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Effects of Pompage Treatment Associated or Not with Photobiomodulation on Pain, Range of Motion, and Quality of Life in Patients with Neck Pain: A Controlled, Randomized and Double Blinded Study Protocol

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Introduction: Chronic neck pain is a persistent condition that affects the cervical region of the spine, causing pain and restricted mobility. Its management often includes manual therapies, with passive and active approaches aimed at pain relief, functional improvement, enhanced mobility, motor control, and reduced inflammation. Chronic neck pain is termed non-specific when it is unrelated to conditions like inflammatory rheumatic disease, osteoporosis, cancer, or radiculopathy. Photobiomodulation (PBM) using lasers and LEDs has shown therapeutic efficacy in treating neck pain, offering a non-invasive, easy-to-apply option for patients and clinicians. This study protocol aims to evaluate the effects of Pompage therapy, alone or combined with PBM using an LED cluster, on pain and neck disability.

Methods and Analysis: This controlled, randomized, double blinded clinical trial will include participants aged 18-62 with non-specific chronic neck pain. Participants will be randomly assigned to two groups: (1) Pompage only (n=28), and (2) Pompage + PBM (n=28), which combines Pompage with PBM using an LED cluster applied to the neck for 10 minutes. The protocol includes 10 sessions, three times per week. The PBM uses a cluster of 264 LEDs (8 mW; 4.89 J; 9.6 J/cm²; 16 mW/cm² per LED), with 132 red (660 nm) and 132 infrared (850 nm) LEDs. Pain, functional disability and quality of life will be assessed using the Visual Analog Scale (VAS), the Neck Pain Disability Index and the WHOQOL-100 before and after treatment, with statistical analysis at α=0.05.

Ethics and Dissemination: Approved by the institutional review board, the study ensures participant confidentiality and data security. Results will be shared in peer-reviewed journals and conferences, with data available in public repositories per data-sharing agreements and regulatory guidelines.

Keywords: Neck pain; photobiomodulation; LED; manual therapy.

1. INTRODUCTION

Neck pain, a syndrome affecting the cervical region, arises from various factors such as mechanical and postural alterations, osteoarthritis, herniated discs, arthritis, and muscle spasms (Da Silva 2012). It significantly impacts quality of life and productivity, contributing to work absences and high treatment costs (Kazeminasab et al. 2022, Multanen et al. 2021). Common causes include muscular tensions, ligamentous involvement, and poor posture (Kazeminasab et al. 2022, Mylonas et al. 2021).

Chronic neck pain, defined as pain persisting for over three months, affects approximately two-thirds of the adult population, with a higher prevalence in females due to lower muscle strength (Multanen et al. 2021). Cervical pain is classified into nonspecific or mechanical, not linked to specific pathologies, and secondary, which arises from underlying conditions (Coulter et al. 2019).

Many instruments can be used to assess neck pain. The Visual Analog Scale (VAS), which grades pain from 0 (no pain) to 10 (very strong pain), is a widely used tool for evaluating pain intensity (Arruda et al. 2019). To evaluate cervical spine mobility, goniometry is one of the most commonly used instruments. The cervical spine allows movements such as flexion, extension, lateral rotation, and bending. The goniometer measures this range, with normal ranges being 0-80 degrees for flexion, 0-50 degrees for extension, 0-45 degrees for lateral bending, and 0-80 degrees for lateral rotation (Sukari 2021, Borges et al. 2013).

Considering the assessment of quality of life and functional disability in these patients, the WHOQOL-100 measures the impact of neck pain on quality of life, while the Neck Disability Index (NDI) evaluates functional disability (González Rueda et al. 2017, Andriollo et al. 2022).

Treatment options for neck pain include medications, photobiomodulation (using lasers

and LEDs), manual therapy, and kinesiotherapy, each with varying effectiveness (Coulter et al. 2019, Kazeminasab et al. 2022, Bernal-Utrera et al. 2020, Karu 2014). Manual therapies, like myofascial release and pompage, have been effective in reducing pain and improving function (Andriollo et al. 2022).

Photobiomodulation (PBM), using lasers and LEDs, is a non-invasive therapy gaining attention for its pain-relief and tissue-repair benefits. It modulates biological processes through light absorption by chromophores, promoting ATP production and reducing oxidative stress (Teixeira et al. 2022, Leotty 2020). Studies have shown PBM to be effective in reducing pain and inflammation, and accelerating tissue repair (Mesquita-Ferrari et al. 2011, Kadhim-Saleh et al. 2013, Chow et al. 2009, Barreto and Svec 2019, Odagiri et al. 2022) highlighted the benefits of PBM in reducing cervical pain, despite some inconclusive evidence. (Odagiri et al. 2004) demonstrated the effectiveness and safety of LED therapy for neck and shoulder pain.

The aim of this study protocol is to evaluate the combined therapeutic effects of pompage and photobiomodulation (PBM) on cervical musculature, pain, and range of motion. While manual therapies are commonly used, the scientific literature lacks robust studies on pompage in this specific context. Additionally, PBM using LEDs provides a non-invasive, easy-to-apply treatment with proven therapeutic benefits. The hypothesis is that the combination of pompage and PBM will lead to greater improvements in the outcomes mentioned, offering a more effective treatment strategy for managing neck pain.

2. METHODS

This is a study protocol for a controlled, randomized, double blinded, clinical trial, approved by the Ethics Committee of Universidade Nove de Julho (UNINOVE - Protocol 6.742.399). The methodologies were designed in accordance with the SPIRIT Statement criteria (https://www.spirit-statement.org/), and the protocol has been registered on the ClinicalTrials platform (https://clinicaltrials.gov/ NCT06416527). All participants will be informed about the study procedures, and if they consent, they will sign an informed consent form. The methodology flowchart of the study is illustrated in Fig. 1.

2.1 Sample Description

Participants of both genders with chronic mechanical neck pain who are not undergoing any concurrent treatment at the moment will be selected for this study. All participants will be explained the objectives and procedures to be carried out and participants may withdraw from participation at any time during the study.

Patient monitoring and attempts to ensure adherence to treatment will be done by sending regular messages and telephone contact.

2.2 Patient Involvement

Patients were not involved in the design, development, or choice of outcomes of this study. Their role was limited to participation in the interventions conducted as part of the research, and they were fully informed about the procedures and objectives of these interventions. Although they were not engaged in the broader aspects of study planning or decision-making, their feedback on the interventions was valuable in understanding their experiences. Following the completion of the study, we plan to share the results with the participants through an accessible summary of findings, ensuring that the information is presented in a clear and understandable format.

2.3 Inclusion Criteria

- Age between 18 and 62 years;
- Both genders;
- Without comorbidities.
- Neck pain for at least three months.

2.4 Exclusion Criteria

- Presence of rheumatic or degenerative diseases in the cervical region
- Ongoing orthodontic treatment
- Ongoing Physiotherapy treatment, massage or acupuncture in the cervical region
- Initiation of any new medication during the study
- Be taking painkillers andante-inflammatory drugs
- Use of bite plate

Patients will be advised that the introduction of new medications and the use of dental plates or braces will not be permited during the study, as they may interfere with the results.

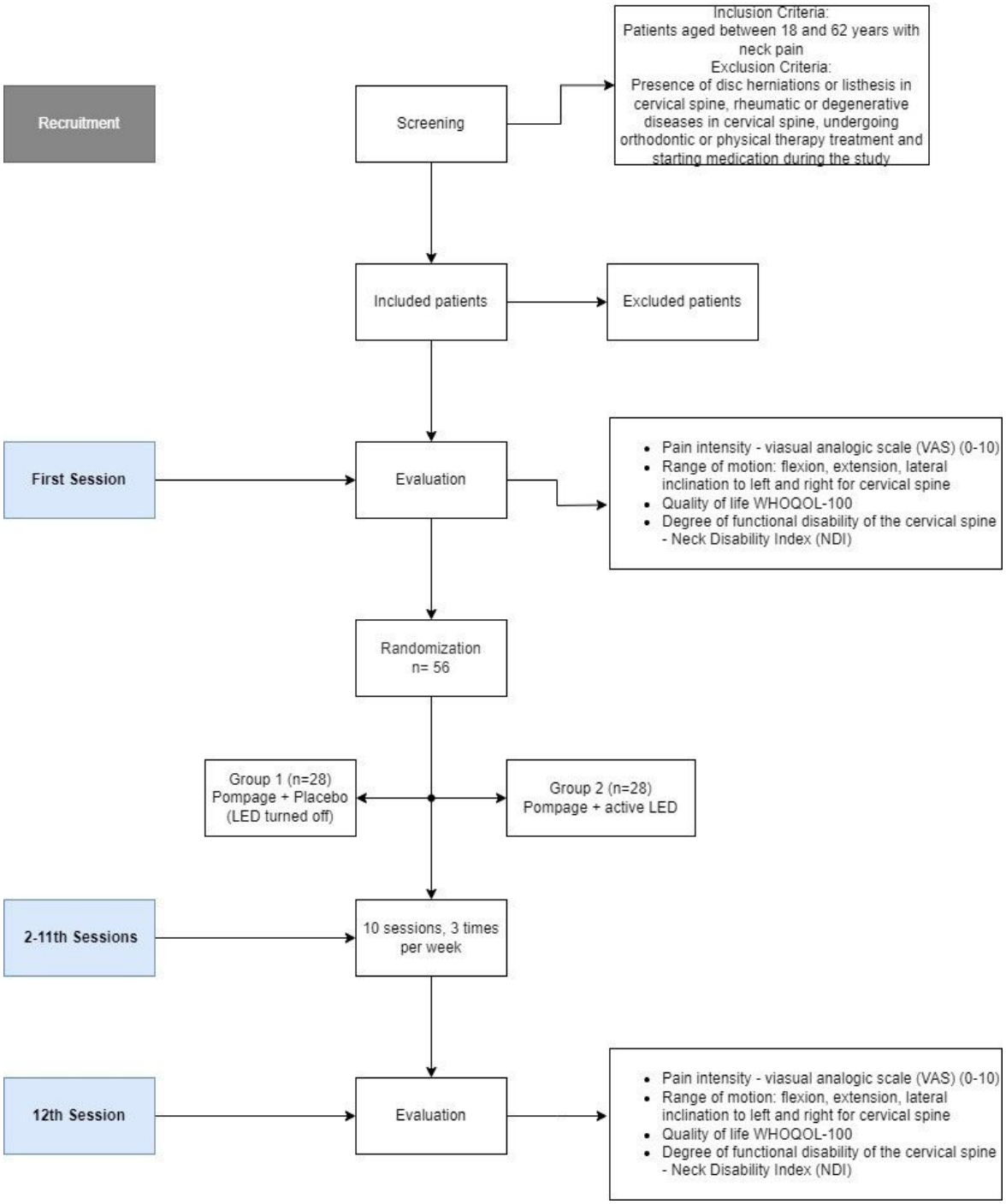

Fig. 1. Flowchart of the protocol following SPIRIT checklist

2.5 Randomization

Participants will be randomly allocated into the experimental groups using a draw conducted through the Sealed Envelope website (https://www.sealedenvelope.com). The allocation will be performed in a blocked manner, with participants evenly distributed (1:1) between two groups. To achieve the required sample size, participants will be divided into two groups of 28 patients each. Sequentially numbered opaque envelopes (1 to 56) will be prepared, each containing the group assignment based on the draw results. These envelopes will remain sealed until the time of treatment. The draw and envelope preparation will be carried out by an individual who is not directly involved in the clinical aspects of the study. Immediately before

treatment, the researcher responsible for administering the PBM will open the envelope (without altering the numerical sequence) and perform the indicated procedure.

2.6 Sample Size Calculation

The determination of sample size was based on the study conducted by (Gur et al. 2004) which assessed non-specific pain at rest in the cervical region using the Visual Analog Scale (VAS) for groups undergoing PBM with low-level laser irradiation (LBI) or placebo. Sample size calculation was performed using the tool availableathttps://www.stat.ubc.ca/~rollin/stats/ssize/n2.html, applying the Z-test method with a significance level of 0.05 (resulting in a 95% confidence interval), an absolute error of 5%, and a power of 80%. The calculation initially indicated that 22 patients per group would be necessary. To account for a potential 20% dropout rate and to ensure adequate power, the sample size was adjusted to 28 patients per group, resulting in a total of 56 participants for the study.

2.7 Recruitment

Participants will be recruited through announcements in health clinics and at the university where the study is being conducted, in Sao Paulo-SP Brazil.

2.8 Data Collection Plan

All instructions regarding outcomes, assessments, and patient monitoring will be carried out to ensure patient retention and completion of follow-up.

2.9 Data Monitoring

The blinded evaluator and the treatment administrator will conduct the treatment and assessments according to the presented flowchart. If they notice in each session the emergence of an exclusion criterion, such as the initiation of another treatment (medicinal or otherwise), they will interrupt and discontinue the treatment. Only data collected prior to this exclusion criterion will be used, and the patient will be considered as intention-to-treat up to that point.

2.10 Procedures

The study team will be formed by two physical therapists who will apply the Pompage technique and photobiomodulation with clusters of LED in cervical region and an evaluator blinding to the study who will make the patients evaluations. These evaluations will be made in the first and in the last sessions and will analyze the neck pain intensity, the range of motion, the quality of life and the degree of functional neck disability.

The following instruments will be used to evaluate the patients:

1) VAS visual analogue scale to validate pain.
2) Goniometer for cervical range of motion (ROM);
3) The WHOQOL-100 questionnaire;
4) The Neck Disability Index (NDI) questionnaire.

Patients will sign a free and informed consent form to participate in clinical research in which they will be informed about the objectives of the study, benefits, possible risks and guarantee of confidentiality.

The patients will be allocated in one of the two groups of treatment:

1) Pompage Group (Control): Patients will receive treatment through the application of the pompage technique, a manual therapy involving mobilization and sliding movements performed by the therapist's hands in the cervical region and a simulation of photobiomodulation using a LED cluster The device will be positioned on the cervical region for 10 minutes while turned off (inactive), with a recorded beep sound to simulate the treatment. This treatment will consist of 10 sessions, conducted 3 times per week, excluding weekends.
2) Pompage + PBM Group (Experimental): Patients in this group will undergo 10 sessions combining the pompage technique with photobiomodulation using a LED cluster applied to the cervical region. This combined treatment will also be administered 3 times per week, excluding weekend.

2.11 Blinding Implementation

To randomly allocate participants into the experimental groups, a randomization process will be conducted with 56 numbers using the Sealed Envelope website (https://www.sealedenvelope.com). Participants

will be distributed equally (1:1) between the two groups in a blocked manner. To achieve the required sample size, 8 groups of 8 patients each will be randomly assigned. Opaque envelopes will be numbered sequentially from 1 to 56 and will contain the group assignment based on the order of the randomization process. These envelopes will remain sealed and in numerical order until the time of treatment. The randomization process and preparation of the envelopes will be managed by an individual not directly involved in the clinical aspects of the study. Immediately before treatment, the researcher responsible for administering PBM will open one envelope (without altering the numerical sequence) and proceed with the indicated procedure.

Patients and evaluators will be blinded to group allocation. During the treatment sessions, patients will wear protective eyewear to prevent them from discerning whether they are receiving LED treatment or a placebo. For the sham treatment, the cluster of LED will be turned off and a recorded sound signal will be used to mask the operational status of the equipment, ensuring that patients will not be able to distinguish between active and inactive treatment, thus maintaining effective blinding.

3. OUTCOMES

3.1 Pain

The Visual Analog Scale (VAS) is a visual graduated scale ranging from 0 to 10 cm, where 0 represents no pain and 10 represents the most intense pain. This scale is used to measure the pain experienced by the patient, providing a straightforward method to assess and monitor treatment progression. Patients will be asked to rate their pain intensity, and the corresponding number on the scale will be recorded (Arruda et al. 2019).

3.2 Cervical Range of Motion (ROM)

The Goniometer is used to measure the degrees of range of motion (ROM) of the cervical region. Normal ROM standards are: flexion from 0 to 80 degrees; extension from 0 to 50 degrees; lateral flexion to the right and left from 0 to 45 degrees; and right and left rotation from 0 to 80 degrees (Sukari et al. 2021, Borges et al. 2013). This tool will be utilized to assess and monitor treatment progression. To measure the range of motion in degrees for extension (Fig. 2.A) and flexion (Fig. 2.B) of the cervical spine, the axis of the goniometer was positioned at the level of the acromion in the same plane as the seventh cervical vertebra, with the fixed arm parallel to the ground and the movable arm aligned with the ear lobe (Chaves et al. 2008).

To measure lateral inclination movement (Fig. 2.C), the fixed arm of the goniometer was positioned at the level of the C7 vertebra, parallel to the ground, with the movable arm at the midline of the cervical spine (Chaves et al. 2008). To measure cervical spine rotation (Fig. 2.D), the axis of the goniometer was positioned at the center of the head, with the movable axis aligned with the nose (Chaves et al. 2008).

3.3 Quality of Life

The WHOQOL-100 questionnaire is extensively used to evaluate the quality of life in patients with neck pain. It assesses various aspects, including psychological, physical, spiritual, independence level, social relations, and environmental factors (). This abbreviated instrument, developed by the World Health Organization, comprises 26 items divided into four main domains: Physical, Psychological, Social Relationships, and Environment. Each item will be rated on a 5-point Likert scale, from 1 ("not at all") to 5 ("extremely"). Scores for each domain will be calculated by averaging the responses for the relevant items and then multiplying by 4 to scale the results from 0 to 100. Higher scores will reflect a better perception of quality of life in that domain (21-Fleck MPA, WHO 2024).

3.4 Degree of Functional Disability

The Neck Disability Index (NDI) questionnaire assesses the degree of functional disability in the cervical region. It is a self-administered questionnaire consisting of 10 sections, each with 6 responses, reflecting 6 stages of functional disability. Scores range from 0 to 5, with 0 indicating the lowest and 5 indicating the highest level of disability (González Rueda et al. 2017).

4. INTERVENTIONS

4.1 Pompage

To perform cervical Pompage, the patient either lies comfortably on their back or sits upright. The therapist identifies the target area on the cervical spine. Using gentle pressure, the therapist applies traction to the cervical spine, stretching

the muscles and fascia. The traction is maintained for 20 seconds before being released, allowing the cervical spine to return to its neutral position. This process will be repeated three times, with adjustments made based on the patient's response and comfort level.

4.2 Photobiomodulation Using LED Cluster

Photobiomodulation using a diode-emitting light (LED) cluster device SportLux (Cosmedical, São Paulo, Brazil) will be administered to the cervical region of each patient. In the Placebo group, the device will be positioned on the cervical region for 10 minutes while turned off (inactive), with a recorded beep sound to simulate the treatment duration. In the Experimental group, the device will be activated for the same duration to deliver the actual photobiomodulation therapy.

The parameters to be used in this protocol are detailed in Table 1.

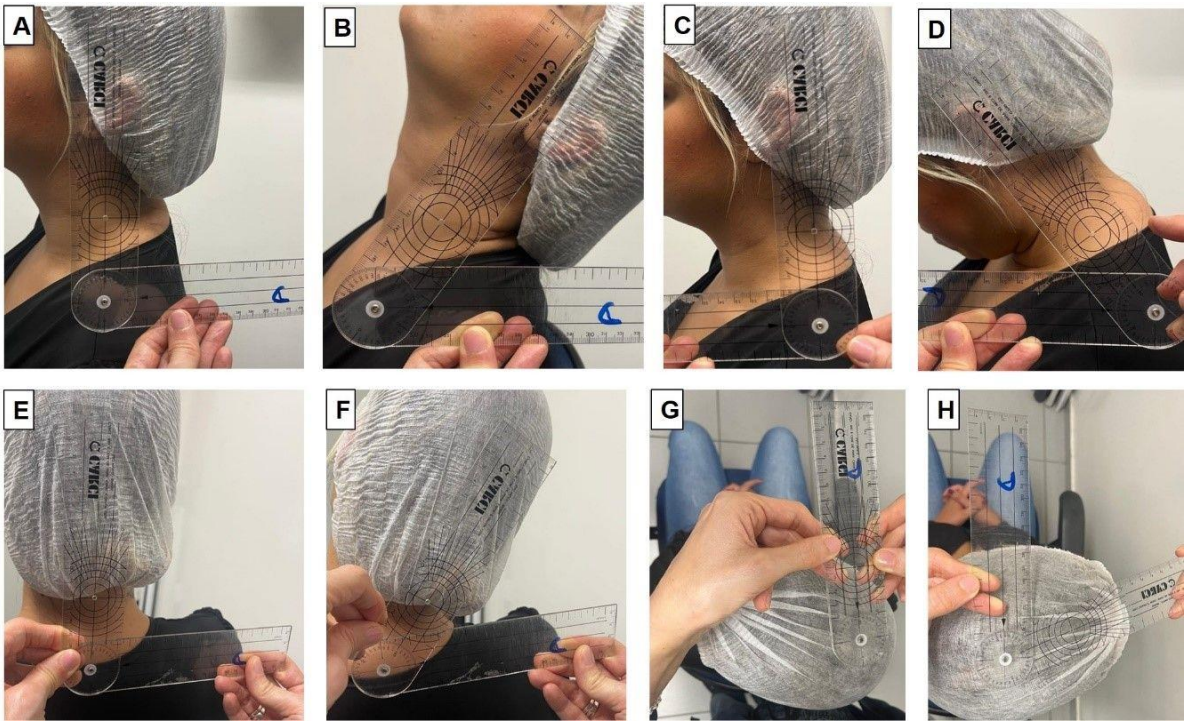

Fig. 2. Cervical Range of Motion (ROM)

A - Measurement of Cervical Spine Extension Range of Motion (ROM) Initial position and extension movement and B - final position of the cervical extension movement; C - Measurement of Cervical Spine Flexion ROM. Initial position and flexion movement and D - Final position of the cervical flexion movement; E - Measurement of Cervical Spine Lateral Inclination ROM. Initial position and lateral inclination and F -Final position of the cervical lateral inclination movement; G - Measurement of Lateral Rotation of the Cervical Spine ROM. Initial position and lateral rotation and H - Final position of the cervical lateral rotation movement

Table 1. PBM parameters

Dosimetric parameters	Values
Light Source	LED
Application mode	Contact
Wavelength (nm)	132 LEDs with 660 nm 132 LEDs with 850 nm
Spectral Bandwidth (nm)	20
Beam area on the target (cm^2)	0,5
Average power of each LED (mW)	8
Irradiance (mW/cm^2)	16
Exposure time (s)	10
Radiant Energy per LED (J)	4,8

Dosimetric parameters	Values
Radiant exposure (J/cm²)	9,6
Light emission angle	90º
Energy per cluster (J)	633,6J with 660 nm 633,6J with 850 nm

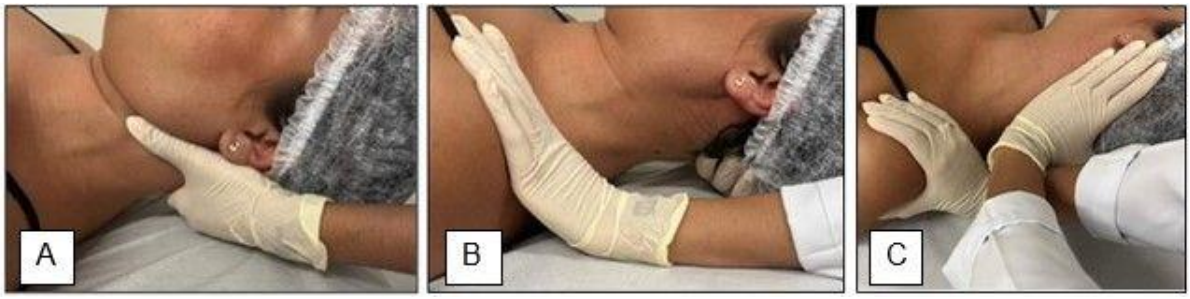

Fig. 3. Neck Pompage procedure
A and B: Stretching of the posterior cervical extensor muscles of the neck; C- Stretching of the neck rotators

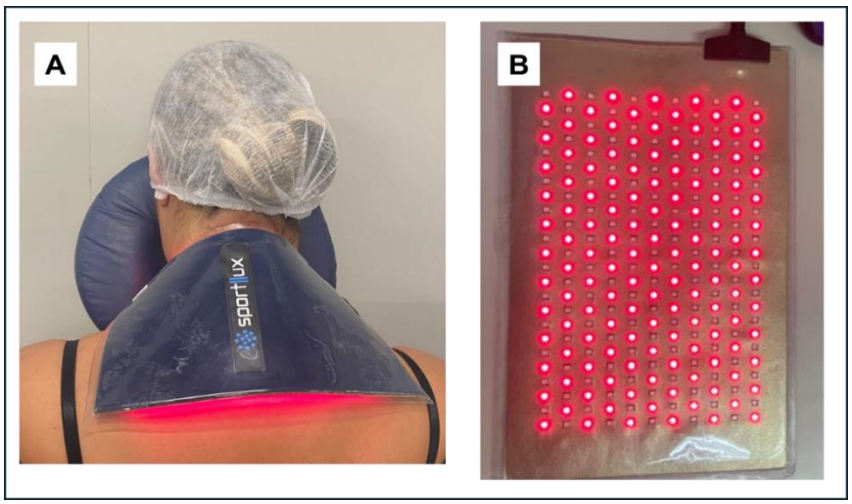

Fig. 4. PBM procedure
A: Placement of the device on the patient; B: LED cluster

5. STATISTICAL ANALYSIS

Initial descriptive analyses will be conducted for all measured variables, including quantitative variables (mean and standard deviation) and qualitative variables (frequencies and percentages). Normality tests will then be performed to determine the appropriate statistical tests for each dataset. Specific statistical tests will be applied accordingly. For all tests, a significance level of 5% or the corresponding p-value will be adopted. Subgroup analyses may be conducted, considering outcomes by gender, age, or pain severity.

6. CONCLUSION

The conclusion will be drawn after carried out the study.

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Authors hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc.) and text-to-image generators have been used during the writing or editing of this manuscript.

CONSENT AND ETHICAL APPROVAL

All ethical and safety considerations relevant to this study have been thoroughly reviewed and approved by the appropriate institutional review board (IRB)/ethics committee. Participants' confidentiality and data security will be strictly maintained in accordance with established guidelines and regulations. Any adverse events or ethical concerns will

be promptly addressed following standard protocols.

The investigators and sponsor will develop a dissemination policy to communicate trial results to participants, healthcare professionals, the public, and other relevant groups, which may include publication in scientific journals, reporting in results data bases, or other data-sharing arrangements, with clear outlines of any publication restrictions.

- **Data availability Statement**- all data will be available for the readers.
- **Ethics approval Statement -** The project received approval from the Research Ethics of Universidade Nove de Julho (process: 6.742.399). All stages of the study will be monitored by this committee, which is composed of researchers from the University.
- **Patient consent Statement –** All the participants included signed an Informed consent. The CI document was in writing.
- **Clinical trial registration:** NCT 06416527 (initial release: April 30th 2024.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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