, it was exempted from informed consent requirement by the hospital administration.

Approval: This protocol has been prepared for registration on ClinicalTrials.gov