Study Protocol and Statistical Analysis Plan

Official Title: The Effect of Shoulder Mobilization on Muscle Strength and Proprioception: A Randomized Double-blind Study

NCT Number: NCT06910332

Document Date: March 07, 2025

This document contains the full study protocol and statistical analysis plan (SAP).

Study Protocol

Background and Purpose:
To investigate the acute effects of a single session of shoulder joint mobilization on muscle strength and proprioception in healthy individuals using a randomized, double-blind, placebo-controlled design.

Study Design:
Randomized, double-blind, placebo-controlled trial with 48 healthy university students (aged 18-25) allocated to:
- Mobilization group (n=24): passive glenohumeral joint mobilization
- Sham group (n=24): simulated mobilization without mechanical glide

Primary Outcomes:
- Isometric shoulder muscle strength (flexion, abduction, internal/external rotation) measured by handheld dynamometer
- Proprioception assessed via laser-assisted joint position reproduction (JPR) test

Data Collection Time Points:
- Baseline
- Immediately after intervention

Statistical Analysis Plan:
- Normality: histograms, Q-Q plots, Shapiro-Wilk test
- Baseline group comparisons: t-tests or Mann-Whitney U
- Main analysis: linear mixed-effects models (group, time, group*time), random effect: subject
- Software: Jamovi v2.4 with GAMLj3
- Significance: $p < 0.05$

Ethical Considerations:
- Approved by Acıbadem University and Acıbadem Healthcare Institutions Medical Research

Ethics Committee (ATADEK) with the approval number 2025-04/185
- Informed consent obtained from all participants
- Registered at ClinicalTrials.gov (NCT06910332)