

Effects of Neurocognitive Loading on Neuromuscular Control, Kinesiophobia, and Clinical Outcomes Following Anterior Shoulder Stabilization Surgery: A Randomized Controlled Trial

NCT number and document date, title: FTREK26/24-16/04/2026-Anterior Omuz Stabilizasyon Cerrahisi Sonrası Nörokognitif Yüklenmenin Nöromuskuler Kontrol, Kinezyofobi ve Klinik Sonuçlara Etkisi: Randomize Kontrollü Çalışma

Study Design

- **Study Type:** Interventional (Clinical Trial)
- **Intervention Model:** Parallel Assignment (Participants are assigned to one of two groups in a 1:1 ratio)
- **Number of Arms:** 2 Arms (Neurocognitive Loading Group vs. Standard Rehabilitation Group)
- **Masking/Blinding:** Not Blind
- **Allocation:** Randomized
- **Enrollment Target:** 32 participants (calculated sample size of 28 analysis-eligible individuals plus an anticipated 15% attrition buffer).
- **Primary Purpose:** Treatment / Rehabilitation

Statistical Analysis Plan (SAP)

1. Data Cleaning and Distribution Analysis

- Statistical analyses will be conducted using IBM SPSS Statistics software.
- The normal distribution of all continuous variables will be verified objectively using the **Shapiro-Wilk test**, supplemented by visual inspection of histograms and Q-Q plots.
- Descriptive statistics will be reported as follows:
 - **Normally distributed continuous data:** Mean and standard deviation
 - **Non-normally distributed continuous data:** Median with minimum-maximum ranges.
 - **Categorical variables:** Frequencies and percentages

2. Baseline Homogeneity (Group Comparisons)

To ensure successful randomization and check for baseline demographic or pre-injury clinical imbalances between the intervention and control groups, the following tests will be applied:

- **Independent Samples t-test:** For continuous, normally distributed variables.
- **Mann-Whitney U test:** For continuous, non-normally distributed parameters.
- **Chi-square test (or Fisher's Exact test** where cell counts are small): For all categorical demographic and clinical classification data.

3. Primary and Secondary Hypotheses Testing

To analyze the primary outcome (Active Joint Position Sense error scores) and secondary outcomes (force reproduction, strength, kinesiophobia, pain, WOSI scores, and functional tests) across multiple post-surgical timelines, the primary focus will evaluate the Group \times Time interaction effect:

- **Two-Way Mixed-Model ANOVA (Mixed ANOVA):** Utilized for variables that meet the parametric assumptions of normality and homogeneity of variance.
- **Linear Mixed Models (Generalized Linear Mixed Models):** Utilized if parametric assumptions are violated, or to effectively manage any missing data points by allowing all available participant data to be integrated into the model without losing statistical power.
- **Non-Parametric Alternatives:** If assumptions are severely violated, within-group changes over time will be analyzed using the **Friedman test**, and between-group differences at specific intervals will be evaluated using the **Mann-Whitney U test**.
- **Post-Hoc Analysis:** When a significant interaction or main effect is detected, pairwise comparisons across the different follow-up periods (Baseline, 6 weeks, 12 weeks, 24 weeks) will be isolated using **Bonferroni corrections** to control for Type I error inflation.

4. Specialized and Time-Specific Metrics

- **Return-to-Sport Readiness (SI-RSI):** Because psychological readiness to return to sports is strictly captured at the conclusion of the rehabilitation protocol (Postoperative Week 24), group differences will be analyzed cleanly via an **Independent Samples t-test** or **Mann-Whitney U test**.
- **Clinical Significance & Effect Size:** To supplement traditional p -values and establish clinical relevance, effect sizes will be systematically calculated and reported as **Cohen's d** (for coordinate pairs) or **partial eta squared** for variance frameworks.
- **Analysis Approach:** The trial will officially utilize a **per-protocol analysis framework**.
- **Significance Level:** For all statistical operations, alpha will be set a priori at $p < 0.05$. All intervals and output estimates will be accompanied by 95% confidence intervals (CI).