STUDY PROTOCOL
Protocol Version: 1.0
Protocol Date: 15 June,2025
Ethics Approval:
Approved by IREB, University of Lahore
Approval No: UOL/IREB/25/09/0030
Approval Date: June 30, 2025

Title: Static versus Dynamic Wrist-Hand Splints for Wrist Spasticity in subacute Stroke Patients: A Randomized Clinical Trial

Introduction

Stroke, or cerebrovascular accident, occurs when blood supply to part of the brain is blocked or a cerebral vessel ruptures, resulting in loss of oxygen and essential nutrients. This often leads to paralysis, weakness, impaired coordination and balance, limited mobility, or even death [(1–3)]. Neurological damage disrupts motor control pathways, commonly manifesting as muscle weakness. Following initial injury, the brain undergoes spontaneous recovery through neural plasticity and reorganization [(4–6)]. Stroke is a leading cause of disability globally, with 24.9 million people living with stroke and 11.6 million new cases reported annually in Western Europe [(7,8)].

Stroke is classified into ischemic (≈80%) and hemorrhagic types [(9)]. Ischemic stroke results from cerebral artery obstruction causing neuronal apoptosis and necrosis in motor regions, while hemorrhagic stroke involves vessel rupture, increased intracranial pressure, and secondary neuronal damage [(7)]. Clinical symptoms include impaired speech, dysphagia, visual and sensory deficits, cognitive impairments, altered muscle tone with spasticity, and inability to walk or grasp objects [(10)].

Motor dysfunction, low muscle strength, joint stiffness, muscular hypertonia, and muscle contracture are common complications post-stroke [(11–13)]. Post-stroke upper limb spasticity frequently involves involuntary wrist and finger flexor contraction, limiting muscle lengthening and prehensile grasping [(14,15) (16,17)]. Approximately 85% of stroke patients experience delayed upper limb recovery, with wrist spasticity affecting 4–46% in chronic stages [(18,19)].

Rehabilitation through targeted exercises, occupational therapy, and constrained-induced movement therapy improves motor recovery [(20,21)]. Orthotic interventions, including static and dynamic splints, prevent deformities, relieve spasticity, and enhance hand function [(22,23)]. Dynamic splints utilize springs or pulleys to provide gentle, adjustable stretching, and have shown superior efficacy in reducing spasticity when used 6 hours daily [(24,25)]. Despite evidence supporting both types, direct comparisons remain limited [(26,27)].

Rationale

This study evaluates the comparative effectiveness of static and dynamic wrist-hand splints in post-stroke rehabilitation, aiming to provide evidence-based guidance for clinicians to optimize treatment strategies and patient outcomes.

Materials and Methods

Study Design: A randomized controlled trial (RCT) compared static versus dynamic wrist-hand splints on spasticity, functional hand recovery, and pain in subacute stroke patients.

Setting: Markaz Bahali-E-Mazooran Rehabilitation Center, Faisalabad, with trained physiotherapists and occupational therapists supervising interventions.

Study Duration: Nine months; each participant underwent a structured 4-week intervention with assessments at baseline and post-intervention.

Sample Size: 25 participants initially targeted; after adjustment for dropout, 20 participants (10 per group) completed the study.

Sampling Technique: Purposive sampling; participants randomly assigned to groups via computer-generated randomization.

Inclusion Criteria: Adults 30–65 years, diagnosed with hemiplegic stroke within last 6 months, moderate to severe wrist spasticity (MAS ≥1).

Exclusion Criteria: Severe neurological or musculoskeletal disorders, cognitive impairment, contraindications to splint use, or inability to comply with protocols.

Outcome Measures: MAS, pain scores, grip strength, functional outcomes, and patient satisfaction at baseline and week 4.

Statistical Analysis: Paired t-tests, Wilcoxon signed-rank tests, Mann-Whitney U tests, and repeated-measures ANCOVA used to evaluate changes and compare groups.

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