**STUDY PROTOCOL WITH STATISTICAL ANALYSIS PLAN AND INFORMED CONSENT FORM**

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**Title of the Study:**

**Efficacy of Inspiratory Muscle Training on Objective and Subjective Sleep Parameters in Apneic Patients: A Randomized Controlled Trial**

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**Principal Investigator:**

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## 1. Background and Rationale

Obstructive Sleep Apnea (OSA) is a sleep-related breathing disorder characterized by recurrent partial or complete collapse of the upper airway during sleep, associated with respiratory effort and oxygen desaturation. In OSA, sleep architecture is impaired because frequent awakenings during apnea episodes disrupt the sleep-wake cycle. This leads to poor sleep quality, excessive daytime sleepiness, and increased risk of cardiovascular complications. It is necessary to consider the complexity of OSA, its repercussions, and to seek treatment in an attempt to reduce the complications of this disease. Inspiratory Muscle Training (IMT) is a low-cost, non-invasive intervention that may strengthen respiratory muscles and improve breathing patterns during sleep. The

search for therapies with proven effectiveness in treating OSA can improve clinical outcomes in this population.

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## 2. Objectives

**Primary Objective:**

- To evaluate the effectiveness of four weeks of IMT on objective and subjective sleep parameters in patients with OSA moderate to severe compared to a control group receiving IMT.

**Secondary Objectives:**

- Analyze the sleep pattern: total sleep time, number of nighttime awakenings, sleep efficiency, total time in bed, total awake time during sleep.
- Evaluate sleep quality and excessive daytime sleepiness.
- Analyze hypoxic burden during sleep.

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## 3. Study Design

- **Study Type:** Interventional (Clinical Trial)
- **Allocation:** Randomized
- **Intervention Model:** Parallel Assignment
- **Masking:** Triple-blind ( Investigator, Participant and Statistician)
- **Primary Purpose:** Treatment
- **Estimated Enrollment:** 30 participants
- **Study Duration:** 4 weeks

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## 4. Eligibility Criteria

**Inclusion Criteria:**

- Patients of both sexes;
- Aged 18 to 70 years;
- Diagnosis of moderate to severe OSA confirmed by polysomnography;
- Not having started treatment for OSA.

**Exclusion Criteria:**

- Patients with neuromuscular, infectious, or immune diseases, tumors, or conditions that prevent IMT, manuvacuometry, or respiratory muscle tests;
- Patients with unstable angina, untreated or uncontrolled high blood pressure, left heart dysfunction, brain aneurysm, or other heart problems that prevent respiratory muscle tests or IMT;
- Deformities in the arms or hands that stop the use of actigraph or oximetry sensors;
- Other sleep disorders like insomnia, hypoventilation syndrome, or needing continuous oxygen at home;
- Cognitive impairments that make it hard to understand study procedures.
- Starting or currently using CPAP treatment during the study week;
- Attended pulmonary rehab within 6 months before the study;
- Doing moderate or vigorous physical activities regularly in the last 30 days (according to IPAQ);
- Using sleep medication for insomnia;
- Having severe obesity;
- Living in places with poor phone or internet access that prevent contact or data transmission from devices (actigraph or oximeter).

**5. Interventions**

**Experimental Group:**

- Inspiratory Muscle Training using Powerbreathe® Classic Light device
- Frequency: 2 times per day, 7 days per week, for 4 weeks
- Progressive load: 50%, 60%, and 75% of PIMax over four weeks

**Control Group:**

- Same schedule using an unloaded device (no spring resistance)

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**6. Outcome Measures**

**Primary Outcomes:**

- Sleep quality and  Severity of the disease.

**Secondary Outcomes:**

- Epworth Sleepiness Scale (ESS)
- Pittsburgh Sleep Quality Index (PSQI)
- International Physical Activity Questionnaire (IPAQ)
- Respiratory muscle strength and endurance
- Sleep pattern (actigraphy)
- Hypoxic burden (Home polysomnography.)

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**7. Study Procedures**

- Screening of patient records and phone contact.
- Initial evaluation and informed consent
- Baseline measurements
- Randomization into intervention or control group
- 4-week training protocol
- Post-intervention assessments
- Daily monitoring via telephone
- Sleep data collected for 9 days before and after training using wearable devices

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**8. Data Collection and Management**

- Data collected via validated questionnaires and electronic spreadsheets
- Sleep data extracted from actigraphy and oximetry equipment Home polysomnography)
- All information coded to protect participant confidentiality
- Data stored securely for a minimum of 5 years

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**9. Statistical Analysis Plan**

- Software: SPSS v26.0
- Normality tested using Shapiro-Wilk
- Two-way ANOVA for inter- and intra-group comparisons
- Tukey's post-hoc test for subgroup analysis
- Significance level set at $p < 0.05$

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**10. Ethical Considerations**

- Approved by the Ethics Committee for Research Involving Human Beings at UFPE
- Informed Consent Form provided and signed prior to enrollment
- Participants may withdraw at any time without penalty
- All data treated confidentially and used exclusively for scientific purposes

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**11. Monitoring and Safety**

- Weekly in-person visits for training load adjustment
- Daily telephone follow-up
- Participants instructed to report any adverse effects
- Adverse events documented and managed by the study team

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**12. Data Sharing Statement**

- No personal or individual-level data will be publicly shared
- Aggregated study results may be published in scientific journals or conferences

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**13. Study Location**

Sleep Outpatient Clinic
Hospital Otavio de Freitas
Recife – Pernambuco, Brazil

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**14. Appendices**

- Appendix A: Informed Consent Form
- Appendix B: Patient assessment
- Appendix C: Training Protocol Timeline
- Appendix D: Evaluation Questionnaires (ESS, PSQI, IPAQ,PGIC)
- Appendix E: Sleep Data Collection Forms (Actigraphy)

**INFORMED CONSENT FORM**

**FEDERAL UNIVERSITY OF PERNAMBUCO**
**CENTER FOR HEALTH SCIENCES**
**DEPARTMENT OF PHYSIOTHERAPY**
**GRADUATE PROGRAM IN PHYSIOTHERAPY**

**INFORMED CONSENT FORM**

(**FOR ADULTS OVER 18 YEARS OLD OR LEGALLY EMANCIPATED**)

You are invited to participate as a volunteer in the research study entitled: **"Efficacy of Inspiratory Muscle Training on Objective and Subjective Sleep Parameters in Apneic Patients: A Randomized Controlled Trial,"** conducted by **Shirley Nogueira de Souza**, residing at Rua Porto União, 185, Afogados, Recife-PE, 50770-480.
Phone: (81) 99674-2087 — Email: shirley.nsouza@ufpe.br

The study is supervised by **Dr. Anna Myrna Jaguaribe de Lima** (Phone: 81 99899-0222, Email: anna.myrna@ufrpe.br) and co-supervised by **Dr. Armele de Fátima Dornelas de Andrade** (Phone: 81 98781-8965, Email: armele.andrade@ufpe.br).

You are free to ask any questions you may have. Only after all your doubts have been clarified and you agree to participate, please initial each page and sign at the end of this document, in two copies—one for you and one for the principal investigator.

Participation is entirely voluntary. You may refuse or withdraw at any stage without penalty or consequences

**RESEARCH INFORMATION**

**JUSTIFICATION:**

Obstructive Sleep Apnea (OSA) negatively impacts general health and quality of life. It increases the risk of car and workplace accidents due to excessive sleepiness and is associated with serious conditions such as hypertension and heart disease. Treatment depends on severity, and low-cost, easy-to-use alternatives with proven efficacy may benefit individuals with moderate to severe OSA.

**OBJECTIVE:**

To evaluate the effectiveness of inspiratory muscle training on both objective and subjective sleep parameters in individuals with moderate to severe obstructive sleep apnea, compared to a control group.

**METHODOLOGY:**

This is an experimental clinical trial. Initially, patient records with previous sleep studies (polysomnography) will be reviewed. Those diagnosed with moderate to severe OSA will be contacted by phone and invited to participate.

Participants who agree will attend an in-person visit at the Sleep Outpatient Clinic of Otavio de Freitas Hospital to sign this consent form and provide personal information. Participants will be randomly assigned to either the intervention or control group.

Participants will receive a device and instructions to perform inspiratory muscle training twice a day, seven days a week, for four weeks. Device load will be adjusted weekly per protocol. A training diary will be provided for notes or adverse reactions.

Sleep data will be collected using:

- **Actigraphy device** (worn like a wristwatch): worn 9 days before and 9 days after training, 24 hours/day except during bathing.
- **Oxygen saturation sensor** (portable oximeter): worn on the finger for one night after training.

- **Type III portable home sleep monitoring (polysomnography)**: performed at home by the participant following instructions.

Participants will also complete questionnaires before and after the 4-week program to assess:

- Daytime sleepiness
- Sleep quality
- Physical activity level

Inspiratory muscle strength and performance will also be assessed using validated equipment.

All sleep, oximetry, and polysomnography data will be downloaded, analyzed with specific software, and interpreted by trained professionals.

After completing the protocol, participants will complete a questionnaire about perceived health changes and treatment satisfaction.

**RISKS:**

Potential risks include:

- Privacy breaches if health data were to be disclosed (mitigated by coded/anonymized records).
- Muscle fatigue or discomfort from training if improperly performed.
- Skin irritation or allergic reaction to the actigraphy, polysomnography, or oximeter devices.

Precautions include:

- Instruction from a physiotherapist on proper equipment use and rest intervals.
- Daily phone support from the research team.
- Written records of any adverse events.

If allergic reactions occur, participants may remove the device and seek medical or pharmaceutical care. Participants will be advised to adjust device fit to prevent

discomfort. The research team is not responsible for medical treatment but will provide guidance.

- Access to a low-cost, easy-to-use alternative therapy.
- Strengthening of respiratory muscles, which may improve breathing, exercise tolerance, and reduce dyspnea.
- Potential benefit for those unable to access or tolerate CPAP.

Participants in the control group will be offered the training after data collection if desired.

All participants will receive an individual report with their results via email or WhatsApp.

Participation is voluntary and refusal will not affect any services. Confidentiality will be strictly maintained. Results will only be disclosed in scientific forums or publications without personal identification.

Data will be stored securely for a minimum of 5 years by the principal investigator.

No fees or payments are involved. Compensation will be provided only in cases of proven harm related to participation, per judicial or extrajudicial decision. Transportation and meal costs will be reimbursed if needed.

For ethical concerns, contact the UFPE Research Ethics Committee:
Address: Avenida da Engenharia, s/n – 1st Floor, Room 4 – Cidade Universitária, Recife-PE, ZIP: 50740-600
Phone: (81) 2126-8588 — Email: cephumanos.ufpe@ufpe.br

## CONSENT TO PARTICIPATE AS A VOLUNTEER

I, _____, CPF: _____, having read (or listened to a reading of) this document and had my questions answered by the investigator, freely consent to participate in the study

entitled:**"Efficacy of Inspiratory Muscle Training on Objective and Subjective Sleep Parameters in Apneic Patients: A Randomized Controlled Trial."**

I understand the procedures, risks, and benefits involved. I am aware I may withdraw my consent at any time without penalty or loss of care.

**Place and Date: _____**

**Participant's Signature: _____**

**Thumbprint (if applicable):** 

We hereby confirm that consent was requested, explained, and accepted by the participant in our presence (two witnesses not affiliated with the research team):

**Name: _____**

**Signature: _____**

Name: _____

**Signature: _____**