STUDY PROTOCOL

Protocol 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

Ethics Committee Approval: Ankara Bilkent City Hospital, TABED (Ref No: TABED 1/1994/2025)
Initial Ethics Approval Date: December 31, 2025

Ethics Committee Approval for Title Amendment: Ankara Bilkent City Hospital, TABED (Ref No: TABED 1/2862/2026)
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NCT Number: [To be assigned]

1. Study Personnel & Affiliations

- **Principal Investigator:** Hale OZDEMIR, PT, MSc
- **Primary Thesis Advisor:** Assist. Prof. Dr. Azize Reda TUNC
- **Secondary Thesis Advisor:** Prof. Dr. Burcu YANIK
- **Institution:** Lokman Hekim University, Graduate School of Health Sciences, Department of Physical Therapy and Rehabilitation, Ankara, Turkey

2. Conceptual Framework & Rationale

Upper extremity motor deficits, shoulder pain, and glenohumeral subluxation significantly limit functional independence in post-stroke individuals. The early subacute phase (2–4 weeks post-onset) presents a biological window of enhanced neuroplasticity. Conventional neurorehabilitation approaches (Bobath, PNF, Brunnstrom) are crucial but often lack the necessary high-intensity repetition. This protocol outlines a randomized controlled trial to investigate whether integrating robot-assisted therapy (using the ArmeoPower exoskeleton) into conventional rehabilitation provides superior improvements across motor, structural, pain, and cognitive domains compared to standard care alone.

3. Methodology & Study Design

- **Study Type:** Interventional, randomized, controlled, parallel-assignment trial.
- **Sample Size:** 36 participants (1:1 allocation ratio; 18 in the intervention group, 18 in the control group).
- **Blinding:** Single-blind. The biostatistician performing the statistical data analysis will be completely blinded to the group assignments, treatment allocations, and clinical outcomes.

3.1. Eligibility Criteria

- **Inclusion Criteria:** First-time stroke; onset between 2 and 4 weeks (early subacute phase); age 35–70 years; cognitive status suitable to follow instructions; presence of shoulder pain at baseline assessment.
- **Exclusion Criteria:** Prior orthopedic upper extremity disease or history of surgery; pre-existing confounding neurological disorders.

3.2. Intervention Protocols (6 Weeks Total)

- **Control Group (Conventional Therapy):** 30 sessions of standard neurorehabilitation (40 minutes/session, 5 days/week). Interventions include neurodevelopmental techniques (Bobath, PNF, Brunnstrom), passive/active range of motion, stretching to manage spasticity, and targeted strengthening.
- **Intervention Group (Robotic Therapy):** 20 sessions of conventional neurorehabilitation combined with 10 sessions of robot-assisted training via the ArmeoPower exoskeleton (20 minutes/session, 2–3 times/week), ensuring a matched total of 30 physical intervention sessions.

4. Outcome Measures & Assessment Timeline

All clinical parameters will be evaluated at Baseline and at 6 Weeks:

- **Primary Outcome:** Motor function recovery via the Fugl-Meyer Assessment for Upper Extremity (FMA-UE).
- **Secondary Outcomes:**
    - Shoulder pain severity and interference using the Brief Pain Inventory (BPI).

- Structural severity of glenohumeral subluxation using the Finger-Width Palpation Method.
- Multi-domain cognitive screening via the Montreal Cognitive Assessment (MoCA).
- Motor recovery staging using Brunnstrom Motor Stages (Upper Extremity and Hand).
- Independence in daily living via the Functional Independence Measure (FIM).
- Muscle tone and spasticity using the Modified Ashworth Scale (MAS) for shoulder flexors and biceps brachii.

5. Ethical Considerations

This trial is conducted in full compliance with the Declaration of Helsinki. While the principal investigator is affiliated with Lokman Hekim University, official institutional ethics approval was reviewed and granted by the Ankara Bilkent City Hospital Medical Research Ethics Committee (TABED) on December 31, 2025, under approval number TABED 1/1994/2025. Written informed consent will be obtained from all participants prior to any study-related procedures.

Following the thesis defense examination, a minor modification to the study title was requested by the thesis jury. This title amendment was officially reviewed and approved by the Ankara Bilkent City Hospital Medical Research Ethics Committee (TABED) on July 1, 2026, under the new approval number TABED 1/2862/2026.