

Cover Page

Official Study Title

Effect of Peripheral Magnetic Stimulation in Patients With Chronic Lower Back Pain

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Confidentiality Statement

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METHODOLOGY

Study design

A clinical, controlled, randomized, multicenter study will be conducted.

Study Location and Population

The study will be developed at the Physiotherapy School Clinic of the Federal University of Alfenas (MG/Brazil), at the Laboratory of Neuroscience, Neuromodulation and Pain Study - LANNED, located in the municipality of Alfenas, Minas Gerais and at the Egas Moniz School of Health and Science (Portugal), at the Neuromodulation and Pain Unit - NeuroPain, in the Municipality of Almada, Setúbal.

Sample

Individuals with chronic low back pain with a score between 40 and 80 on the Oswestry scale will be selected, and 40 will be selected for treatment at the Physiotherapy School Clinic of the Federal University of Alfenas - MG and Egas Moniz University Clinic - CUEM. Subjects will be divided into 2 groups: the control group and the intervention group.

Inclusion criteria

The inclusion criteria considered: individuals complaining of low back pain for more than three months, non-practicing sports activities, absence of significant pathologies of the spine such as previous history of myelopathy, surgeries, instabilities or deformities in the spine (bone fractures), normal neurological examination for radiculopathies (patellar and Achilles tendon reflexes; voluntary motor function; sensitivity test).

Exclusion criteria

Exclusion criteria are: trauma or systemic dysfunction; use of other alternative treatments; refusal to be randomized; protrusion or prolapse of one or more intervertebral discs with neurological symptoms; previous spine surgery; infectious spondylopathy; low back pain secondary to inflammation, tumor, or autoimmune disease; congenital deformities in the spine; compressive fracture caused by osteoporosis, spondylolysis, or spondylolisthesis (Zaringhalan et al., 2010). Individuals who use prostheses; who have a history of seizures; have a history of epilepsy, and have metal or intracranial devices implanted or non-removable.

Randomization of samples:

Volunteers will be divided into a control group and an intervention group through randomization. To this end, the participants will be allocated by another researcher, who will use the Research Randomizer website in two groups: Control group (CG) and Intervention group (IG).

Sample calculation

The sample size calculation carried out according to Hulley and Cumminhs (1998) estimates the number of 15 volunteers per group. This calculation will be performed to ensure a statistical power of 85% ($\beta=0.20$) and significance level when $p < 0.05$.

Evaluation Instruments:

Visual Analog Scale (VAS)

The VAS is a scale similar to a ruler, numbered with a starting point of zero and ending at ten, with 0 being no pain and 10 being the most unbearable pain felt at that moment by the patient (Collins, 1997).

The VAS was used to quantify the intensity and perception of the individual about their pain, and was graded according to ordinal scores: no pain (0), mild pain (1 to 2), moderate (3 to 5) and severe pain (6 to 10) (Toniolli & Pagliuca, 2003).

Pressure Pain Threshold (PPT)

The LDPs will be evaluated using a portable pressure algometer, with a 1 cm² rubber tip applicator, with a communication interface via Bluetooth, placed perpendicularly on the skin with an application rate of 0 to 15 Kgf/s (Physiocode brand). PPT will be defined as the minimum pressure first evoking a sensation of pain. The PPTs will be measured twice with a 10-second interval for each point, and the average value will be used for statistical analysis. (Balaguier, Madeleine, & Vuillerme, 2016)

Algometry was used to examine the pain threshold for the pressure applied between the spinous processes of the lumbar spine L1-L5. (Binderup, Arendt-Nielsen, & Madeleine, 2010)

Oswestry Range (ODI)

The Oswestry *Disability Index* (ODI) is a disease-specific instrument recommended for the evaluation of spinal disorders. The ODI is an ordinal instrument, where 10 criteria are analyzed with six response alternatives for each criterion. The total count ranges from 0 to 100, with zero corresponding to normal function and 100 indicating great disability. For each item, zero is normality and five is the greatest functional change. The sum of the 10 questions divided by five multiplied by the number of questions answered, and multiplying everything by 100, constitutes the ODI (Fairbank JCT, 2000).

Repeated Peripheral Magnetic Stimulation (rRPMS)

Both groups will use the rRPMS device, with 10 sessions over a period of 2 weeks, in the IG applied in flat tangential orientation lasting 20 minutes and intermittent stimulation

protocol consisting of 5 seconds of stimulation at a frequency of 20 Hz followed by 25 seconds of rest with a minimum intensity of 20% up to maximum intensity to induce sufficient contraction of the paraspinal muscle and in the CG in transverse orientation with The stimulus intensity level set at 5% of the maximum stimulator output to minimize stimulation, both in the most painful lumbar region.

The group will be randomized into IG (n=25) and CG (n=25). A round coil is known to be more advantageous than a figure-8 coil for stimulating structures in a deep layer like the spinal roots and covering a larger area like a paravertebral muscle group (Beaulieu LD, 2015). Thus, we will use the round coil that will be most suitable for the treatment of low back pain.

The stimulation site will be determined based on the patient's most sensitive point before the start of each treatment session. For patients in the rPMS intervention group - in the prone position - the coil will be placed in a flat tangential orientation targeting the most painful lumbar region. In this way, it will allow the coil to be positioned parallel to the surface of the body, thus maximizing the effects of the magnetic stimulation applied to the area.

For patients in the rPMS control group, also in the prone position, the coil will be applied in a transverse orientation in the most painful lumbar region. This position of the coil, at an angle of 90° to the surface of the body, will minimize the effects of magnetic stimulation applied to the area.

Both groups will undergo 10 sessions over a period of 2 weeks. Each session lasted 20 minutes and intermittent stimulation protocol consisted of 5 seconds of stimulation at the 20 Hz frequency followed by 25 seconds of rest. The total number of stimuli over 20 minutes will be 4,000 pulses.

The level of stimulation intensity will be determined at the level that induces sufficient contraction of the paraspinal muscle while still within the patient's tolerable range. For the rPMS control group, the stimulus intensity level will be set at 5% of the stimulator's maximum output to minimize magnetic stimulation.

Both groups will be exposed to an identical clicking sound generated during each session and the coil will be placed in contact with the patient (to have a similar sensation). The application of the rPMS coil in both groups of patients will be conducted by experienced physiotherapists with sufficient preliminary training on the application of rPMS prior to the study.

Ethical Issues

This project was submitted to the evaluation of the Ethics Committee of the Federal University of Alfenas, and will comply with the precepts contained in resolution 466/12 of the National Health Council. It will be submitted to the Egas Moniz Ethics Commission. Before starting to participate in this research, volunteers will receive all information related to the objectives and methodological procedures of the study and after agreeing to participate, they will sign the free and informed consent form. Participants will be informed about the objectives, research procedures, risks, benefits and minimizing measures, the data being presented together, the informant may withdraw his participation at any time.

Statistical Procedures

Data were analyzed using both within-group and between-group comparisons to evaluate the effects of repetitive peripheral magnetic stimulation (PMS) in individuals with chronic low back pain. Continuous variables were summarized as means and standard deviations, and the assumption of normality was assessed using the Shapiro–Wilk test. Paired Student's t-tests were applied to assess within-group (pre- vs. post-intervention) differences, while between-group comparisons of change scores (Δ values) were conducted using Welch's t-tests to account for possible variance inequality.

For binary categorical outcomes, such as the presence of positive clinical signs, McNemar's test was used for within-group comparisons, and Pearson's Chi-square test was applied for between-group analyses using 2×2 contingency tables. The significance threshold was set at $p < 0.05$ for all tests.

Effect sizes were calculated using Cohen's d, derived from the difference in pre-post deltas between groups. Values were interpreted according to standard conventions, with effect sizes around 0.8 or higher considered large. Negative d values indicated greater improvement in the PMS group for outcomes where lower scores reflect improvement (e.g., Oswestry Disability Index, pain VAS), whereas positive d values indicated greater improvement in outcomes where higher scores reflect improvement (e.g., pressure pain thresholds, Schober test).

All statistical analyses were conducted using GraphPad Prism (version 8.0) and IBM SPSS Statistics (version 25).

Informed Consent

Code| IMP-EM-PE-17_03

_____, _____.
(Place) (DD Month YYYY)

You are being invited to participate, as a volunteer, in the research project EFFECT OF PERIPHERAL MAGNETIC STIMULATION IN PATIENTS WITH CHRONIC LOW BACK PAIN - Randomized controlled clinical trial, under the responsibility of the investigator Prof. Dr. Luciano Maia Alves Ferreira.

Read the following carefully and ask me about any questions you have. After being informed about the research, and if you accept to be part of our study, sign at the end of this document, which is contained in two copies. One way belongs to you and the other to the researcher in charge. Your participation is not mandatory, and at any time you may withdraw from participating and withdraw your consent. Your refusal will not cause any harm to your relationship with the researcher or the institution. In case of refusal you will not suffer any penalty.

When reading the items below, you must declare whether you have been sufficiently informed about the stages of the research at the end of this document.

This research aims to investigate the effects of treatment with peripheral magnetic stimulation (rPMS) compared to a placebo treatment with the same equipment in reducing pain and functionality of patients with chronic low back pain.

Your participation in this research will consist of a study that will be developed at the Laboratory of Functional Physical Assessment in Physical Therapy - LAFFFi of Egas Moniz. Individuals with chronic low back pain with a score between 40 and 80 on the Oswestry scale will be selected. Some questionnaires will be applied to assess the patient's quality of life, pain level, measure the functional disability of patients with low back pain and assess pain. It will be done in 10 sessions over a period of 2 weeks, with each session lasting 30 minutes. It will be performed by an experienced professional.

During the execution of the survey, there may be minimal risks such as embarrassment, availability of time to answer the instrument, discomfort when answering the questionnaire and improper disclosure of confidential data. As a minimizing measure, if there are embarrassments and/or discomfort of the participants when answering the questions when poorly formulated, which will also be solved through the previous training of the researchers

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before making the form and the non-obligation to answer them. The participant may interrupt the process whenever they wish; ensure confidentiality and privacy. Their participation consists of agreeing to collaborate with the research and answer the questionnaire.

The main risks are related to the physical components of the participants, due to the possibility of discomfort during or after the application of the proposed protocol. During the application of neuromodulation, it is possible that the participant will experience sensations of pain, itching or tingling in the scalp region. It is important to highlight that these sensations have a low frequency, low magnitude, and are related to the stimulation period. The stimulation machine emits a noise with each pulse, which can be a nuisance.

By participating in this work you will contribute to improvements in the research area and it is expected that after the intervention of this research you will bring benefits in the improvement of chronic low back pain.

Your participation in this project will last 10 sessions over a period of 2 weeks, with each session lasting 30 minutes. You will not have any expenses for your participation, and the questionnaires, interviews, classes, courses, lectures, consultations/exams/treatments/etc. are completely free; and will cease to participate or withdraw their consent at any time, without having to justify it, and will not suffer any loss.

You have been informed that the data collected will be used, solely and exclusively, for the purposes of this research, and that the results of the research may be published/disseminated through academic works or scientific articles by professionals in the area.

For these reasons:

I AUTHORIZE () / DO NOT AUTHORIZE () the collection and dissemination of images/photographs/videos/voice sound for the present research.

I, _____, NIF _____, declare that I have been informed and agree to participate, as a volunteer, in the research project described above.

.....
(Signature of the participant)

.....
(Signature of the principal investigator)