



Randomized crossover clinical trial protocol to evaluate the immediate effects of electromassage on pain in hemato-oncological patients

Protocolo de ensaio clínico randomizado cruzado para avaliar os efeitos imediatos da eletromassagem na dor em pacientes hemato-oncológicos

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Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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ABSTRACT

BACKGROUND AND OBJECTIVES: Electromassage combines electrical stimulation and therapeutic massage through conductive gloves and is considered a promising approach for pain management. However, its effects in individuals with hematologic cancer remain unknown. This protocol aims to evaluate the immediate effects of a single electromassage session on pain, muscle tension, and fatigue in patients with hematologic neoplasms.

METHODS: This is a randomized, crossover, single-blind clinical trial with two parallel groups and a pre- and post-intervention design. Individuals of both genders, aged over 18 years, diagnosed with hematologic cancer and presenting cancer-related pain intensity ≥ 4 on the visual numeric scale (0-10), will be recruited. Participants (n=50) will receive either one electromassage session applied to the cervico-thoraco-lumbar region (combined with transcutaneous electrical nerve stimulation (TENS), for 20 minutes or will maintain their usual care routine (Control), without additional intervention, separated by a 7- to 21-day washout period. Primary outcome: pain. Secondary outcomes: fatigue; nausea, vomiting, and queasiness; muscle tension; stress and anxiety; analgesic and opioid consumption; satisfaction with the intervention; and the occurrence of adverse events.

RESULTS: The results may contribute to understanding the potential of electromassage as a non-pharmacological intervention in pain management in hematological-oncological patients.

CONCLUSION: This protocol may contribute to expanding the evidence on electromassage as a non-pharmacological approach for pain management in hemato-oncological patients.

KEYWORDS: Cancer pain, Hematologic neoplasms, Massage, Physical therapy modalities, Transcutaneous electrical nerve stimulation.

RESUMO

JUSTIFICATIVA E OBJETIVOS: A eletromassagem combina estimulação elétrica e massagem terapêutica por meio de luvas condutoras, sendo promissora no controle da dor. No entanto, ainda não são conhecidos os seus efeitos em portadores de câncer hematológico. Este protocolo visa avaliar o efeito imediato de uma única intervenção de eletromassagem sobre a dor, tensão muscular e fadiga em pacientes com neoplasias hematológicas.

MÉTODOS: Ensaio clínico randomizado, cruzado e simples-cego, com dois grupos paralelos, pré e pós-intervenção. Serão recrutados portadores de câncer hematológico, de ambos os sexos, com idade acima de 18 anos, que apresentem intensidade de dor oncológica ≥ 4 na escala visual numérica n(0-10). Os participantes (n=50) receberam uma única intervenção de eletromassagem na região de coluna cervico-toracolombar (associada ao estímulo elétrico por meio da corrente elétrica nervosa transcutânea (TENS), durante 20 minutos) ou manterão sua rotina de cuidados habituais (Controle), sem intervenção adicional, separados por um período de *washout* de 7 a 21 dias. Desfecho primário: dor. Desfechos secundários: fadiga; episódios de enjoo, náusea, vômito; tensão muscular; estresse e ansiedade; consumo de analgésicos e opioides; satisfação com o recurso e presença de eventos adversos.

RESULTADOS: Os resultados poderão contribuir para o entendimento do potencial da eletromassagem como intervenção não farmacológica no manejo da dor em pacientes hemato-oncológicos.

CONCLUSÃO: Este protocolo poderá contribuir para ampliar as evidências sobre o uso da eletromassagem como intervenção não farmacológica no manejo da dor em pacientes hemato-oncológicos.

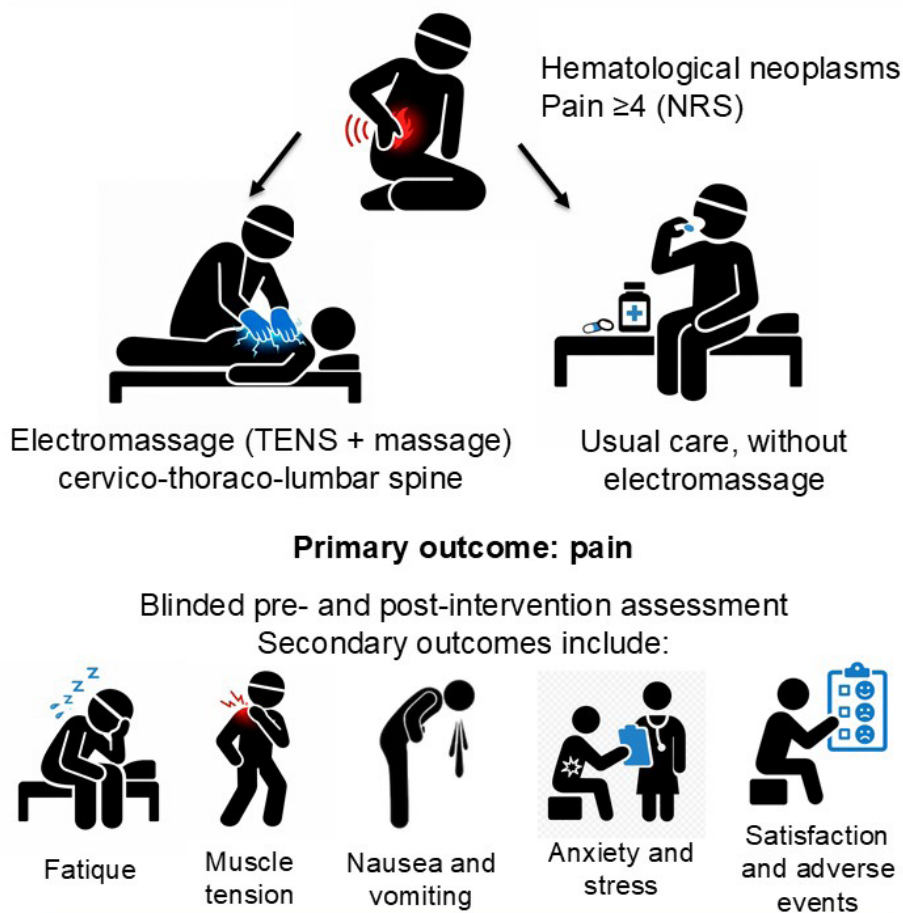
DESCRITORES: Dor do câncer, Estimulação elétrica nervosa transcutânea, Massagem, Modalidades de Fisioterapia, Neoplasias hematológicas.

HIGHLIGHTS

- The protocol will investigate the immediate effects of electromassage—a combination of TENS and therapeutic massage—on pain in patients with hematological malignancies
- The randomized crossover design will allow for the evaluation of acute analgesia and associated symptoms, controlling interindividual variability in a clinically heterogeneous population
- Electromassage is a non-pharmacological, safe, and low-cost intervention with potential application in hospital and outpatient oncology services

GRAPHICAL ABSTRACT

Electromassage in hemato-oncology patients: clinical trial protocol



INTRODUCTION

Hematological malignancies include leukemia, lymphoma, and multiple myeloma, affecting the blood, bone marrow, and lymphatic system¹. These diseases often cause pain and fatigue, impacting patients' quality of life, especially during chemotherapy treatment^{2,3}. It is estimated that pain affects more than half of cancer patients throughout the course of the disease and that, in approximately one-third of cases, suffering could be significantly reduced through appropriate interventions to control symptoms³. In this sense, physical therapy in oncology acts to reduce physical dysfunctions resulting from treatment, relieving pain and discomfort⁴.

Cancer pain, which has multiple causes, can be acute or chronic and is related to the disease itself, the adverse effects of treatment,

or complications^{5,6}. In addition to pain, fatigue is also one of the most common complaints among individuals undergoing treatment⁷. Given this scenario, it is essential to seek safe and effective therapeutic strategies for the proper management of these symptoms.

In this context, electrotherapy, especially transcutaneous electrical nerve stimulation (TENS), is an effective tool for controlling cancer pain⁸. According to the literature, massage therapy is also safe and practical for relieving pain in hematological patients undergoing chemotherapy⁹. Electromassage, which combines the use of TENS with therapeutic massage using conductive gloves, still lacks robust evidence in patients with hematological cancer. However, the existing data are promising, demonstrating

efficacy in chronic conditions^{10,11} and indicating relevance in future scientific studies.

Thus, the objective of this protocol was to evaluate the immediate effects of a single application of electromassage on pain relief in hematological-oncological patients undergoing treatment and/or in remission. In addition, it presented, as secondary objectives, the evaluation of its effects on: muscle tension; fatigue; anxiety and stress; episodes of nausea, vomiting, and sickness; consumption of analgesics and opioids; as well as the level of satisfaction with the intervention and the presence of adverse effects.

METHODS

Study design and location

This is a randomized, crossover clinical trial with a pre- and post-intervention design and blinded evaluator, conducted at the Hospital Complex of the Federal University of Paraná (CHC-UFPR), including patients admitted to the Oncology and Hematology Unit or treated on an outpatient basis. Fifty participants over the age of 18 were diagnosed with leukemia, lymphoma, or multiple myeloma were included. They were randomly allocated into two groups: Group A (Intervention followed by Control) and Group B (Control followed by Intervention), in a 1:1 ratio, with crossover after a washout period of 7 and 21 days (Figure 1).

The Control Group continued with usual care only, without additional physiotherapy intervention. To minimize the influence of external factors, participants were instructed to maintain their usual sleep, eating, and drug routines on the day of the intervention. The use of routine analgesics was maintained in both groups, with all drugs recorded in a clinical diary for consideration in the interpretation of results.

This design was chosen to observe the natural course of the condition and assess the actual impact of electromassage, ensuring its potential feasibility and applicability within the operational routines of the health service. The randomized crossover design was chosen because it allows each participant to act as their own control, reducing interindividual variability, which is particularly relevant in oncological populations with wide clinical heterogeneity, thus increasing the internal validity of the study. Considering that the objective of the study was to evaluate the immediate effects of a single electromassage session, the crossover design is appropriate for short-term interventions, provided it is accompanied by a sufficient washout period to avoid residual effects.

The washout interval between 7 and 21 days was defined based on evidence indicating that the analgesic effects of TENS and massage therapy are predominantly transient, lasting from hours to a few days after application, with no cumulative effects described after a single session. The variability in the interval aimed to accommodate the clinical logistics of the service and the clinical condition of the patients, maintaining a conservative

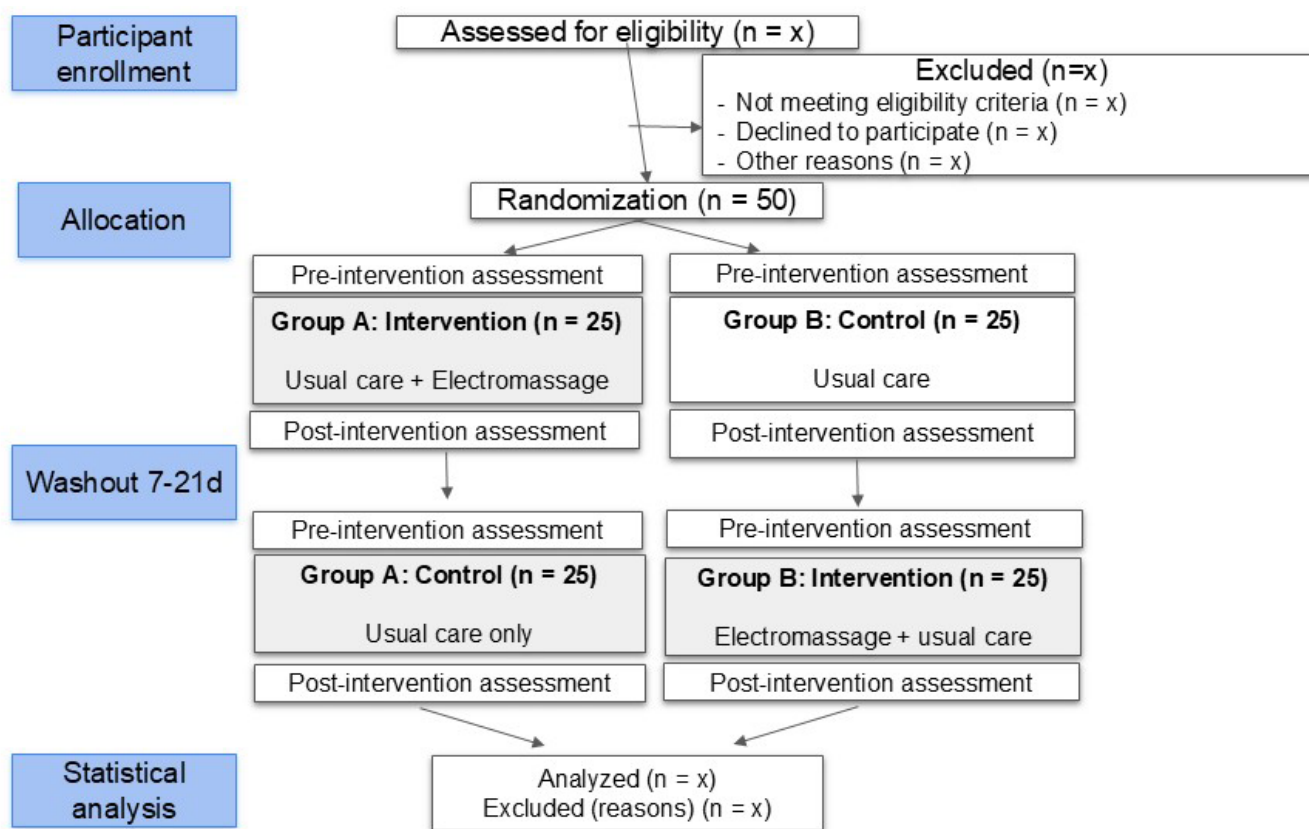


Figure 1. Clinical trial flowchart according to CONSORT guidelines.

minimum period to minimize sensory learning or conditioned expectation effects. In addition, as this is a non-pharmacological intervention with no known residual biological action, this interval is considered sufficient to reduce the risk of carryover.

Study protocol guideline

The study protocol was developed in accordance with the Standard Protocol Items Recommendations for Interventional Trials (SPIRIT 2013) and Consolidated Standards of Reporting Trials (CONSORT 2025) guidelines, ensuring transparency, methodological rigor, and ethics. The research was conducted at the Hospital Complex of the Federal University of Paraná (CHC-UFPR) by faculty and students of the Physical Therapy program. The project was approved by the Ethics Committee of the Hospital Complex of the Federal University of Paraná (CAAE: 87056525.5.0000.0096), followed the Good Clinical Practices (International Council for Harmonisation – Good Clinical Practice, ICH-GCP) and was registered on the Brazilian Clinical Trials Registry (ReBEC - under number RBR-4qmbypq). A completed SPIRIT 2013 checklist was submitted as supplementary material, ensuring transparency and compliance with the guidelines for clinical trial protocols.

Participants and recruitment

Participants will be selected at the Oncology and Hematology Unit, in the High-Risk Chemotherapy Service of CHC-UFPR, including patients hospitalized or receiving outpatient care undergoing active cancer treatment, under the institution's standard care. Screening will be performed by analyzing the medical records of patients present at the time of collection, under the supervision of the physical therapist from the Oncology and Hematology Department. Eligible participants will be invited, guided by the researcher in charge, and, after acceptance, will sign the Free and Informed Consent Term (FICT). The entire process will follow the guidelines of the department team, respecting the care routine.

After signing up for the FICT, participants completed a data collection form to gather sociodemographic and clinical information (name, gender, age, lifestyle, history, diagnosis, staging, treatments, and complementary tests) in order to verify eligibility criteria and the profile of hematological-oncological patients.

Eligibility criteria

Patients of both genders, aged over 18 years, diagnosed with leukemia, lymphoma, or multiple myeloma, undergoing active treatment (chemotherapy, immunotherapy, or radiotherapy), who present pain related to the tumor, treatment, or functional limitations, regardless of the location of the pain, with an intensity ≥ 4 on the Numerical Rating Scale (NRS) in the last 24 hours¹². Participants must be able to communicate verbally in Portuguese, have adequate cognitive abilities, and score 0 to 3 on the Eastern Cooperative Oncology Group Performance Status (ECOG-PS) index¹³.

The origin of the pain will be clinically characterized during the initial assessment, based on a review of medical records, a structured interview, and the location reported by the patient, and will be classified as predominantly related to the tumor, cancer treatment, or mixed. This information will be used for sample description and exploratory analysis, recognizing the multifactorial nature of cancer pain and the frequent overlap between these mechanisms.

Patients who are illiterate; have previously identified psychiatric disorders or cognitive deficits; have hearing loss that impairs verbal comprehension; are pregnant or breastfeeding; have pain unrelated to cancer (e.g., chronic low back pain, arthritis, osteoarthritis); those using specific analgesic therapies (radiation, bone cement, nerve block); those with contraindications to massage therapy (spinal tumors, coagulopathies such as hemophilia, paresthesias, open wounds, recent surgeries, catheters, deep vein thrombosis); or to electrotherapy (pacemaker, metals in the application region, implanted neuromodulators, epilepsy, arrhythmias, dermatological diseases or fragile skin, allergy to electrodes)¹⁴. In addition, participants who had used analgesics and opioids outside of their usual prescription in the two hours prior to and during the intervention and data collection period will be excluded.

Randomization, allocation, and blinding

After evaluation of clinical and sociodemographic data, participants underwent outcome assessment. Then, participants (n=50) were randomized (1:1) in a crossover design into Group A and Group B. Group A (Intervention followed by Control) initially received a single application of therapeutic massage on the cervical-thoracolumbar spine, associated with TENS, applied with conductive gloves for 20 minutes. After a washout period of 7 to 21 days, participants followed the outcome assessment protocol and then were allocated to the Control group, which received usual care without physiotherapeutic electromassage intervention. Group B followed the reverse order, starting with Control and then undergoing Intervention after the washout period.

Participants were allocated to group A (n = 25) or group B (n = 25) using the block randomization technique to achieve similar group sizes, and the random block was sized as 6 blocks of size 4. Randomization will be performed after the initial assessment of outcomes by a previously designated member of the research team, with the aid of a computerized randomization program. The design and nature of this study make blinding impossible for participants and the person applying the technique, due to the nature of the procedure. However, blinding was possible for the evaluator and data analyst. The clinical outcome evaluator was not aware of the allocations to reduce the risk of observer bias. Similarly, participants were coded with identification numbers to ensure confidentiality during data analysis.

Intervention

During electromassage, participants were positioned in the lateral decubitus position. The application occurred in the posterior region of the trunk (cervical-thoracolumbar spine), previously cleaned with 70% alcohol. The choice of application site followed

evidence indicating efficacy in this area due to the high density of innervation and nociceptive modulation^{15,16}.

The TENS/FES VIF 995 Four Quark device manufactured by Ibramed was used (Figure 2). Electrical stimulation followed the parameters: conventional TENS with balanced symmetrical rectangular biphasic wave (Figure 3), frequency of 100 Hz, pulse width of 150 μ s, and duration of 20 minutes. The intensity was adjusted individually to the maximum tolerable sensory level, i.e., below the motor threshold, and readjusted if habituation occurred, as recommended in the literature^{8,17}.

The current was conducted through Konmed brand conductive gloves (Figure 4), moistened with drinking water¹⁰, to optimize electrical transmission. The gloves and device were sanitized before and after each use with water and 70% alcohol, preventing cross-

contamination, which is an essential measure in immunosuppressed patients.

Electromassage was performed with manual therapeutic maneuvers associated with electrical stimulation. Massage therapy techniques (Table 1) included: unidirectional sliding, starting superficially and advancing to deep sliding with continuous pressure; kneading, with rhythmic movements that mobilize subcutaneous tissues by lifting, compressing, and displacing skin and muscles; pinching, performed with the thumb and index finger (or middle finger) in skin pinching movements; and rolling, performed with fixed thumbs and the other fingers sliding, promoting a wave-like movement that mobilizes the fascia and tissues, favoring deep muscle relaxation¹⁶. The procedure could be interrupted at any time, at the participant's request or in the presence of any discomfort.



Figure 2. VIF 995 Four Quark TENS/FES equipment (IBRAMED, Amparo, SP, Brazil). Illustrative image from the manufacturer, used for descriptive purposes only.

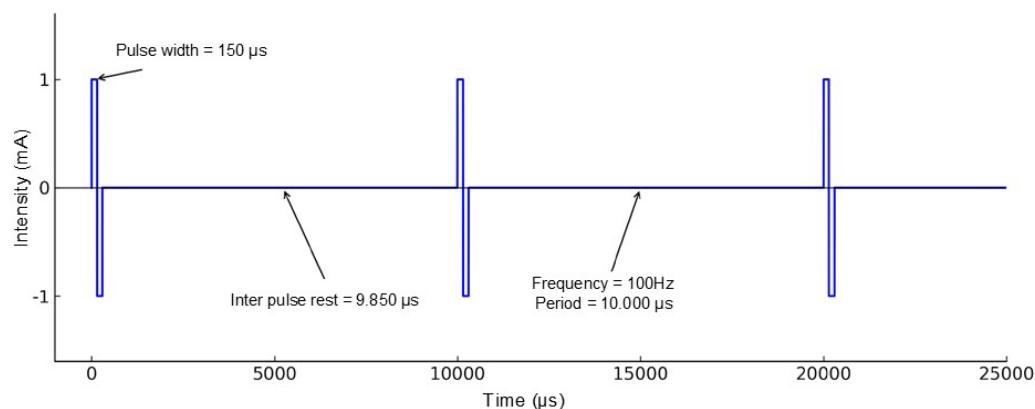


Figure 3. Graphical representation of the electrical current (balanced rectangular symmetrical biphasic wave) and selection parameters.



Figure 4. Conductive silver fiber gloves (manufacturer Konmed, RP Importação & Comércio, São Paulo, Brazil). Illustrative image from the manufacturer, used for descriptive purposes only.

Table 1. Location of the intervention, massage therapy maneuvers, and duration.

Muscle	Maneuver	Duration (min)
Trapezius	Sliding	02:30
	Kneading	02:30
	Pinching	02:30
	Rolling	02:30
Latissimus dorsi	Sliding	02:30
	Kneading	02:30
	Pinching	02:30
	Rolling	02:30

Outcomes assessed

Participants will be assessed at three time points: before the intervention (T0) and immediately after (T1). The primary outcome, pain intensity, will also be measured 15 minutes after the start of the intervention. A previously trained researcher will be responsible for data collection, ensuring standardization and reliability of the evaluations.

Primary outcomes

The primary outcome was pain reduction, regardless of its location, assessed using a Numerical Rating Scale (NRS), which rates pain from 0 (no pain) to 10 (worst pain imaginable), with the score of ≥ 10 mm considered clinically relevant. Considering: absence of pain (0), mild pain (1 to 3), moderate pain (4 to 6), severe pain (7 to 9), and worst pain imaginable (10)¹². Pain was also assessed using the Brief Pain Inventory – Brazilian version (BPI-B)¹⁸. The two-dimensional scale assesses pain intensity (minimum, average, current, and worst) and functional impact (general activities, mood, sleep, work, relationships, among others) on a scale of 0 to 10. It

also includes a body diagram and percentage of pain relief. Average scores define severity: 1–4 (mild), 5–7 (moderate), and 8–10 (severe). The instrument will be self-administered.

Secondary outcomes

Secondary outcomes were previously ranked based on clinical relevance and physiological plausibility. Cancer-related fatigue and muscle tension were defined as main secondary outcomes due to their direct association with pain and the mechanisms of action of electromassage. The other outcomes (nausea, vomiting, anxiety, stress, analgesic consumption, satisfaction, and adverse events) were analyzed exploratively, thus generating hypotheses for future studies, without a confirmatory character.

Fatigue was measured by the Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F), using the 13 items of the fatigue subscale, which assess its impact on daily activities. This instrument, derived from FACT-An, has been shown to be effective in differentiating fatigue levels between groups with cancer and anemia¹⁹. The instrument was self-administered.

Symptoms of muscle tension, nausea, vomiting, sickness, anxiety, and stress were assessed up to one hour after the intervention using a Numerical Rating Scale (0–10), where 0 represents absence and 10 represents maximum intensity. The categories are: 1–4 (mild), 5–6 (moderate), and 7–9 (severe)²⁰. The scale was applied by a previously trained evaluator.

The consumption of analgesics and opioids were recorded in a drug diary on the day of the intervention, collecting data from the patients' medical records, such as the type, dose, and time of administration of the agent.

Patient satisfaction was researched using the Patient Global Impression of Change (PGI-C), a 7-point scale that rates the participant's perception of improvement, ranging from "much better" to "much worse"²¹. In addition, five additional questions about the experience with the intervention were asked, with scores ranging from 1 (very dissatisfied) to 5 (very satisfied). The tool was delivered to the participant and was self-administered.

Finally, any adverse events or clinical changes identified after electromassage were also recorded and analyzed in a data recording and intervention follow-up file.

Statistical analysis

Sample calculation

Based on previous evidence on the effects of complementary therapies on pain in cancer patients, a 10 mm decrease in the Numeric Rating Scale (NRS) represents a clinically relevant change²², and a standard deviation of 25 mm is acceptable. Adopting a statistical power of 80% and a significant level of 5%, it was estimated that approximately 50 participants in total would be needed to detect a significant difference between the interventions, considering the cross-over design of the study (Equation 1),

$$n = \frac{((Z\alpha/2 + Z\beta)^2 \times 2(1-r) \times \sigma^2)}{\delta^2} \quad (1)$$

$$n = ((1.96 + 0.84)^2 \times 2(1 - 0.5) \times 25^2) / 10^2$$

$$n = (2.8^2 \times 1 \times 625) / 100$$

$$n = (7.84 \times 625) / 100$$

$$n = 4900 / 100$$

$$n = 49 \text{ participants (no losses)}$$

With the following values:

$$Z\alpha/2 = 1.96 \text{ (5\% significance level)}$$

$$Z\beta = 0.84 \text{ (80\% power)}$$

$$r = 0.5 \text{ (intra-individual correlation)}$$

$$\sigma = 25 \text{ mm (standard deviation)}$$

$$\delta = 10 \text{ mm (minimum clinically significant difference)}$$

Statistical analysis

The data was tabulated in IBM SPSS version 22.0, with a significance level set at $p < 0.05$, and calculation of the size effect compatible with the statistical test used²³. The researcher blinded

to the groups analyzed the observable data, which was then coded to maintain participant confidentiality.

The analytical strategy was directed primarily at the primary outcome (pain intensity), using models compatible with the crossover design and sample size. The main analysis was performed using repeated measures ANOVA, considering condition (intervention vs. control) and time (pre vs. post). The main secondary outcomes followed the same analytical approach.

Exploratory endpoints were analyzed descriptively and with simple inference, without correction for multiple comparisons, and their results were interpreted with caution. Type I error control was prioritized by limiting the number of confirmatory tests. Missing data was treated using the last observation carried forward (LOCF) method, as recommended for short-term clinical studies²⁴.

DISCUSSION

Although TENS and massage therapy are well-established interventions for pain management, their combination through electromassage and applied specifically to cancer patients has been explored little. Despite the existence of previous studies on electromassage applied to other clinical conditions^{10,11}, to the authors knowledge, this randomized crossover study was one of the first to investigate the effects of electromassage in hematological cancer patients for pain relief. This study will contribute to the currently limited knowledge about the effect of electromassage as an adjunctive therapy in different clinical outcomes.

Pain is considered one of the most commonly reported symptoms by cancer patients, and insufficient relief of this symptom can be devastating, negatively affecting individuals' performance and emotional well-being. Recent advances in oncology, such as greater awareness and knowledge of treatment among healthcare professionals, the publication of guidelines for cancer pain management²⁵, drugs, and treatment strategies, may have had a positive effect on reducing the prevalence and severity of cancer pain in recent decades. However, one study²⁶ revealed that 44.5% of cancer patients still experience pain, especially in patients with advanced, metastatic, and terminal cancer (54.6%). Thus, this prevalence remains high, emphasizing the need for continued attention to its management, and there is still room for improvement, including safe and non-pharmacological approaches in clinical practice.

Treatment guidelines²⁷ for cancer survivors recommend rehabilitation services based on specific symptoms or disease treatment. For pain management, the National Comprehensive Cancer Network²⁸ recommends non-pharmacological rehabilitation interventions and modalities, including TENS and movement-based therapies.

Although electrotherapy is a well-established resource in clinical practice, including in oncology, the evidence to support its use in the management of cancer pain is still inconclusive²⁹⁻³¹. Clinical studies have demonstrated positive effects of TENS application in reducing pain in patients with chemotherapy-induced peripheral neuropathy over a 6-week period¹⁷ or in palliative care patients over a 12-hour period of application¹⁴. Interestingly, a clinical

study³² demonstrated a reduction in pain intensity, opioid use, and a tendency toward improvement in nausea and loss of appetite in cancer patients in palliative care through the use of TENS for 30 minutes at four different points (dermatome corresponding to the organ causing the pain; dermatomes from C7 to T8 for relief of symptoms such as nausea, vomiting, and dyspnea; and over the tibial nerve in the medial malleoli of the ankle to relieve constipation).

In addition, TENS has a level B recommendation rating for the treatment of cancer patients because it involves the application of mild electrical current to the cutaneous nerve through surface electrodes. This mechanism is closely related to neuronal modulation, primarily aiming to increase endogenous opioid substances, or through the exploration of the gate control theory, which directly influences the central nervous system (CNS) with the aim of providing a significant increase in the pain threshold³¹.

Despite uncertainties regarding the efficacy of TENS in cancer pain, corroborating reference author³³, patients will continue to use TENS regardless of the opinions of clinicians, policymakers, or guideline recommendations because TENS is readily available without a prescription. TENS generates a pleasant sensory experience; it is similar to relieving pain using thermotherapy; and technological developments such as smart wearable TENS devices will improve its use in the future. Thus, research is needed on how best to integrate TENS into existing pain management strategies in specific patient populations.

On the other hand, among movement-based therapies, therapeutic massage stands out. It's a modality that applies force to muscle, tendon, and connective tissue structures to promote improved circulation, pain relief, tension relief, and muscle relaxation. Swedish massage is the most widely used technique in cancer treatment³⁴ and uses five types of movements (sliding, kneading, tapping, rubbing, and vibrating); other techniques can also be used, such as myofascial release, craniosacral therapy, reflexology, deep tissue massage, among others. There is encouraging, although not definitive or strong, evidence for the use of massage therapy in reducing pain, anxiety, sleep, and mood disorders.

In a recently published recent meta-analysis⁹, massage therapy provides pain relief, especially for hematological and oncological patients, followed by patients with breast and digestive system cancer. Foot reflexology and acupressure were the best methods for pain relief, with a duration of 10 to 30 minutes and a program lasting ≥ 1 week showing the best benefits. There are hypothesis that the mechanism for inducing analgesia through massage therapy can be justified by local biochemical changes in soft tissues, through descending modulatory circuits, improving blood and lymphatic flow, oxygenation, and muscle metabolism, as well as by inducing the release of substances that act as pain receptors, such as oxytocin, vasopressin, adenosine, endorphins, and serotonin.

Therefore, the literature already documents the benefits of combining therapeutic massage and TENS current in relieving pain, fatigue, and muscle tension in patients with diseases that cause chronic pain^{10,11,35,36}. However, there are still few studies that use this combination in patients with hematological cancer, which reinforces the relevance of the present proposal. Electromassage can be an effective, accessible, and low-risk complementary intervention. The technique is performed by trained physical

therapists, has a low cost and is easily adaptable to different clinical contexts, including the Brazilian public health system.

Therefore, it is pertinent to further discuss the evidence related to the use of TENS and massage therapy, either alone or in combination, in the management of cancer pain. It is worth noting that although the application of electromassage in the cervical-thoracolumbar spine region does not directly correspond to the topography of pain in all patients, this choice is clinically justifiable and supported by established physiological mechanisms in pain management. Electrical stimulation associated with therapeutic massage in richly innervated paravertebral regions promotes nociceptive modulation through segmental and suprasegmental mechanisms, resulting in global analgesia³¹⁻³³. Evidence in oncology and palliative care shows that TENS can reduce pain intensity, opioid consumption, and associated symptoms even when applied outside the primary site of pain, especially in cases of diffuse or multifactorial pain^{14,32}. Complementarily, massage therapy has consistent effects on pain, muscle tension, anxiety, and fatigue, and is considered safe and well tolerated in cancer patients, including those with hematological neoplasms^{9,34,37,38}. Thus, the choice of the cervical-thoracolumbar are aimed to enhance systemic analgesic effects and relieve concomitant symptoms, in line with current recommendations for the non-pharmacological management of cancer pain^{28,31}.

This practical applicability increases its potential for adoption as an auxiliary resource in pain management in oncology units. Among the limitations of the study, the absence of medium- and long-term follow-up should be highlighted, since the objective of this study was to evaluate exclusively the immediate effects of a single application of electromassage. This methodological choice allowed to isolate the acute effect of the intervention and generate preliminary data necessary for the design of future trials with a greater number of sessions and prolonged follow-up.

Another relevant methodological limitation refers to the absence of a placebo or sham intervention in the control group, which consisted exclusively of usual care. Considering the sensory nature of electromassage, which combines therapeutic touch and electrical stimulation and the use of pain as a subjective primary outcome, the influence of expectations and contextual effects on symptom perception cannot be ruled out. Previous studies on cancer pain show that simulated interventions, such as turned off TENS, light touch, or massage without electrical stimulation, can reduce this bias and improve the internal control of clinical trials. In the present protocol, the decision not to include a sham group was based on aspects of clinical feasibility, patient acceptability, and the specific objective of evaluating the immediate effects of the intervention in conditions close to actual care practice. Nevertheless, it is recognized that future trials should incorporate placebo comparators to better discriminate the specific effects of electromassage from those related to the therapeutic context and patient expectations.

Therefore, if the effects of electromassage are confirmed, the technique could be incorporated into cancer rehabilitation protocols, offering a safe alternative to the excessive use of analgesic drugs. In addition, the present study may serve as a basis for future research evaluating prolonged effects, a greater number of sessions, and other cancer populations.

SPIRIT version and compliance note

This protocol is aligned with the recommendations of SPIRIT 2013 (Standard Protocol Items Recommendations for Interventional Trials). As this is a single, non-invasive, low-risk intervention, no independent data monitoring committee was established. The results of the present study will be published in peer-reviewed journals and presented at national and international scientific conferences in the field of physical therapy and oncology.

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SUPPLEMENTARY MATERIAL

Supplementary material accompanies this paper.

SPIRIT 2025 checklist of items to address in a randomized trial protocol

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