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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**

Institution**: Federal University of São Paulo – Paulista Medical School (EPM)**

Principal Investigator**: Paulo Santoro Belangero**

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INFORMED CONSENT FORM (ICF)

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

Principal Investigator: Paulo Santoro Belangero.

Research Site: Instituto Buran (São Caetano do Sul, SP, Brazil).

You are being invited to participate as a volunteer in this research because you have a medical diagnosis of a rotator cuff injury and have been referred for physical therapy treatment. Your contribution is very important, but you should not participate against your will.

1. Purpose of the Research

This research is being conducted due to the need for a better understanding of the relationship between physical therapy and sleep quality in patients with Rotator Cuff Syndrome, aiming at the development of more effective and less invasive interventions. The objective is to compare the effect of sleeping posture guidance (experimental intervention) with standard physical therapy (control group) on sleep quality and pain, using validated questionnaires.

1. Participant Criteria

The study will include 64 individuals of both sexes, aged between 18 and 70 years, with a confirmed diagnosis of tendinopathy or partial rotator cuff tear (up to 50%) identified by physical examination and MRI. Participants must be referred for physical therapy and exhibit poor sleep quality as measured by the PSQI questionnaire.

2. Study Procedures

If you agree to participate, the following steps will occur:

- **Initial Assessment:** You will complete four questionnaires: Mini Sleep Questionnaire (MSQ), Pittsburgh Sleep Quality Index (PSQI), Visual Analog Scale (VAS) for pain, and the American Shoulder and Elbow Surgeons Score (ASES).

- **Randomization:** You will be randomly assigned (by draw) to one of two treatment groups with equal chances.
    - **Group 1 (Experimental):** Standard physical therapy (2 sessions per week for 5 weeks) plus personalized guidance on the best sleeping posture for your case.
    - **Group 2 (Control):** Standard physical therapy only (2 sessions per week for 5 weeks).
- **Assessment Moments:** Both groups will be evaluated at the 1st, 5th, and 12th weeks after the start of treatment.
- **Data Collection:** Data collection at weeks 1 and 5 will be in person. At week 12, a link to an online questionnaire will be sent for remote completion.
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3. Risks and Discomforts

- **Physical:** Participants are instructed not to exceed the limit of muscular discomfort during physical therapy. However, delayed onset muscle soreness may occur after the first week of intervention, typically normalizing within 72 hours. If pain persists, the intervention will be suspended, and free physical therapy care will be provided until recovery.

- **Privacy:** There is a minimal risk of unintentional disclosure of identity. This will be minimized by using numerical codes to ensure your name or initials are not disclosed.
- **Psychological:** Any discomfort while answering questionnaires can be addressed by stopping the interview at any time.

4. Benefits

By participating, you will receive full physical therapy treatment aimed at improving shoulder pain and function. If you are in Group 1, you will also receive postural guidance. If the results show that postural guidance is more effective, this guidance will be provided to the control group participants at the end of the study.

5. Confidentiality and Data Handling

Your identity will be kept strictly confidential through the complete omission of any data that allows for your identification. Data will be collected and managed via a digital platform (Google Forms) using security codes for all communications. Original materials will be kept for five years and then destroyed.

6. Voluntary Participation and Costs

- **Right to Withdraw:** You may withdraw your consent or refuse to participate at any time without penalty or loss of benefits.
- **Costs:** There are no costs for participating. Any expenses related to exams, transport, or food (including for a companion) will be reimbursed. There is no financial compensation for participation.

- **Damages:** Immediate, integral, and free medical assistance is guaranteed if any damage results from the research, with the possibility of compensation as per legal regulations.

7. Contact Information

- **Principal Investigator:** Paulo Santoro Belangero. Phone: +55 (11) 97571-9802 / Cell: +55 (11) 97571-9815. Address: Rua Amazonas, 363, Centro, São Caetano do Sul, SP. Email: thiburan@hotmail.com.
- **Ethics Committee:** This study was approved by the UNIFESP Ethics Committee (CEP), Protocol No. 93319125.3.0000.5505. Contact: +55 (11) 3385-4343 (ext 8699) or email cep@unifesp.br.

8. Consent Declaration

I declare that I have been informed about the objectives of this research, I have read (or had read to me) the procedures, risks, and benefits, and all my questions have been answered. I agree to participate voluntarily and authorize the use of my data for research purposes, ensuring my identity remains confidential.

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Participant Name: _____
Signature: _____ **Date:** //_____

Investigator Name: _____
Signature: _____ **Date:** //_____