

Physiotherapeutic protocol for the studies of the effects of photobiomodulation on breast cancer

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Abstract

Background: Breast cancer, the second most common oncological disease in Brazil, is estimated to have approximately 73,000 new cases in the Brazilian female population in the 2023-2025 triennium. Considering the treatments offered, physiotherapy emerges as a tool in the treatment of various conditions, such as musculoskeletal disorders and pain resulting from traditional antineoplastic therapies, with resources such as laser therapy available for this management. **Objective:** To establish a physiotherapeutic intervention protocol, based on scientific evidence, for women with breast cancer. **Method:** This is a physiotherapeutic protocol that is part of a randomized, placebo-controlled, double-blind clinical trial, approved by the Research Ethics Committee of SCS/UFPR (CAAE: 71033323.9.0000.0102), to evaluate the effects of photobiomodulation on breast cancer. The study will recruit 60 women with breast cancer, aged between 21 and 60 years, who are undergoing active antineoplastic treatment. The developed protocol consists of four physiotherapeutic techniques: cervical pumpage associated with breathing exercises, kinesiotherapy, and clay therapy. Clay therapy consisted of applying white clay to the entire face of the participant, lasting approximately 15 minutes. Kinesiotherapy included range of motion exercises of rotation, inclination, flexion, and extension of the cervical spine, in a prescription of 2 sets of 10 repetitions, in addition to static stretching of the upper limbs, in 2 sets of 60 seconds. The pumpage and breathing exercises combined cervical rotation with pursed-lip breathing, lateral cervical inclination with diaphragmatic breathing, and the *pranayama surya bedhana* technique with the pumpage of the pectoralis major. **Conclusion:** The proposed protocol is expected to be an efficient resource for managing the well-being of study participants during Modified Intravascular Laser Blood Irradiation applications, potentially providing comfort associated with the therapeutic application of the laser.

Keywords: Physical therapy modalities; breast neoplasms; laser therapy; clinical trial protocol; evidence-based practice.

BACKGROUND

Breast cancer is one of the most frequent neoplasms in women and represents the leading cause of mortality in Brazilian territory, after non-melanoma skin tumors, ac-

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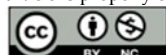
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According to the National Cancer Institute (INCA). Such neoplasia is characterized by the disordered proliferation of abnormal cells, which have the ability to form tumors and, in more advanced stages, invade other organs, resulting in metastases. In Brazil, breast cancer is the second most common in all regions, with higher rates in the South and Southeast regions. It is estimated that for each year of the 2023-2025 triennium, approximately 73,610 new cases will occur, which represents an adjusted incidence rate of 41.89 cases per 100,000 Brazilian women^{1,2}.

Conventional treatments for the pathology consist of antineoplastic therapies, which have varied objectives depending on the stage of the disease and the functional profile of the patient, but are mainly based on the control and/or eradication of cell proliferation, prevention of recurrences, reduction of the risk of metastases, improvement in the immune response, and, in advanced cases, assisting in the palliative care of the cancer patient^{3,4}.

Traditionally, the symptoms are related to the types of treatment offered to individuals with breast cancer. Radiotherapy, which consists of the emission of ionizing radiation for the control of the condition, is characterized by a prevalence of skin disorders, such as skin dryness, redness, swelling, itching, and severe developments like radiodermatitis⁵. Chemotherapy, which uses specific medications that act on cell division, presents a prevalence of symptoms such as nausea, dizziness, and muscle fatigue⁶.

Furthermore, therapies with a recent history in the Brazilian market, such as hormone therapy and immunotherapy, present symptoms like hormonal dysregulation and changes in the circadian cycle. Moreover, in this context, considering the biopsychosocial complexity of the cancer condition, symptoms such as depression and anxiety are also common among individuals throughout the treatment⁷.

Considering these issues, physiotherapy, within the multiprofessional approach to the oncological patient, aims to alleviate physical-functional and musculoskeletal disorders resulting from treatment, address postoperative complications, manage pain clinically through various therapeutic resources, as well as instruct on health education topics within this patient scope⁸.

Among the physiotherapeutic resources that can be employed as a complementary treatment, Low-Level Laser Therapy (LLLT) stands out, which has the therapeutic potential to reduce the numerous side effects resulting from different types of antineoplastic therapies, with the aim of improving the quality of life of women diagnosed with breast cancer⁹. In this sense, within the spectrum of laser therapy, intravascular blood irradiation with Modified Intravascular Laser Blood Irradiation (mILIB) emerges as a resource that consists of irradiating the laser attached to a bracelet to transdermally irradiate a blood vessel, facilitating the treatment and making it painless and easy to apply.

Biostimulation, tissue healing, reduction of inflammation, whether chronic or acute, analgesia, and antimicrobial action are examples of benefits obtained with mILIB¹⁰, in addition to the considerable reduction of episodes of side effects from chemotherapeutic and antineoplastic drugs¹¹.

Therefore, it is understood that mLIB is a resource that can integrate complementary practices into traditional antineoplastic treatment, promoting comfort to patients and bringing innovations to the scientific field in the areas of oncology and physiotherapy¹². Given the aforementioned, this study aimed to establish a physiotherapeutic intervention protocol associated with the therapeutic application of mLIB, based on scientific evidence, for women with breast cancer.

METHODS

The development and application of the protocol involve an integrative intervention of photobiomodulation, clay therapy, breathing exercises, manual therapeutic resources, and kinesiotherapy. The study, which is a double-blind, placebo-controlled randomized clinical trial, was approved by the Research Ethics Committee of the Health Sciences Sector of the Federal University of Paraná (UFPR), under CAAE: 71033323.9.0000.0102. The inclusion criteria for the sample of participants included 60 women aged between 21 and 60 years, diagnosed with breast cancer and currently undergoing active treatment with radiotherapy, hormone therapy, chemotherapy, or others. The structure of the present research was designed for two groups, intervention and placebo. Both will undergo 10 sessions of 30 minutes, twice a week, with each session dedicated to one of the therapies along with the application of the mLIB laser.

The focus of the study is photobiomodulation, a non-invasive therapy that uses low-intensity light. Among its therapeutic effects, it stands out for reducing pain, inflammation, and edema, as well as accelerating the tissue regeneration process¹³. The application of this research is carried out using mLIB, with an exposure time of 30 minutes, an energy density of 1800 J/cm², with 180J of radiant energy per intervention, and direct application via a bracelet positioned on the left radial artery.

Oncological treatments have as one of their side effects the drying and sensitization of the skin, a factor that contributed to the selection of white clay for the study, due to its richness in silicon (Si) and aluminum (Al), its antiseptic, soothing, tightening properties, and its ability to promote the regulation of blood flow¹⁴.

Thus, the white clay used will be from the brand Buona Vita®, with a pH between 3.0 and 8.5 (close to the skin), which contains in its composition aluminum silicate, magnesium, copper, zinc, aluminum, calcium, potassium, nickel, manganese, lithium, sodium, and iron, as described on its label. The application, detailed in Figure 1, will be carried out in thick layers and only on the face, considering the importance of preserving the participant's body from excessive exposure. The materials necessary for the application of white clay are presented in Figure 2.

1. The participant must be positioned in the dorsal decubitus position, with the upper limbs laterally aligned along the body and the lower limbs extended along the stretcher, which will be properly sanitized and covered with a disposable sheet
2. If the participant wishes, cover them with a blanket/coverlet in order to provide thermal comfort during the application procedure
3. The participant will be instructed to arrive at the location with a properly cleansed face and without any cosmetic products on the skin
4. At the very beginning, the researcher, with their personal hygiene equipment (mask and disposable gloves), will place the cap on the participants' hair so that they can start the procedure
5. The first step consists of cleaning any impurities present on the participants' skin. Using a cotton pad soaked in cleansing emulsion, making circular and firm movements all over the face
6. In the bucket, the researcher will dilute a scoop (15 grams) of white clay in 100ml of tap water at room temperature, around 15°C to 20°C, stirring with the wooden stick until it reaches a homogeneous consistency
7. The white clay will be applied evenly over the entire skin with the help of a wooden stick on the surface of the face, avoiding the areas around the eyes and mouth
8. After application, keep the product on for at least 15 minutes
9. After 15 minutes, using a wooden stick, apply Buona Vita© moisturizer onto the white clay to soften the product and make it easier to remove. Then, remove the product with the help of the wooden stick and finish with facial cleansing using wet wipes in running water at room temperature

Figure 1. Step-by-step application of clay therapy

Quantity	Material
1	Pair of disposable gloves for the researcher's use
1	Disposable mask (for researcher use)
1	Disposable hair cap (for participant use)
1	Disposable sheet for the stretcher
1	Package of cotton balls
15g (grams)	Cleaning emulsion from the brand Buona Vita©
1	Moisturizer from the brand Buona Vita©
3	Compressed towels

1	Silicone bucket
2	Wooden sticks
1	Water spray bottle
1	Circular scoop 14cm x 3.5cm/15g
1	White clay from the brand Buona Vita®
100mL (milliliters)	Water at room temperature
1	Blanket/cover for the participant's thermal comfort during the proced

Figure 2. Materials used for the application of white clay

For better absorption of the positive effects, performance, and relaxation, respiratory exercise techniques and manual therapeutic resources are performed together. Breathing exercises contribute to the increase in respiratory function along with lung capacity, also providing respiratory control and helping to reduce anxiety¹⁵. Pumping is the technique of manual therapy and myofascial release, for tension in soft tissues and joint regions, which promotes joint regeneration, muscle relaxation, and improved blood circulation¹⁶.

Three breathing exercise techniques (lip closure, diaphragmatic breathing, and pranayama surya bedhana technique) and three manual therapeutic resource techniques (cervical and pectoralis major pumping) were selected, which will be applied for approximately 10 minutes each, totaling 30 minutes of intervention. The execution of each technique will be performed bilaterally, with a duration of 5 minutes on each side, interspersed with a 1-minute rest interval between techniques. For the execution of the pumping technique, the fascia should be kept under tension for 5 to 7 seconds, with 15 repetitions on each side¹⁵. The execution of the techniques will be carried out according to Figure 3, 4, and 5.

Participant's position	Lying supine on the stretcher
Therapist's position	Preferably sitting on a high stool, near the top of the participant's head; One hand positioned under the participant's head and the other under the participant's shoulder
Execution	Perform a cervical rotation, that is, "turn" the head towards the ear; and provide gentle traction and a slight separation between the muscles in the area, such as the sternocleidomastoid and trapezius, thus promoting relaxation, improved circulation, and joint regeneration ¹⁵ . Along with the execution of cervical pumping, the patient will be instructed to take a slow inhalation in about 2 seconds (inhale through the nose) with the mouth closed, and then a gentle exhalation in about 4 seconds (exhale through the mouth) with the lips partially closed ¹⁷

Figure 3. Lip brake exercise associated with cervical pumping (cervical rotation)

Participant's position	Lying supine on the stretcher
Therapist's position	Preferably sitting on a high stool, near the top of the participant's head; One hand positioned under the side of the head and the other under the participant's shoulder
Execution	Perform a cervical tilt, that is, bring the ear towards the shoulder; Just like exercise 1, the execution of this movement will provide traction and a slight separation to the neck and shoulder muscles, such as the sternocleidomastoid and trapezius ¹⁵ . The associated breathing technique consists of controlling the breath through diaphragmatic muscles. The execution should be performed by inhaling through the nostrils, distending the diaphragm and expanding the abdomen (pulling the air through the nose so that you feel the belly move outward), in a gentle manner and in about three seconds. Then, hold the air in the lungs for about three seconds and exhale slowly through the mouth, contracting the diaphragm and the abdomen in about six seconds ¹⁸

Figure 4. Diaphragmatic breathing exercise associated with cervical pumping (lateral inclination)

Participant's position	Lying supine on the stretcher
Therapist's position	Preferably sitting on a high stool, near the top of the participant's head; One hand positioned under the chest/breast area and the other under the participant's shoulder.
Execution	The execution of the technique consists of performing a gentle traction and a gentle separation of the pectoralis major muscle, a movement that should occur in a cranio-caudal direction (from the head towards the lower part of the body) ¹⁵ . In conjunction with the pumping, the participant will be instructed to inhale slowly through the right nostril for 3 seconds (at this moment, the left nostril should be obstructed with the help of the ring finger). Next, an apnea should be performed for about 3 seconds and then exhale slowly through the left nostril (at this moment, the right nostril should be obstructed with the help of the ring finger) ¹⁸ .

Figure 5. Exercise of the surya bedhana pranayama technique associated with pectoralis major pumping

Considering the physiological effects of physical exercise on oncology patients, the protocol includes kinesiotherapy involving range of motion (ROM) exercises and stretching of the cervical and shoulder regions (pectoralis major, triceps brachii, spinal portion of the deltoid, pectoralis minor, infraspinatus, and teres minor), with the aim of promoting relaxation, contributing to joint range and muscle length. The proposed intervention is based on the execution of joint movements in the cervical region, which include extension, flexion, lateral inclination, rotation, protrusion, and retraction. The prescription for ROM follows 2 sets of 10 repetitions, with 1 minute of rest between sets. Finally, the stretching prescription consists of 2 sets, holding each movement for 60 seconds, with 1-minute rests between sets¹⁹.

CONSIDERATION

The present physiotherapeutic intervention protocol, developed and proposed, is part of the research project titled "Effects of Modified Intravascular Laser Blood Irradiation in Women with Breast Cancer," which aims to describe the step-by-step applications

of complementary physiotherapeutic techniques to promote well-being, as an alternative during the application of the resource of real or placebo modified mLIB, which is the main object of study of the research, in women with breast cancer.

For the assessment of fatigue, the Cancer Fatigue Scale (B-CFS)²⁰ will be used. Oral mucositis will be assessed using the NCI-CTCAE® (National Cancer Institute Common Terminology Criteria for Adverse Events), complemented by the Oral Mucositis Quality of Life (OMQoL)²¹. Photosensitivity will be measured by the "Skin and subcutaneous tissue disorders" of the NCI-CTCAE®²². The level of elasticity, moisture, and oiliness of the skin will be assessed with the Digital Skin Moisture Meter®²³. Tactile sensitivity will be measured with the Semmes-Weinstein esthesiometer, while body weight will be recorded with a digital scale, accompanied by the NCI-CTCAE® questionnaire²².

For the secondary outcomes, the Hospital Anxiety and Depression Scale (HADS)²⁴ will be applied, divided into two subscales: HADS-a for anxiety and HADS-d for depression. The quality of sleep will be assessed using the Epworth Sleepiness Scale (ESS)²⁵ and functionality and symptoms will be evaluated using the EORTC QLQ-BR23²⁶. Finally, the satisfaction questionnaire will be applied for the overall evaluation of the implementation of the interventions.

DISCUSSION

Oncological physiotherapy is a specialty within the profession that is responsible for the care of patients diagnosed with neoplasms, whether benign or malignant. In a multiprofessional approach, it is the role of the physiotherapist to maintain the functionality of the oncology patient, as well as to treat musculoskeletal disorders and pain conditions resulting either from the disease itself or from traditional oncological treatments, such as radiotherapy, chemotherapy, among others^{27,28}.

Based on what the literature presents, the proposed protocol was supported by the most common symptoms resulting from antineoplastic treatments and sought to analyze the physiotherapeutic methods used for their treatment. In this sense, the four techniques described as complementary resources (aiming at the well-being of the participants) were associated with the therapeutic application of mLIB. Expanding on what some authors suggest²⁹, the clinical prescription of physical exercise in the form of stretching is an important resource for increasing the range of motion of the shoulder joint and maintaining the muscles involved in the main movements of the shoulder and arm complex. As described, the kinesiotherapy protocol included stretches that prioritized muscles such as the deltoid, triceps, sternocleidomastoid, scalene, among others.

In this sense, pumping also proves to be a clinical component for maintaining shoulder mobility, but addressing elements such as the tensioning of the muscle fascia, thus allowing for better sliding between the muscles. The technique, as discussed by Zanon and collaborators³⁰, not only aids in this mobility but also in the blood circulation of the musculature and the joint, in addition to providing a calming effect in the area. Associated with manual therapy, respiratory techniques cause a greater sensation of muscle relaxation and respiratory control, enhancing the therapeutic management of clinical conditions related to breast cancer³.

Furthermore, regarding the management of secondary symptoms from oncological therapies, the incidence of skin disorders, such as dryness, redness, itching (and more severe developments, such as radiodermatitis), commonly uses laser therapy for treatment, with favorable scientific evidence for its clinical use by physiotherapists. The use of laser modalities promotes tissue repair by reducing inflammation/pain and inducing the synthesis of collagen that constitutes the skin. Associated with these factors, natural treatments such as clay therapy stand out as complementary alternatives, as they act directly on the skin layers, producing effects such as skin oxygenation and toning, toxin elimination, and stimulation of the production of constituents like elastin. Thus, it becomes an effective and accessible form of treatment for those who undergo it^{32,33}.

CONCLUSION

It is concluded that the techniques described in the protocol present benefits, individually pertaining to each technique. It is expected that, together, they will be effective as tools to manage the well-being of the study participants, and thus bring greater comfort to the participants during the therapeutic application of mLIB.

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