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Study Title**: Effect of Sleeping Posture Guidance on Sleep Quality in Patients with Rotator Cuff Syndrome Undergoing Physical Therapy: A Randomized Controlled Trial**

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STUDY PROTOCOL

1. Objectives

The primary objective is to evaluate the effect of sleeping posture guidance combined with physical therapy on the sleep quality of patients diagnosed with Rotator Cuff Syndrome (RCS). Secondary objectives include assessing improvements in shoulder function and pain intensity.

2. Study Design

This is a single-blind, two-arm, parallel-group randomized controlled clinical trial.

- **Experimental Group (n=32):** Standard Physical Therapy + Sleeping Posture Guidance.
- **Control Group (n=32):** Standard Physical Therapy only.

3. Intervention Protocol

Both groups will undergo 10 physical therapy sessions (twice weekly for 5 weeks).

- **Standard Physical Therapy:** Includes manual therapy (articular mobilization), stretching, and progressive strengthening exercises (isometric and isotonic).
- **Sleeping Posture Guidance (Experimental only):** In the 1st week, patients will receive specific instructions on optimal sleeping positions to reduce nocturnal subacromial pressure, including the use of supportive pillows. Monthly reinforcements will be conducted.

4. Data Collection and Follow-up

Assessments will be conducted at three points:

- **T0 (Baseline):** Week 1, before intervention.
- **T5 (Post-intervention):** Week 5, immediately after 10 sessions.
- **T12 (Follow-up):** Week 12, remote assessment via online questionnaire.

STATISTICAL ANALYSIS PLAN

1. Sample Size Calculation

Based on previous studies using the Pittsburgh Sleep Quality Index (PSQI) as the primary outcome, a sample size of **64 participants** (32 per group) was determined to achieve a power of 80% and a significance level of 0.05, accounting for a 20% expected dropout rate.

2. Primary and Secondary Outcomes

- **Primary Outcome:** Change in sleep quality scores (PSQI and Mini-Sleep Questionnaire).
- **Secondary Outcomes:** Change in shoulder function (ASES score) and pain intensity (Visual Analog Scale - VAS).

3. Statistical Methods

- **Descriptive Analysis:** Quantitative data will be expressed as mean and standard deviation (or median and interquartile range for non-normal data). Qualitative data will be expressed as frequencies.
- **Normality Testing:** The Shapiro-Wilk test will be used to determine data distribution.
- **Inference:** * To compare baseline characteristics between groups, Independent T-tests or Mann-Whitney U tests will be used.
    - To evaluate the effect of the intervention over time (T0, T5, T12) and between groups, **Generalized Estimating Equations (GEE)** or Mixed-Model ANOVA will be applied.
    - The level of significance is set at **$p \leq 0.05$** with a 95% Confidence Interval (CI).
- **Software:** All analyses will be performed using SPSS (Statistical Package for the Social Sciences) or R software.