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Effects of photobiomodulation therapy associated with motor control exercise for chronic non-specific low back pain: protocol for a randomised placebo-controlled trial

Marcelo Ferreira Duarte de Oliveira,[1] Jan Magnus Bjordal,[2] Jociane Schardong,[3,4] Rodrigo Della Méa Plentz,[3,4] Heliodora Leão Casalechi,[1] Ernesto Cesar Pinto Leal-Junior ,[1,2] Shaiane Silva Tomazoni [2]

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For numbered affiliations see end of article.

Correspondence to
Dr Shaiane Silva Tomazoni; shaiane.tomazoni@gmail.com

ABSTRACT

Photobiomodulation therapy (PBMT), as an adjunct therapy to exercise, can reduce pain in musculoskeletal disorders. In addition, PBMT associated with exercise decreases fatigue, accelerates muscle recovery and enhances performance and gain through different training protocols. Although it has not been investigated, the association of PBMT and exercise therapy could be an alternative to improve the positive effects of exercise in patients with non-specific low back pain (LBP). Therefore, we aim to evaluate the effects of PBMT associated with motor control exercise (MCE) versus placebo associated with MCE in patients with chronic non-specific LBP. This is a prospectively registered, two-arm, randomised, placebo-controlled, triple-blind trial. A total of 148 patients with chronic non-specific LBP will be randomised to either active PBMT associated with MCE or placebo PBMT associated with MCE. Treatment sessions will be provided twice a week for 6 weeks. The primary outcomes will be pain intensity and general disability measured at the end of the treatment. The secondary outcomes will be pain intensity and general disability measured 1 month after the end of the treatment, 3, 6 and 12 months after randomisation, in addition to levels of prostaglandin E2 measured at the end of the treatment. Medication intake, cointerventions and adverse events will be measured at all time points. This study was approved by the Research Ethics Committee of Irmandade de Santa Casa de Misericórdia de Porto Alegre. The results will be disseminated through scientific publications and presentations at scientific meetings.
Trial registration number: NCT05487118.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Photobiomodulation therapy (PBMT) isolated and/or associated with other therapies has analgesic effects in different health conditions.
⇒ PBMT is associated with different types of exercise and has ergogenic effects.
⇒ Exercise therapy is effective in treating patients with chronic non-specific low back pain. However, the effects are moderate.

WHAT THIS STUDY ADDS

⇒ This study addresses the gap in the scientific literature regarding the association of PBMT and exercise to enhance the positive effects of exercise therapy in patients with chronic non-specific low back pain.
⇒ This study addresses the need to investigate the ergogenic effects of PBMT in treating patients with chronic non-specific low back pain.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The results found in the main trial could change the estimated effect of PBMT in patients with non-specific chronic low back pain.
⇒ If PBMT associated with a motor control exercise protocol proves beneficial, it could be implemented in clinical practice to increase the effect size of exercise therapy in treating patients with chronic non-specific low back pain.

INTRODUCTION

Low back pain (LBP) is a highly prevalent condition worldwide[1] and the leading cause of years lived with disability.[2] It is estimated that 85% of LBP is non-specific since the pathological cause remains unidentified.[1] However, although the origin is unknown, patients with non-specific LBP may have impairment in the control of the muscles responsible for maintaining coordination and stability of the spine, such as the transversus abdominis and multifidus,[3–5] in addition to the decreased strength in the trunk extensor muscles.[6 7] Additionally, an increase in inflammatory markers often observed in painful conditions, such as prostaglandin E_2 (PGE_2), may also be associated with non-specific LBP.[8 9]

Non-pharmacological interventions are available and recommended by the main clinical practice guidelines for treating chronic LBP, prioritising patient self-care, physical and psychological therapies, and some forms of complementary medicine.[10–12] In addition, the major endorsement by these guidelines is the use of exercise. However, this intervention has moderate effects in the best-case scenario.[1] The recommendation in this case is that patients undergo gradual physical activity, and the exercise protocol to be used should take into account the needs, preferences and functional capacity of the patients.[13] Motor control exercises (MCEs) were developed to restore coordination, control and capacity of the trunk muscles[14] and may be an interesting alternative in the treatment of patients with LBP.[3 4] MCE consists of training the trunk's deep muscles, promoting greater integration between them in more complex static, dynamic and functional tasks.[15 16]

Another option to treat patients with chronic LBP, according to the American College of Physicians clinical practice guidelines, is photobiomodulation therapy (PBMT).[11] PBMT is a non-ionising and non-thermal light therapy applied in the form of light emitting diodes (LEDs), light amplification by the stimulated emission of radiation and/or other light sources with a broader spectrum ranging.[17] PBMT is a therapeutic agent that effectively reduces pain, modulates inflammation and regenerates tissues in different health conditions.[18–20] Evidence has shown that PBMT, as an adjunct therapy to physical exercise, can reduce pain intensity in musculoskeletal disorders such as tendinopathy,[21] epicondylitis,[22] fibromyalgia[23] and osteoarthritis.[24] In addition, over recent years, it has been demonstrated that PBMT has ergogenic effects, that is, when applied in association with physical exercise, it increases physical performance, decreases fatigue and accelerates muscle recovery.[25] Finally, evidence has demonstrated that PBMT can enhance gains in different training protocols, such as strength and aerobic training.[25]

Over the years, PBMT isolated and as an adjunct to other interventions for treating LBP has been investigated.[26–28] However, in these cases, the effectiveness of PBMT is uncertain.[29 30] On the other hand, the effects of PBMT associated with exercise to enhance the beneficial effects of exercise already observed for treating LBP are unknown. In other words, the ergogenic effects of PBMT in treating LBP have not yet been investigated. Some previous studies that used PBMT as an adjunct to exercise did not irradiate all muscles exercised before the exercise, as recommended by the best available evidence in the area.[25] Furthermore, in these studies, exercise was used to treat all patients, regardless of their allocated group. Finally, no studies have investigated the ergogenic effects of PBMT on postural muscles.

We hypothesised that PBMT will be able to enhance the beneficial effects of MCEs over and above placebo effects in patients with chronic non-specific LBP. Therefore, we aim to evaluate the ergogenic effects of PBMT associated with MCE versus placebo associated with MCE on pain intensity, general disability and levels of PGE_2 in patients with chronic non-specific LBP.

METHODS

Study design

A superiority, parallel-group, randomised, placebo-controlled, triple-blind trial (patients, therapists and assessors) will be performed. The protocol of this study has been prospectively registered on ClinicalTrials.gov (NCT05487118).

Study setting

This study will be conducted at the Santa Casa de Misericórdia de Porto Alegre Hospital, Porto Alegre, Brazil.

Eligibility criteria

The participants will be included based on patient history and clinical examination. The inclusion criteria will be patients seeking care for chronic non-specific LBP, defined as pain or discomfort between the costal margins and the inferior gluteal folds, with or without referred symptoms in the lower limbs, for at least 3 months[31]; with a pain intensity of at least three points (measured by a 0–10 pain Numerical Rating Scale)[32]; aged between 18 and 65 years; able to read Portuguese. The exclusion criteria will be patients with evidence of nerve root compromise (ie, one or more of motor, reflex or sensation deficit)[33]; serious spinal pathology, such as tumours, fracture, inflammatory and infectious disease; previous back surgery; body mass index ≥30); decompensated severe cardiovascular and metabolic diseases; patients with severe skin diseases (eg, severe dermatitis, psoriasis, eczema and hives lupus); patients with cancer and pregnancy.

Randomisation

The randomisation schedule will be generated using a computer programme (Excel Office 2010) and performed by a researcher not involved in patient recruitment, assessment and treatment. Other researchers will be responsible for programming the PBMT device into active or placebo therapy and coding the treatments according to the randomisation schedule. We will generate a simple randomisation schedule with an allocation ratio 1:1. Concealed allocation will be achieved using sequentially numbered, sealed and opaque envelopes. Before initiation of treatment, eligible patients will be allocated into their respective intervention groups (active PBMT+MCE or placebo PBMT+MCE) by one of the therapists who opened the next available numbered envelope.

Blinding

The researcher who will programme the device into active PBMT or placebo PBMT will be instructed not to disclose the programmed intervention to the assessors, therapists, patients and other researchers involved in the

study until its completion. An assessor will collect study outcomes unaware of the patient's allocation. The PBMT device will produce the same sounds, lights and information on the display during irradiation, regardless of the mode used (active PBMT or placebo PBMT). In addition, both groups will perform the same exercise protocol, ensuring blinding of the therapists and patients. At the end of the study, the assessors, patients and therapists will be asked to guess the patients' group allocation to measure blinding success.

Interventions

According to previous randomisation, patients from both groups will receive treatment twice a week (on non-consecutive days) for 6 weeks, totalling 12 treatment sessions. The choice of treatment frequency was based on a previous study that used the same exercise protocol (MCE) for patients with chronic non-specific LBP that will be applied in this study.[34] For the PBMT (active or placebo) treatment, patients will be positioned preferably in a prone position; however, in specific cases in which the patient does not tolerate that position due to pain, patient preference will be respected. Patients will receive the following interventions according to the allocation groups:

Active PBMT

Active PBMT will be performed using a class 3B laser manufactured by Thor Photomedicine (Chesham, UK), using a cluster probe with 5 diodes of 810 nm. Four sites in the patients' lumbar region will be irradiated: two sites to the right and two sites to the left over the paravertebral muscles at L2 and L3, L5 and S1. In addition, six sites in the abdominal region will be irradiated: three sites to the right and three sites to the left of the linea alba. The iliac crest will be used as an inferior reference, and the xiphoid process will be used as a superior reference. The choice of application sites was made to cover the largest possible area of the paravertebral and abdominal muscles, as recommended by the best evidence available.[25 35] Patients will receive a dose of 30 J per site of irradiation, totalling 60 J in the right paravertebral muscles, 60 J in the left paravertebral muscles and 180 J in the abdominal muscles. Table 1 details the PBMT parameters that will be used. The choice of dose (per irradiation site) was based on previous studies that showed that PBMT could trigger ergogenic effects in strength training in non-athlete volunteers.[36 37] Finally, the PBMT will be irradiated before the exercise protocol since this is the recommendation provided by the best available evidence.[25 35 38]

Placebo PBMT

Placebo PBMT treatment will be like the active PBMT treatment; the same sites and irradiation time will be used, but without any emission of therapeutic dose. Placebo PBMT will be irradiated before the exercise protocol.

Table 1 PBMT parameters

Parameter (unit)	Value or method
Class	3B
Number of diodes	5
Wavelength (nm)	810
Frequency (Hz)	Continuous
Power output (mW)—per diode	200
Spot size (cm^2)—per diode	0.0364
Power density (W/cm^2)—per diode	5.495
Energy density (J/cm^2)—per diode	164.85
Dose (J)—per diode	6
Irradiation time per site (s)	30
Total dose per site (J)	30
The total dose applied in each muscle group (J)	60 J in the right paravertebral muscles, 60 J in the left paravertebral muscles and 180 J in the abdominal muscles
Application mode	Direct skin contact and slight pressure

PBMT, photobiomodulation therapy.

Exercise protocol: MCE protocol

All patients will be submitted to an MCE protocol after the active or placebo PBMT treatment. The MCE protocol will consist of:

- MCE in supine:
  - Abdominal bracing
  - Abdominal bracing with heel slide
  - Abdominal bracing with leg lifts
  - Abdominal bracing with bridging
  - Bracing with single leg bridging
- MCE in bipedal support:
  - Abdominal bracing in standing
  - Isometric torsion
  - Abdominal bracing with walking
- MCE in lateral support:
  - Lateral support with knees flexed
  - Lateral support with knees flexed and bracing
  - Lateral support with knees extended
  - Lateral support with knees extended and bracing
  - Advanced Lateral Bridge
- MCE in quadruped support:
  - Quadruped arm lifts with bracing
  - Quadruped leg lifts with bracing
  - Quadruped opposite arm and leg lift with bracing.

Each of these four blocks of exercises will be a progression of complexity ranging from easier to more difficult exercises. This MCE protocol was based on a previous study that evaluated the effects of MCE protocol associated with neuromuscular electrical stimulation in patients with chronic non-specific LBP.[34] Detailed description of

the MCE protocol can be found in online supplemental appendix 1.

Experimental groups

Patients will be allocated into two experimental groups according to previous randomisation:

1. PBMT+MCE: Patients will receive active PBMT before the MCE protocol.
2. Placebo+MCE: Patients will receive a placebo PBMT before the MCE protocol.

Outcomes

Initially, volunteers will be screened to confirm the eligibility criteria. Afterwards, the volunteers will be invited to participate and sign the written informed consent form. Subsequently, clinical and demographic characteristics will be collected. Finally, primary and secondary outcomes will be collected at baseline before randomisation.

The primary outcomes will be pain intensity[32] and general disability[39 40] measured at the end of the treatment (6 weeks after randomisation). The secondary outcomes will be pain intensity[32] and general disability[39 40] measured 1 month after the end of the treatment, 3, 6 and 12 months after randomisation. PGE_2[9] levels will be measured at the end of the treatment (6 weeks after randomisation). Medication intake, cointerventions and adverse events will be measured at the end of the treatment (6 weeks after randomisation), 1 month after the end of the treatment, 3, 6 and 12 months after randomisation.

Pain intensity will be measured by the Pain Numerical Rating Scale,[32] which evaluates pain intensity levels perceived by the patient on an 11-point scale ranging from 0 (no pain) to 10 (the worst possible pain). Patients will be instructed to score the level of pain intensity based on the last 7 days. General disability will be measured by the 24-item Roland Morris Disability Questionnaire,[39 40] which measures disability associated with back pain ranging from 0 (no disability) to 24 (high disability). Levels of PGE_2 will be measured by ELISA, using a commercial kit and following the manufacturer's instructions (R&D Systems, Minnesota, USA). For this, a qualified nurse will obtain blood samples from an antecubital vein. Each sample will be centrifuged at 3000 rpm for 20 min 1 hour after collection. The reading will be performed in a spectrophotometer with a wavelength of 450 nm and a correction of 570 nm. The results will be expressed in pg/µL. Adverse events, medication intake and cointerventions will be measured from self-report. Patients will be asked if they had had adverse effects related to the therapy, if they had taken any medication (and which medication), and if they had used any cointervention, such as conventional physiotherapy, Pilates, yoga, acupuncture, etc. The assessments will be conducted over the telephone 1 month after the end of treatment, 3, 6, and 12 months after randomisation.[30]

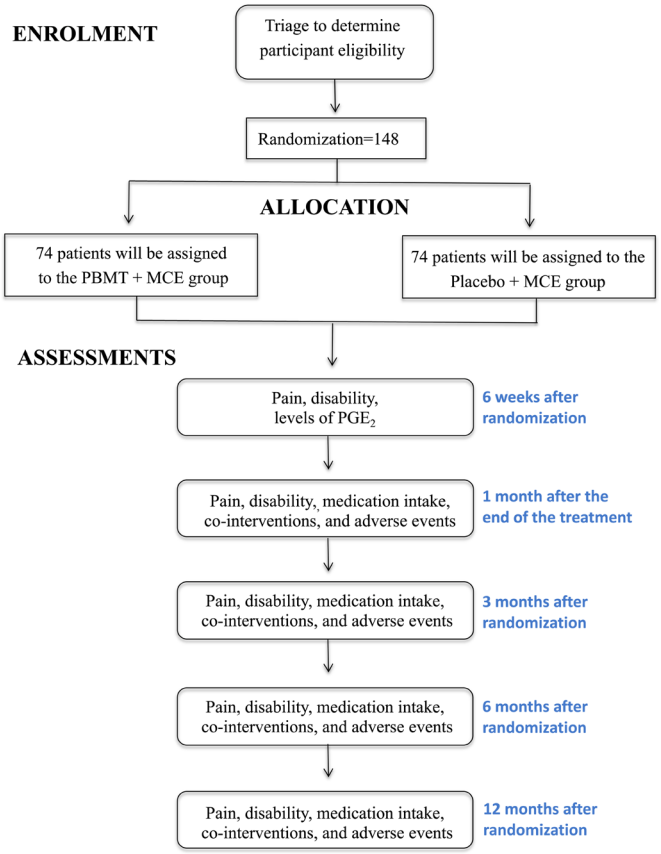

Figure 1 Schematic diagram of the study. MCE, motor control exercise; PBMT, photobiomodulation therapy; PGE_2, prostaglandin E2.

Participant timeline

A schematic diagram summarising experimental procedures and patients is shown in figure 1.

Sample size

A sample of 148 patients (74 per group) provided 80% statistical power to detect a 1-point difference for pain intensity (with an estimated SD of 1.84 points)[32] and a 4-point difference for disability (with an estimated SD of 4.9)[39 40] considering a level of significance of 5% and a possible lost to follow-up of up to 15%. Despite the clinically important changes being estimated as 2 points for pain intensity and 5 points for disability, we performed the sample size calculation with lower values to generate a larger statistical precision.[41]

Recruitment

Patients seeking treatment for LBP will be recruited at primary and secondary care health services.

Statistical analysis

Statistical analysis will be conducted following intention-to-treat principles.[42] The findings will be tested for their normality using the Shapiro-Wilk test. The between-group differences and their respective 95% CIs will be calculated by two-way repeated

measures (analysis of variance, time vs experimental group) with post hoc Bonferroni correction. Parametric data will be expressed as mean, SD and non-parametric data as median and respective upper and lower limits. The Friedman and Wilcoxon tests will be used for non-parametric data.

Dissemination policy

This trial will be disseminated through publication in peer-reviewed international journals and presentations at national and international conferences. The main results will be disseminated individually to patients by email.

Patient and public involvement

Patients and/or the public will not be involved in this study's design, recruitment or conduction. The main results will be disseminated individually to participants by email.

DISCUSSION

The effects of PBMT on non-specific LBP are still controversial. Although some studies have demonstrated that PBMT effectively reduces pain intensity and disability,[43–45] in some cases, the effect size is small and not clinically important.[43 44] In contrast, there are also studies demonstrating that PBMT is not effective in improving clinical outcomes, such as pain and disability, in patients with non-specific LBP.[28 30 46] Finally, the most up-to-date systematic review with meta-analysis in this field concluded that there is low-quality evidence that PBMT is not superior to placebo in treating non-specific chronic LBP. This aspect demonstrates that conducting new studies could change the estimated effect, especially if they are studies that present high methodological quality and an adequate sample size.[29]

Exercise therapy is considered first-line treatment for patients with chronic LBP by the main clinical practice guidelines,[10 12] although their effects are considered moderate.[1] Therefore, it is important to find strategies that might increase the estimates of the effect of exercise therapy for patients with chronic LBP. Since the evidence points out that PBMT enhances the positive effects of exercise,[25] combining both therapies could be an alternative in treating LBP. However, to date, we are unaware of high-quality trials investigating the effects of PBMT associated with exercise, aiming to improve their effects in patients with LBP. Our trial aims to fill this gap and determine whether PBMT associated with MCE can modulate the inflammatory process and promote ergogenic effects on irradiated muscles, resulting in improved structure and, consequently, improved muscle function. This would contribute to the reduction of pain intensity and disability in patients with chronic non-specific LBP.

This trial was prospectively registered, allocation will be concealed, true randomisation and intention-to-treat analysis will be performed. In addition, this trial will be triple-blind (patients, therapists and assessors), and a placebo will be used to control possible confounding factors, such as placebo effects and regression to the mean and therapist bias. The sample size calculation was performed to provide statistical power to detect precise differences in the trial's primary outcome. Finally, this trial can be considered to have high methodological quality. Therefore, we believe this trial may contribute to eventually changing the previously observed estimated effect of PBMT in treating previously observed LBP.[29]

Author affiliations
[1]Laboratory of Phototherapy and Innovative Technologies in Health (LaPIT), Postgraduate Program in Rehabilitation Sciences, Universidade Nove de Julho, Sao Paulo, Brazil
[2]Department of Global Public Health and Primary Care, University of Bergen, Bergen, Norway
[3]Universidade Federal de Ciências da Saúde de Porto Alegre, Porto Alegre, Brazil
[4]Irmandade Santa Casa de Misericórdia de Porto Alegre, Porto Alegre, Brazil

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Competing interests ECPL-J receives research support from Multi Radiance Medical (Solon - OH, USA), a laser device manufacturer. SST has a personal relationship with ECPL-J. The remaining authors declare that they have no support from any organisation for the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationship or activities that may appear to have influenced the submitted work.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study was approved by the Research Ethics Committee of Irmandade de Santa Casa de Misericórdia de Porto Alegre – —ISCMPA (#5.558.508). Ethical guidelines, following the Helsinki Declaration of Helsinki, will be strictly adhered to. All patients eligible for the study will be informed by the study assessor of the objectives, invited to participate, and required to complete and sign the written informed consent form (see supplementary appendix online supplemental appendix 2). The participation of the patients will be entirely voluntary, with the option to withdraw without impacting their treatment. Research personnel will take all appropriate and customary steps to ensure that data and biological material remain secure and that patient privacy and confidentiality will be maintained. All samples will be immediately destroyed after analysis of biological material. The corresponding author will make the final trial datasets available uponon reasonable request.

Provenance and peer review Not commissioned; internally peer reviewed.

Data availability statement Data sharing is not applicable as no datasets were generated and/or analysed for this study.

ORCID iDs
Ernesto Cesar Pinto Leal-Junior http://orcid.org/0000-0001-6393-7616
Shaiane Silva Tomazoni http://orcid.org/0000-0002-0822-4864

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