methods and protocols

MDPI

Study Protocol

Photobiomodulation for the Treatment of Post-Stroke Spasticity: A Randomized Controlled Trial Protocol Including Muscle Oxygenation Assessment by Near-Infrared Spectroscopy

Illora Aswinkumar Darbar Shimozato [1], Barbara Glenda Castro Chaves [1], Julia Emy Wadamori [1], João Eduardo Pontes Nozaki [1], Maria Fernanda Setúbal Destro Rodrigues [1], Raquel Agnelli Mesquita-Ferrari [1], Rodrigo Labat Marcos [1] and Rebeca Boltes Cecatto [1,2,*]

[1] Biophotonics-Medicine Post-Graduate Program, Universidade Nove de Julho/UNINOVE, 249 Av Vergueiro, Liberdade, São Paulo 01504-001, SP, Brazil; illorashimozato@uni9.edu.br (I.A.D.S.); barbaraglen-da@uni9.edu.br (B.G.C.C.); juliawadamori1@gmail.com (J.E.W.); joao.nozaki@uni9.edu.br (J.E.P.N.); fernandarodrigues@uni9.pro.br (M.F.S.D.R.); raquel.mesquita@gmail.com (R.A.M.-F.); labat@uni9.pro.br (R.L.M.)

[2] Instituto de Reabilitação Lucy Montoro IRLM (Morumbi) HCFMUSP, Universidade de São Paulo, São Paulo 05716-150, SP, Brazil

* Correspondence: rebeca.boltes@gmail.com or rebeca.boltes@uni9.pro.br

Abstract

Stroke is a leading cause of disability worldwide, with spasticity of the triceps surae being one of the most common and functionally debilitating sequelae. Despite available therapeutic options, no single intervention provides fully satisfactory and long-lasting results. Photobiomodulation (PBM) has emerged as a promising adjunctive therapy, with evidence suggesting beneficial effects on muscle fatigue, pain, and performance. Background/Objectives: This protocol aims to evaluate the effects of PBM on triceps surae spasticity in hemiplegic patients after stroke. Methods: This is a phase II, blinded, parallel-group, randomized, placebo-controlled clinical trial. Forty-two participants with hemiparetic stroke will be randomized to receive active PBM (850 nm LED, 4 J per point, 12 points, once weekly for eight weeks) or placebo PBM (device switched off), both in addition to standard rehabilitation therapy. The primary outcome is spasticity of the triceps surae, measured by the Modified Ashworth Scale (MAS). Secondary outcomes include pain (Numerical Pain Scale), ankle range of motion, lower limb functionality (Fugl–Meyer Assessment and Functional Independence Measure), muscle oxygenation (muscular near-infrared spectroscopy), muscle force (Medical Research Council scale) and the occurrence of adverse events before and after the intervention. Comparisons between groups and between time points will be performed using a two-way repeated measures ANOVA test and the Generalized Estimating Equations (GEE) test. A pilot interim analysis, when recruitment reaches a size of 10 participants per group, will be performed using a two-way/repeated measures ANOVA to assess effect size and recalculate sample size, making adjustments to the design if necessary. Conclusions: This pioneering randomized controlled clinical trial will evaluate the effects of PBM applied to the gastrocnemius muscles after stroke, assessing not only antispastic effects and modifications in lower limb functionality, but also changes in tissue oxygenation by NIRS and muscle strength.

Keywords: spasticity; photobiomodulation; near-infrared spectroscopy; rehabilitation; hemodynamics

Check for updates

Academic Editor: Fernando Albericio

Received: 9 October 2026
Revised: 19 November 2026
Accepted: 25 November 2026
Published: 27 November 2026

Copyright: © 2026 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license.

1. Introduction

Stroke is the second leading cause of death and the leading cause of disability worldwide [1]. The Global Burden of Disease Study 2021 predicts that one in six people will experience a stroke in their lifetime [1]. Motor impairment, particularly hemiparesis, affects 33–80% of survivors [2], leading to significant functional limitations and reduced quality of life.

Spasticity is a common and debilitating motor complication after stroke, characterized by a velocity-dependent increase in muscle tone resulting from hyperexcitability of the stretch reflex [3]. When left untreated, spasticity can lead to pain, joint contractures, and functional decline. The triceps surae is the most frequently affected muscle group in the lower limb, contributing to equinovarus deformity and impairing gait and mobility [4]. Current treatment options include physiotherapy, oral medications, botulinum toxin injections, and surgical interventions. However, these modalities have limitations, including systemic side effects, invasiveness, transient efficacy, and lack of consensus on optimal management [5].

Photobiomodulation (PBM) is based on the use of lasers or light-emitting diodes (LEDs) that deliver light within a specific spectral range, using non-ionizing and non-thermal sources to induce biological responses through interactions with tissues at the cellular and molecular levels [6]. Although these interactions may generate a small negligible amount of localized heat, the underlying mechanisms of PBM are predominantly photochemical, with photochemical effects consistently prevailing over photothermal effects [7–10]. In contrast to pharmacological interventions, PBM has no known adverse effects when appropriately indicated and administered [11]. Its reported biological effects include increased endogenous opioid levels, elevation of the thermal pain threshold, enhanced local blood flow, stimulation of adenosine triphosphate and cellular neurotransmitter production, modulation of oxygen consumption, and changes in anti-inflammatory cytokine levels [11].

Several previous studies have documented the effects of light irradiation on muscle contraction, demonstrating its ability to attenuate skeletal muscle fatigue, prolong physical activity, reduce pain perception, and enhance muscle performance in healthy individuals and those with acute or chronic injuries [6,12,13].

In pathological or injured muscle tissue, PBM has also demonstrated the ability to reduce oxidative stress and accelerate repair processes following acute injury [14].

In this context, the application of PBM for the management of spasticity has been investigated in experimental and clinical models, through both central neurological stimulation and peripheral neural and muscular stimulation [13].

The first clinical publications on this topic emerged only in the 1980s. Initially, the first studies investigating the use of PBM as a therapy for spasticity targeted the neural pathway, either the sensory or motor peripheral nerve supplying the affected muscle group, or through stimulation intended to inhibit central neuronal release [15,16]. From 2015 onward, however, a shift occurred in research on the effects of PBM on spastic muscle [17,18]. Although previous publications had already demonstrated the effects of PBM on muscle contraction, strength, and fatigue parameters in animals and healthy humans, it was only from 2015 onward that clinical trials began to emerge investigating these outcomes in patients with spasticity undergoing PBM protocols directly targeting the spastic muscle fibers, rather than exclusively the neural pathway. These studies are particularly interesting because they demonstrate that the use of photobiomodulation in spastic muscles can improve muscle function independently of its effects on neural pathway inhibition. They open a new window of opportunity for the use of PBM in the treatment of spasticity, suggesting that, as with conventional physical rehabilitation therapies, improvements in the quality of the muscular

substrate, even in spastic muscle fibers, can be achieved through PBM and may contribute to the clinical improvement of spasticity observed in these patients. Therefore, they suggest that PBM protocols aimed at improving spasticity may target not only the hyperexcitable neural pathway but also the maintenance of muscle fiber quality and function as strength, fatigue, range of motion and local pain [19–24].

Taken together, over 40 years of research, these studies suggest that PBM has considerable potential as an adjuvant therapy to physical therapy in the treatment of spasticity, either by reducing the degree of spasticity, an effect already demonstrated in studies through neural stimulation, or by improving muscle fatigue, strength, and contraction, effects already demonstrated in healthy individuals and in individuals with spastic sequelae of stroke through direct stimulation of local muscle fibers. PBM is a non-invasive non-thermal method that uses low-intensity light to stimulate cellular and molecular processes [6]. The proposed mechanisms by which PBM reduces spasticity include the regulation of oxidative stress responses, increased ATP production and cellular metabolism, promotion of tissue repair and regeneration, and modulation of neurotransmitter release at synapses [25]. Unlike pharmacological therapy, when appropriately indicated and administered, PBM has no known side effects. Furthermore, unlike botulinum toxin, it is non-invasive.

Despite these promising findings, few studies have evaluated the effects of PBM applied directly to the gastrocnemius muscle on spasticity, muscle oxygenation, and lower limb functionality in patients after stroke. This protocol describes a randomized controlled trial designed to fill this gap. We hypothesize that photobiomodulation, applied to the gastrocnemius muscles of patients after stroke, will reduce triceps surae spasticity, pain, improve range of motion, muscle oxygenation, and lower limb functionality to a greater extent than placebo, when used as an adjunct to standard rehabilitation treatment. The objective of this study is to evaluate the effects of photobiomodulation on spasticity of the triceps surae, as well as on associated secondary parameters (pain, range of motion, lower limb functionality, muscle oxygenation, muscle contraction strength, and adverse events), in participants with stroke sequelae.

2. Materials and Methods

This is a phase II, single-center, blinded, parallel-group, superiority, randomized, placebo-controlled clinical trial with a 1:1 allocation ratio. The study will be conducted at the Specialized Rehabilitation Center II (CER II) in Guarulhos, São Paulo, Brazil. The protocol adheres to the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines [15]. The Template for Intervention Description and Replication (TIDieR) checklist [16] and SPIRIT checklist [15] are presented in the Supplementary Materials.

2.1. Ethics and Dissemination

The study protocol was approved by the Institutional Research Ethics Committee before commencement (Approval Number 97137226.6.0000.5388/8.627.601), 5 August 2026. All participants will provide written informed consent after receiving comprehensive oral and written information about the study, including its purpose, procedures, potential risks and benefits, and their right to withdraw at any time without penalty. The study will be conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. Any protocol amendments will be communicated to the ethics committee, trial registries, and investigators.

2.2. Participants

Inclusion Criteria:

- Adult patients (≥18 years) with a documented diagnosis of ischemic or hemorrhagic stroke, confirmed by computed tomography or magnetic resonance imaging;
- Patients undergoing multiprofessional rehabilitation at the study center;
- Motor pattern of spastic hemiparesis after stroke;
- Presence of orthostatic activity or therapeutic or functional gait.

Non-Inclusion Criteria:

- Uncontrolled systemic diseases (e.g., cancer, infections, decompensated diabetes mellitus);
- History of photosensitivity;
- Grade 4 spasticity of the triceps surae on the Modified Ashworth Scale (MAS) at initial assessment;
- Fixed anatomical ankle deformities preventing at least 60 degrees of ankle joint movement;
- Malnutrition;
- Exposed tumors or undiagnosed lesions at the irradiation site;
- Application of botulinum toxin to the triceps surae within six months prior to study start.

Exclusion Criteria:

- Acute or unstable clinical conditions;
- Change in drug class for spasticity during the study period (dosage changes will be accepted and reported);
- The use of any anti-spasticity medication other than baclofen;
- Application of botulinum toxin to the triceps surae during the study;
- Abandonment of follow-up physical therapy treatment.

2.3. Sample Size Calculation

No previous studies have evaluated PBM in this population with these specific outcomes. Using data from Chen et al. [26] which evaluated MAS reproducibility in spastic patients (mean 1.7, SD 1.3) and considering a minimum clinically significant difference of 1.43, a sample size of 34 participants was calculated using G-Power software (Version 3.1.9.6). Accounting for 20% attrition, we aim to recruit 42 participants (21 per group).

2.4. Recruitment and Baseline Assessment

Potential participants will be identified during routine physiotherapy assessments at CER II. Patients will be provided with information about the study and invited to participate. Eligible patients those who agree will provide written informed consent. Baseline data will be collected, including demographics, clinical characteristics, and medication use, followed by randomization.

2.5. Randomization and Allocation Concealment

Participants will be randomized 1:1 to the PBM treatment group or the placebo group using a computer-generated random sequence with permuted blocks of four. The sequence will be generated by an independent researcher not involved in participant allocation. Allocation will be concealed using sequentially numbered, opaque, sealed envelopes. The investigator will open the envelope at the time of the first intervention session and assign the participant to the corresponding group.

2.6. Blinding

This is a double-blind trial. Participants, outcome assessors, and data analysts will be blinded to group allocation. The researcher responsible for PBM application will not be

involved in outcome assessments or data analysis. Patients blinding will be maintained by using the same equipment and procedures for both groups, with the device turned off for the placebo group. The device emits infrared light (invisible to the naked eye), and an audio recording of the device's operational sound will be played during placebo sessions to mimic active treatment. Unblinding will be permitted only in the event of a serious adverse event requiring knowledge of the intervention.

2.7. Interventions

Standard Rehabilitation Group (Both Groups):

All participants will continue to receive their standard individualized rehabilitation treatment at CER II, which occurs once weekly for 45 min. The standard treatment includes neurological physiotherapy, stretching, strengthening, sensory and proprioceptive stimulation, functional training, and gait training, as clinically indicated. To improve adherence to intervention/comparator protocols, participants assigned to the comparison groups—whether PBM or placebo—will undergo the interventions on the same day they visit the rehabilitation center for standard institutional therapy, thereby avoiding extra visits to the rehabilitation center. All clinical care and follow-up will be maintained in coordination with the medical and therapeutic team responsible for the participants.

Active Photobiomodulation (Intervention Group):

Participants will receive active PBM therapy once weekly, on the same day as their standard rehabilitation treatment session, for eight consecutive weeks. The intervention will be performed using a Laserpulse device (IBRAMED, Amparo, SP, Brazil), with an 850 nm wavelength.

No previous published studies have specifically investigated PBM for post-stroke spasticity in the target muscle group using the outcomes proposed in the present study. Therefore, the selected parameters represent an evidence-informed adaptation of previously investigated musculoskeletal PBM protocols and previous clinical evidence. The 850 nm LED wavelength was selected as an adaptation of the 808 nm laser protocol described by das Neves et al. [24]. Both wavelengths belong to the near-infrared range and have similar optical properties, with relatively low absorption by several biological chromophores and the potential to deliver light beyond superficial tissue layers. The selection of the slightly longer wavelength was intended to favor light penetration into the underlying muscle tissues, although actual penetration depends on several factors, including tissue optical properties and light source characteristics. The 4 J per point dose was based on the recommendations of the World Association for Laser Therapy [27] (WALT, 2010), which recommends a minimum energy of 4 J per point for musculoskeletal applications, and on the randomized clinical trial by das Neves et al. [24]. In that study, PBM using an 808 nm laser (100 mW, 4 J per point) was applied to the quadriceps muscle and resulted in significant changes in pain, time to muscle fatigue, and peak torque. The irradiance selected for the present protocol (200 mW/cm^2) is consistent with low-intensity phototherapy, in which photochemical and photobiological effects are expected to predominate over photothermal effects [8,10,11,28,29]. The weekly treatment schedule was established as a feasible repeated-treatment regimen within the rehabilitation setting, considering the absence of previous studies defining the optimal frequency of PBM application for this specific population and clinical condition. The PBM therapy parameters, adapted from das Neves et al. [10], are detailed in Table 1.

Table 1. The PBM therapy parameters.

Title 1	Title 2
LED light source type	LED probe
Wavelength (nm)	850 ± 20%
Operating mode	Continuous
Application technique	Contact
Device output power (mW)	200
Irradiance (mW/cm^2)	400
Beam area at the target (cm^2)	0.5
Energy density at the aperture (J/cm^2)	8
Radiant energy per point (J)	4
Number of points	12
Total energy per session (J)	48
Number and frequency of sessions	Once per week, for 8 weeks

LED: Light-Emitting Diode; nm: nanometer; mW: milliwatt; cm^2: square centimeter; J: Joule; mW/cm^2: milliwatts per square centimeter; J/cm^2: Joule per square centimeter.

The application points will be distributed equally across the medial and lateral heads of the gastrocnemius, with 2 cm spacing between points, covering the entire muscle bellies in a total of 12 points (Figure 1). Participants and examiners will wear protective glasses during the intervention.

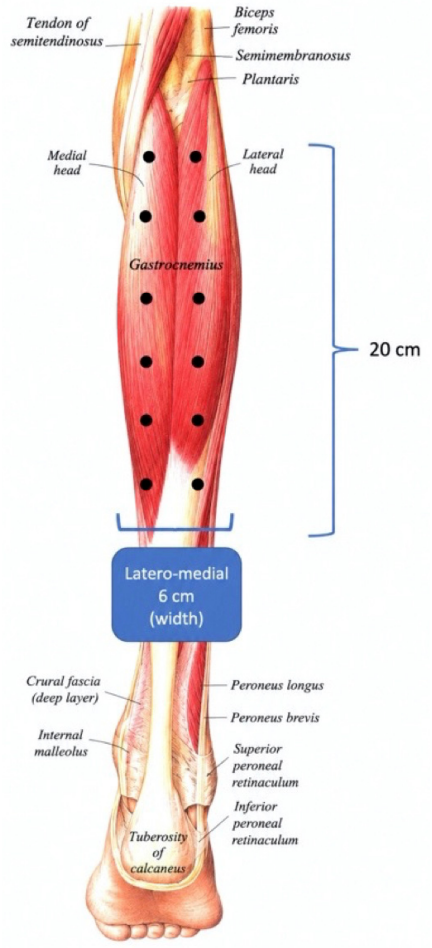


Figure 1. Distribution of the 12 measurement points across the gastrocnemius muscle. The points are uniformly distributed in the lateromedial and longitudinal dimensions within a 20-cm muscle segment, covering a 6-cm lateromedial width. Conceptual illustration prepared by the authors.

Placebo Photobiomodulation (Control Group):

Participants in the placebo group will undergo the same procedures, including application of the device at the same anatomical points and duration, but the device will remain switched off. The audio recording of the device's operational sound will be played to mimic active treatment.

2.8. Outcomes

Primary Outcomes:

- Spasticity Grade: Assessed using the Modified Ashworth Scale (MAS) [18], a 4-point ordinal scale (0–4) evaluating resistance to passive movement of the ankle joint. MAS will be measured immediately before and after each weekly session and at the end of the eight-week intervention.
- Quantity of antispastic medications used: Information regarding the medications (class, quantity, dose, and route of administration) used by participants for the treatment of spasticity before and after the end of the 8-week therapeutic period will be collected from medical records.

Secondary Outcomes:

1. Pain Intensity: Assessed using the Numerical Pain Scale (0–10) [13], measured before and after each weekly session and at the end of the eight-week period.
2. Ankle Range of Motion (ROM): Passive and active dorsiflexion and plantarflexion ROM will be measured using a universal goniometer, before and after the eight-week period.
3. Lower Limb Functionality: Functional Independence Measure (FIM) [19], Fugl–Meyer Assessment for Lower Extremity (FMA-LE) [14]. Both will be measured before and after the eight-week period.
4. Muscle Oxygenation: Assessed using a transcutaneous muscular near-infrared spectroscopy (NIRS) sensor (TrainRed.Fyer®, Elst, The Netherlands) at rest and during maximal passive stretching of the triceps surae, before and after PBM sessions on the first, fifth and last PBM session. NIRS measurements at rest will provide the primary quantitative assessment of muscle oxygenation under standardized conditions. Measurements during maximal passive stretching are additionally included as an exploratory physiological assessment to investigate changes in muscle hemodynamics in response to mechanical stretching. We hypothesize that PBM-induced improvements in local microvascular function and oxygen availability may become more apparent under this condition, particularly in spastic muscles, in which increased muscle tone may contribute to mechanical compression of local blood vessels. However, measurements obtained during stretching will be interpreted cautiously, considering the possibility of motion artifacts and physiological responses associated with the stretching maneuver. NIRS is an objective manner to quantify relative changes in the concentration of local oxy- and deoxyhemoglobin and obtain tissue oxygen saturation in the evaluated muscle [20]. Muscular NIRS employs spatially resolved spectroscopy, which allows for an absolute measurement of muscle hemodynamics in relation to the percentage of oxygen in the muscle tissue. Light at two wavelengths (760 nm and 850 nm), with a 3.5 cm spacing between the emitter and detector, penetrates the superficial tissue, where it is absorbed by the heme group of hemoglobin in the vascular bed and by the heme group of myoglobin in the muscle fibers. From the values captured by the sensor, the Absolute Tissue Saturation Index (TSI) is measured: oxy[Hb + Mb]/(oxy[Hb + Mb] + deoxy[Hb + Mb]), which corresponds to changes in the concentration of deoxygenated hemoglobin and myoglobin between the two points. NIRS provides information on the relationship between oxygen supply and consumption and may

reflect changes in local blood volume. The positioning for signal acquisition in participants will follow the recommendations of the SENIAM project, which, over the past twenty years, has represented the largest European initiative within the European project "Surface Electromyography for the Non-Invasive Assessment of Muscles" (SENIAM, www.seniam.org). This initiative established internationally standardized methodologies and data acquisition procedures for research and clinical applications of surface muscular motor points, as described in the publication "European Recommendations for Surface Electromyography" [30,31] and available at www.seniam.org. The electrode placement will follow the recommendations of SENIAM and the manufacturer. For the lateral gastrocnemius muscle, the electrodes will be placed along the longitudinal axis of the lateral portion of the posterior calf, at one-third of the distance between the head of the fibula and the heel. For the medial gastrocnemius muscle, the electrodes will be positioned over the most prominent part of the muscle belly, along its medial longitudinal axis.

5. Muscle Contraction Strength: Manual Muscle Strength Test (MRC scale) [21] will be performed before and after the eight-week period.
6. Adverse Events: Monitored weekly throughout the study.

Exploratory Variables:

Data on age, sex, motor dominance, injury time, stroke type, lesion location, affected side, comorbidities, medications, and use of orthoses will be collected from medical records to characterization of sample and subgroups analyses.

The Timeline SPIRIT presents the chronological schedule of enrollment, interventions and clinical assessments in Figure 2.

Recruitment phase	**Day of 1st Assessment**	**Before & After Each PBM Session**	**Days of PBM Session (1st to 8th)**	**After 8th PBM Session**
Eligibility assessment	**X**			
Informed consent administration	**X**			
Randomization	**X**			
Allocation	**X**			
INTERVENTION				
Therapeutic Interventions	**Day of 1st Assessment**	**Before & After Each PBM Session**	**Days of PBM Session (1st to 8th)**	**After 8th PBM Session**
PBM + Standard treatment			**X**	
Placebo PBM + Standard treatment			**X**	
ASSESSMENTS & MEASURES				
Outcomes Assessment	**Day of 1st Assessment**	**Before & After Each PBM Session**	**Days of PBM Session (1st to 8th)**	**After 8th PBM Session**
MAS (Modified Ashworth Scale)	**X**	**X**		**X**
NPS Scale	**X**	**X**		**X**
NIRS (Near-Infrared Spectroscopy)	**X**	**X**		**X**
ROM (Range of Motion/ADM)	**X**			**X**
MRC (Medical Research Council Scale)	**X**			**X**
FIM (Functional Independence Measure/MIF)	**X**			**X**
FM (Fugl–Meyer Assessment)	**X**			**X**
Adverse events monitoring	**X**	**X**		**X**

Figure 2. SPIRIT Timeline. Chronological schedule of enrollment, interventions and clinical assessments. Marks the specific phases or sessions in which clinical procedures or measurements are actively performed.

2.9. Data Management and Statistical Analysis

Data will be recorded on case report forms and entered into a password-protected database (IBM SPSS, version 29). Data quality will be ensured through range checks. All data will be anonymized. The final trial dataset will be accessible to the principal investigator and the study statistician. Analyses will be conducted using IBM SPSS Statistics (version 29) on an intention-to-treat basis. Descriptive statistics (means, standard deviations, frequencies) will summarize baseline characteristics. The primary analysis will compare changes in MAS scores between groups from baseline to the end of the eight-week period using a generalized estimating equation (GEE) model [22], which accommodates repeated measures and non-normal distributionsFor secondary outcomes, two-way repeated-measures ANOVA [23] will be used for normally distributed data. Post-hoc comparisons with Bonferroni correction will be performed as appropriate. Spearman's rank correlation coefficient will be used to assess associations involving ordinal variables, particularly changes in MAS scores. Pearson's correlation coefficient will be used to assess associations between continuous variables when the assumptions of linearity and appropriate distribution are met. A p-value < 0.05 will be considered statistically significant. A blinded interim sample size re-estimation is planned after the enrollment of 20 participants (10 per group) to assess the adequacy of the initially calculated sample size. This reassessment is justified by the potential methodological limitations of the original sample size calculation, particularly regarding the ordinal nature of the MAS. Pooled data from both groups will be used, without disclosure of group allocation or comparison of treatment effects, to estimate the variability of MAS measurements and the correlation between repeated assessments over time. These parameters will be used to reassess the sample size required to detect the prespecified group-by-time interaction using the planned repeated-measures ANOVA model. The prespecified clinically relevant treatment effect, significance level, and target statistical power will remain unchanged. If the reassessment indicates that the originally planned sample size is insufficient, the total number of participants may be increased accordingly. Importantly, this procedure will not involve interim efficacy hypothesis testing, comparisons of treatment effects between groups, or early stopping decisions based on efficacy. The final analysis will follow the prespecified statistical analysis plan.

2.10. Role of the Funding Source

The funders played no role in the design, conduct, or reporting of this study.

2.11. Safety/Harms

To prevent ocular injury during the interventions, both examiner and participant wore protective eyewear. PBM is a safe therapy, and the PI has experience and qualifications in its application. The researchers were trained, specializing in physical therapy and PBM application with clinical experience in assessing, managing, and following up with patients with various disabilities, including neurological and musculoskeletal conditions such as spasticity and joint dysfunction. The team's experience and pre-study training measures were designed to ensure the safety of participants and interventions, and to ensure the accuracy and veracity of data collection, even if evaluation measures with a certain subjectivity have been used.

3. Discussion and Expected Results

This randomized controlled trial protocol aims to investigate the efficacy of photobiomodulation as an adjunctive therapy for triceps surae spasticity in patients after stroke.

Spasticity is a major contributor to disability and reduced quality of life after stroke [4]. Despite the availability of various treatments, including pharmacological agents and bo-

tulinum toxin, their limitations—such as side effects, invasiveness, and transient effects—underscore the need for novel, safe, and effective adjunctive therapies [32].

In parallel, therapeutic laser and LED light, are noninvasive methods that utilizes light to stimulate cellular and molecular processes [29]. The proposed mechanisms by which light modulates biological tissue include the regulation of oxidative stress responses, increased ATP production and cellular metabolism, promotion of tissue repair and regeneration, vasodilation, inhibition of inflammation, and modulation of neurotransmitter release at synapses [6]. Unlike pharmacological therapy, when properly indicated and administered, therapeutic laser has no known side effects.

Regarding PBM therapy for neuromuscular tissue, studies have reported improvements in several outcomes. Particularly in the context of stroke, few comparative studies have evaluated the efficacy of these therapies relative to other interventions or placebo, demonstrated its safety, or quantified its effect size in individuals with spastic hemiplegia. Although primary studies have documented the effects of light on spastic muscle, the findings are heterogeneous, hindering the extraction of robust conclusions with clinical applicability. Moreover, the precise mechanisms by which light affects spastic muscle and its potential clinical effects remain incompletely elucidated.

More recent studies have also investigated the vascular and hemodynamic effects of PBM on healthy muscle fibers. The systematic review by Oliveira et al. [33] compiled 15 randomized clinical trials and reported that, in most studies, pre-exercise PBM was associated with improved performance and recovery and, in some studies, better oxygen consumption. One of the most directly related human studies is the pilot study by Oliveira et al. [34], a randomized, crossover, placebo-controlled, blinded trial. Five women received pulsed 904 nm laser over the rectus femoris prior to a fatigue protocol; NIRS continuously tracked deoxy-Hb + Mb, used as an index of fractional microvascular O_2 extraction. PBM produced a trend toward reduced deoxygenation during exercise, consistent with improved matching between microvascular O_2 supply and utilization, but the result was not statistically significant. Miranda et al. [35] tested 20 men in a placebo-controlled crossover study and observed increased time to exhaustion, distance, and ventilation during cardiopulmonary testing following PBM combining superpulsed lasers and LEDs. This demonstrates altered performance and an integrated exercise response. The result may involve perfusion, pain, peripheral fatigue, metabolism, and ventilatory control.

In the context of stroke, these results are particularly interesting because it is known that muscle disuse due to hemiparesis can significantly impair balance and Tissue Saturation Index (TSI) values, leading to a mismatch between oxygen supply and uptake. If less oxygen is available than required, exercise intolerance and early fatigue will inevitably occur, as well as impairment of muscle function. Changes in muscle oxygen availability may identify alterations in activity, contraction, tone, and therapeutic responses of the musculature to intervention. The microvascularization of skeletal muscles determines muscle blood flow and oxygen availability, which are crucial for muscle function and the physiological contractility of muscle fibers. Likewise, changes in muscle fiber recruitment may be substantially interconnected with oxygen metabolism and muscle hemodynamics [14]. In healthy individuals, low-intensity muscle activation increases muscle oxygen consumption with a corresponding increase in muscle blood flow. However, high levels of exercise overload and muscle contraction, such as those occurring with the constantly increased muscle tone associated with spasticity, induce massive motor unit activation, causing mechanical pressure from muscle fibers on capillaries, which restricts muscle blood flow and oxygen availability [36–38].

This study protocol is pioneering in evaluating, through a randomized controlled clinical trial, the effects of PBM applied to the gastrocnemius muscles after stroke, investigating

not only its potential antispastic effects and modifications in lower limb functionality but also changes in tissue oxygenation and muscle strength. Although previous studies have demonstrated that photobiomodulation is a promising technique for the treatment of muscle injuries of various etiologies, this clinical trial is the first study to assess the safety, immediate response, and effect size of PBM on triceps surae spasticity, alongside improvements to a degree superior to that of placebo, and also simultaneously evaluating the mechanisms of action of this therapy on local tissue hemodynamics. Moreover, the selection of the triceps surae as the target muscle is clinically justified. This muscle group is frequently affected by spasticity after stroke, directly impairing gait and mobility. Functional improvement in this muscle could have a significant impact on independent ambulation and activities of daily living [39]. The study simultaneously investigates a mechanistic hemodynamic rationale in an objective and quantified manner using NIRS, a well-established and reproducible tool for hemodynamic status evaluation [40]. Although preliminary studies suggest that PBM may induce quantifiable changes in muscle hemodynamics and that these changes correlate with fatigue and contraction, studies evaluating whether such modifications are related to functionality and/or spasticity and measured by NIRS are still lacking. To adequately address this question, this study will simultaneously measure muscle NIRS during rest, stretching, and active movement before and after weekly PBM applied over eight weeks, comparing outcomes with a PBM placebo group, both in conjunction with standard physiotherapeutic treatment for triceps surae spasticity.

This protocol has been designed in accordance with the SPIRIT guidelines, is preregistered on the ClinicalTrials.gov database, and has already been approved by the Ethics Committee. The results of this analysis may provide highly reliable evidence.

3.1. Potential Challenges and Limitations

Potential limitations of this study include the single-center design, which may limit generalizability, and the relatively small sample size, which may reduce the power to detect small but clinically meaningful differences. The exclusion of patients with grade 4 spasticity (fixed contractures) means that the results may not be applicable to the most severely affected individuals. In addition, eight weeks may be a short period to observe changes in muscle strength and functionality, which impacts the analysis and progression of these outcomes. Although resting NIRS measurements will provide the primary quantitative assessment of muscle oxygenation, measurements obtained during passive stretching may be influenced by motion artifacts and physiological responses associated with the stretching maneuver, potentially affecting the reliability and interpretation of these signals. Therefore, stretching-related measurements will be considered exploratory. Regarding the therapeutic light source, the present study uses an 850 nm LED probe from the Laserpulse device (IBRAMED, Brazil). Near-infrared wavelengths around 850 nm are widely used in PBM protocols targeting musculoskeletal tissues, and clinical studies have reported the application of LED sources in this wavelength range over skeletal muscles, including the triceps surae [41–43]. Nevertheless, the actual distribution of optical energy within deeper muscle layers depends on several factors, including the characteristics of the light source, application geometry, and the optical properties and thickness of the intervening tissues. Since the present study does not directly measure light transmission or the amount of energy reaching the deeper portions of the soleus muscle, the effective optical dose at this specific tissue depth cannot be established. This should be considered when interpreting the findings, particularly regarding the effects on deeper muscle structures. Moreover, local tissue temperature will not be directly monitored during treatment; therefore, although the intervention is designed and dosimetrically specified as photobiomodulation, a possible thermal contribution cannot be completely excluded. Some limitations related to

the assessment of spasticity should be acknowledged. Although the MAS is a validated, reproducible, and widely used clinical assessment tool, its responsiveness and Minimal Clinically Important Difference (MCID) have not been conclusively established for the stroke population [44]. Therefore, the clinical significance of changes in MAS scores may be difficult to determine. Additionally, although reproducible, the assessment remains examiner-dependent [40,45], and spasticity may exhibit day-to-day variations influenced by factors such as temperature, acute injuries, comorbidities, fatigue, and assessment timing [46,47]. These factors may introduce variability in the assessment of treatment outcomes. Furthermore, the discrete nature and restricted range of MAS scores may limit the detection of treatment-related changes and increase the possibility of a Type II error. Nevertheless, the MAS was selected because it is a validated and reproducible measure, is non-invasive and painless, and can be administered simply and rapidly. Its widespread use in clinical practice, randomized clinical trials, and rehabilitation protocols also facilitates comparisons with previous studies and strengthens the pragmatic relevance and potential applicability of the findings to routine post-stroke rehabilitation [40,44,48–50]. An additional methodological limitation concerns the sample size calculation. Although the repeated-measures ANOVA model for within–between interaction (group × time) was selected because it reflects the longitudinal design of the study and its objective of evaluating differences between groups over time, this approach treats the outcome as a continuous variable. Since the Modified Ashworth Scale (MAS) is an ordinal instrument, the use of mean and standard deviation parameters from [26] study, and an ANOVA-based model for sample size estimation may not fully account for the ordinal nature of the outcome. This limitation should be considered when interpreting the study findings. Another limitation concerns the potential influence of local subcutaneous adipose tissue thickness on NIRS measurements. Although the source–detector separation of 3.5 cm provides an estimated sampling depth of approximately 1.75 cm, the actual sensitivity depth may vary according to individual anatomical characteristics and tissue optical properties. Consequently, differences in superficial tissue thickness may influence light propagation and the contribution of underlying muscle tissue to the recorded NIRS signal. These factors should be considered when interpreting muscle oxygenation measurements, as the recorded signal may reflect contributions from both superficial and deeper tissues. Moreover, anatomical and structural characteristics of the gastrocnemius muscles, such as muscle size, atrophy, and other structural changes, will not be specifically assessed. These characteristics may influence light penetration and local muscle oxygenation measurements obtained by NIRS, potentially contributing to interindividual variability in the results. Finally, although PBM is applied locally to the gastrocnemius muscle, its biological effects may extend beyond the initially irradiated tissue through subsequent physiological responses. Local changes in cellular metabolism, ATP production, microcirculation, and muscle oxygenation may trigger downstream effects that influence neuromuscular function and, potentially, the clinical manifestations of spasticity. Therefore, the outcomes observed following local PBM application may reflect not only direct responses within the irradiated muscle tissue but also the subsequent physiological consequences of these local changes. Nevertheless, given the controlled study design and the well-defined study population, these characteristics are expected to be reasonably comparable between groups, thereby reducing the likelihood that they will systematically affect the comparisons between the intervention groups. Therefore, all these concerns have been mitigated by using a well-validated primary outcome, rigorous randomization and blinding, and a planned interim analysis to assess feasibility and, if necessary, adjust the sample size.

3.2. Expected Implications

If the hypothesis is confirmed, PBM could be integrated into standard rehabilitation protocols as a safe, noninvasive, and cost-effective adjunct to physical therapy, potentially improving functional outcomes and quality of life for stroke survivors. The data on muscle oxygenation will also contribute to the mechanistic understanding of how PBM affects the physiology of spastic muscle tissue. Moreover, the findings may provide a basis for future protocols concerning the sample size necessary to demonstrate significant differences in these outcomes in this population. Negative or inconclusive results will still be valuable, informing the design of future studies and guiding clinical practice regarding the role of PBM in spasticity management.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/mps9060171/s1, Supplementary Materials S1: SPIRIT checklist; Supplementary Materials S2: The Template for Intervention Description and Replication (TIDieR) checklist.

Author Contributions: I.A.D.S.: Conceptualization, Methodology, Resources, Writing—Original Draft, Data Curation, Writing—Review & Editing; B.G.C.C.: Resources, Writing—Review & Editing; J.E.W.: Resources, Writing—Review & Editing; J.E.P.N.: Resources, Writing—Review & Editing; M.F.S.D.R.: Resources, Writing—Review & Editing; R.A.M.-F.: Resources, Writing—Review & Editing; R.L.M. Methodology, Resources, Writing—Review & Editing; R.B.C.: Conceptualization, Methodology, Data Curation, Supervision, Resources, Validation, Writing—Review & Editing, Project Administration. All authors have read and agreed to the published version of the manuscript.

Funding: This research was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior—Brasil (CAPES)—Finance Code 001 and with the support of Universidade Nove de Julho (UNINOVE)—Researcher Training Scholarship Program. The author IADS received a personal support (Programa de Excelência Acadêmica—CAPES/Number 88887.976667/2024-00). The funders played no role in the design, conduct, or reporting of this study. Sponsor: Universidade Nove de Julho (UNINOVE).

Institutional Review Board Statement: The study protocol was approved by the Institutional Research Ethics Committee Research of the Padre Bento de Guarulhos Hospital Complex (CHPBG), before commencement (Approval Number 97137226.6.0000.5388/8.627.601, 5 August 2026). All participants will provide written informed consent after receiving comprehensive oral and written information about the study, including its purpose, procedures, potential risks and benefits, and their right to withdraw at any time without penalty. The study will be conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. Any protocol amendments will be communicated to the ethics committee, trial registries, and investigators.

Informed Consent Statement: Informed consent will be obtained from all subjects involved in the study.

Data Availability Statement: Results of the study will be published in a peer-reviewed open-access journal, regardless of whether findings are positive, negative, or inconclusive. Authorship eligibility will follow the ICMJE guidelines. No professional writers will be used. De-identified individual participant data will be made available on an open-access repository (e.g., Mendeley Data) upon publication of the main results, in accordance with data-sharing policies and participant consent. Participant data will be handled in accordance with the Brazilian General Data Protection Law (Lei Geral de Proteção de Dados, LGPD—Lei 13.709/2018). All data will be anonymized and stored securely on the institution's encrypted drive, accessible only to authorized research team members. Data will be retained for five years after study completion.

Acknowledgments: The authors would like to thank the staff and patients of the Specialized Rehabilitation Center II (CER II) in Guarulhos for their support and participation. Artificial intelligence (AI) tool ChatGPT (OpenAI) was used to assist on Figure 1, to placement and distribution of the measurement black points on the muscle. AI was NOT used to generate text, data, or graphs, nor

to assist in the study design, nor to support data collection, analysis, or interpretation. All authors remain responsible for the accuracy, originality, and integrity of the submitted manuscript, including the text, data, figures, references, and any other materials included in the submission.

Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

PBM	Photobiomodulation
LED	Light-Emitting Diode
nm	nanometer
mW	milliwatt
cm^2	square centimeter
J	joule
J/cm^2	joule per square centimeter
mW/cm^2	milliwatts per square centimeter
MAS	Modified Ashworth Scale
ROM	Range of Motion
FIM	Functional Independence Measure
FMA-LE	Fugl–Meyer Assessment for Lower Extremity
NIRS	Near-Infrared Spectroscopy
TSI	Tissue Saturation Index
MRC	Medical Research Council Scale
ANOVA	Analysis of Variance
GEE	Generalized Estimating Equations
TIDieR	Template for Intervention Description and Replication
PI	Principal Investigator
ATP	Adenosine Triphosphate
O_2	Oxygen
Hb	Hemoglobin
Mb	Myoglobin
CAPES	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior
UNINOVE	Universidade Nove de Julho
LGPD	Lei Geral de Proteção de Dados

References

1. Chen, R.; Li, X.; Zhao, R.; Zhao, X.; Ma, L.; Miao, Q.; Zhang, R. G20 stroke burden 1990–2035: Trends, projections and precision health insights. *Neurol. Sci.* **2025**, *46*, 5863–5878. [CrossRef] [PubMed]
2. Lee, H.J.; Song, J.-K.; Moon, J.; Kim, K.; Park, H.-K.; Kang, G.-W.; Shin, J.-H.; Kang, J.; Kim, B.-G.; Lee, Y.-H.; et al. Health-Related Quality of Life Using WHODAS 2.0 and Associated Factors 1 Year after Stroke in Korea: A Multi-Centre and Cross-Sectional Study. *BMC Neurol.* **2022**, *22*, 501. [CrossRef] [PubMed]
3. Young, R.R. Spasticity: A Review. *Neurology* **1994**, *44*, S12–S20. [PubMed]
4. Turner-Stokes, L.; Ashford, S.; Esquenazi, A.; Wissel, J.; Ward, A.B.; Francisco, G.; Lains, J.; Suputtitada, A.; Serrano, S.; Baguley, I.J.; et al. A comprehensive person-centered approach to adult spastic paresis: A consensus-based framework. *Eur. J. Phys. Rehabil. Med.* **2018**, *54*, 605–617. [CrossRef] [PubMed]
5. NICE. *Spasticity in Under 19s: Management*; National Institute for Health and Care Excellence (NICE): London, UK, 2016.
6. Dompe, C.; Moncrieff, L.; Matys, J.; Grzech-Leśniak, K.; Kocherova, I.; Bryja, A.; Bruska, M.; Dominiak, M.; Mozdziak, P.; Skiba, T.; et al. Photobiomodulation—Underlying Mechanism and Clinical Applications. *J. Clin. Med.* **2020**, *9*, 1724. [CrossRef] [PubMed]
7. Karu, T. Mitochondrial Mechanisms of Photobiomodulation in Context of New Data About Multiple Roles of ATP. *Photomed. Laser Surg.* **2010**, *28*, 159–160. [CrossRef] [PubMed]
8. Karu, T. Primary and Secondary Mechanisms of Action of Visible to Near-IR Radiation on Cells. *J. Photochem. Photobiol. B* **1999**, *49*, 1–17. [CrossRef] [PubMed]
9. Karu, T.I. Cellular and Molecular Mechanisms of Photobiomodulation (Low-Power Laser Therapy). *IEEE J. Sel. Top. Quantum Electron.* **2014**, *20*, 143–148. [CrossRef]
10. Frankowski, D.W.; Ferrucci, L.; Arany, P.R.; Bowers, D.; Eells, J.T.; Gonzalez-Lima, F.; Lohr, N.L.; Quirk, B.J.; Whelan, H.T.; Lakatta, E.G. Light Buckets and Laser Beams: Mechanisms and Applications of Photobiomodulation (PBM) Therapy. *Geroscience* **2025**, *47*, 2777–2789. [CrossRef] [PubMed]

11. Hamblin, M.; Huang, Y. *Handbook of Photomedicine*; CRC Press: Boca Raton, FL, USA, 2013.
12. Ferraresi, C.; Huang, Y.; Hamblin, M.R. Photobiomodulation in Human Muscle Tissue: An Advantage in Sports Performance? *J. Biophotonics* **2016**, *9*, 1273–1299. [CrossRef] [PubMed]
13. Stamborowski, S.F.; Lima, F.P.S.; Leonardo, P.S.; Lima, M.O. A Comprehensive Review on the Effects of Laser Photobiomodulation on Skeletal Muscle Fatigue in Spastic Patients. *Int. J. Photoenergy* **2021**, *2021*, 5519709. [CrossRef]
14. Nascimento, J.J.A.C.; Machado, A.S.D.; Della-Santa, G.M.L.; Fernandes, D.C.; Ferreira, M.C.; Machado, G.A.P.; Chaves, B.C.G.; Costa, K.B.; Rocha-Vieira, E.; Oliveira, M.X.; et al. Effects of Photobiomodulation Therapy on Functional Recovery, Angiogenesis and Redox Status in Denervated Muscle of Rats. *Einstein* **2021**, *19*, eAO6001. [CrossRef] [PubMed]
15. Walker, J.B. Temporary Suppression of Clonus in Humans by Brief Photostimulation. *Brain Res.* **1985**, *340*, 109–113. [CrossRef] [PubMed]
16. Asagai, Y.; Ueno, R.; Miura, Y.; Ohshiro, T. Application of Low Reactive-Level Laser Therapy (LLLT) in Patients with Cerebral Palsy of the Adult Tension Athetosis Type. *Laser Ther.* **1995**, *7*, 113–118. [CrossRef]
17. Tsuchiya, K.; Harada, T.; Ushigome, N.; Ohkuni, I.; Ohshiro, T.; Musya, Y.; Mizutani, K.; Maruyama, Y.; Suguro, T. Low Level Laser Therapy (LLLT) for Cerebral Palsy. *Laser Ther.* **2008**, *17*, 29–33. [CrossRef]
18. Dabbous, O.A.; Mostafa, Y.M.; El Noamany, H.A.; El Shennawy, S.A.; El Bagoury, M.A. Laser Acupuncture as an Adjunctive Therapy for Spastic Cerebral Palsy in Children. *Lasers Med. Sci.* **2016**, *31*, 1061–1067. [CrossRef] [PubMed]
19. Santos, M.T.B.R.; Pinto, M.d.S.; Nascimento, K.S.D.; Maciel, S.C. Photobiomodulation effect on the masseter muscle in children with cerebral palsy: A case report. *Acta Fisiatr.* **2015**, *22*, 39–42. [CrossRef]
20. Santos, M.T.B.R.; Nascimento, K.S.; Carazzato, S.; Barros, A.O.; Mendes, F.M.; Diniz, M.B. Efficacy of Photobiomodulation Therapy on Masseter Thickness and Oral Health-Related Quality of Life in Children with Spastic Cerebral Palsy. *Lasers Med. Sci.* **2017**, *32*, 1279–1288. [CrossRef] [PubMed]
21. dos Reis, M.C.R.; de Andrade, E.A.F.; Borges, A.C.L.; de Souza, D.Q.; Lima, F.P.S.; Nicolau, R.A.; Andrade, A.O.; Lima, M.O. Immediate Effects of Low-Intensity Laser (808 Nm) on Fatigue and Strength of Spastic Muscle. *Lasers Med. Sci.* **2015**, *30*, 1089–1096. [CrossRef] [PubMed]
22. das Neves, M.F.; Pinto, A.P.; Maegima, L.T.; Lima, F.P.S.; Lopes-Martins, R.Á.B.; Lo Schiavo Arisawa, E.A.; Lima, M.O. Effects of Photobiomodulation on Pain, Lactate and Muscle Performance (ROM, Torque, and EMG Parameters) of Paretic Upper Limb in Patients with Post-Stroke Spastic Hemiparesis—A Randomized Controlled Clinical Trial. *Lasers Med. Sci.* **2024**, *39*, 88. [CrossRef] [PubMed]
23. das Neves, M.F.; Aleixo, D.C.; Mendes, I.S.; Lima, F.P.S.; Nicolau, R.A.; Arisawa, E.A.L.; Lopes-Martins, R.A.B.; Lima, M.O. Long-Term Analyses of Spastic Muscle Behavior in Chronic Poststroke Patients after near-Infrared Low-Level Laser Therapy (808 Nm): A Double-Blinded Placebo-Controlled Clinical Trial. *Lasers Med. Sci.* **2020**, *35*, 1459–1467. [CrossRef] [PubMed]
24. das Neves, M.F.; dos Reis, M.C.R.; de Andrade, E.A.F.; Lima, F.P.S.; Nicolau, R.A.; Arisawa, E.Â.L.; Andrade, A.O.; Lima, M.O. Effects of Low-Level Laser Therapy (LLLT 808 Nm) on Lower Limb Spastic Muscle Activity in Chronic Stroke Patients. *Lasers Med. Sci.* **2016**, *31*, 1293–1300. [CrossRef] [PubMed]
25. Glass, G.E. Photobiomodulation: A Review of the Molecular Evidence for Low Level Light Therapy. *J. Plast. Reconstr. Aesthet. Surg.* **2021**, *74*, 1050–1060. [CrossRef] [PubMed]
26. Chen, C.-L.; Chen, C.-Y.; Chen, H.-C.; Wu, C.-Y.; Lin, K.-C.; Hsieh, Y.-W.; Shen, I.-H. Responsiveness and minimal clinically important difference of Modified Ashworth Scale in patients with stroke. *Eur. J. Phys. Rehabil. Med.* **2020**, *55*, 754–760. [CrossRef] [PubMed]
27. World Association Laser Therapy WALT WALT Recommended Treatment Doses for Low Level Laser Therapy 780–860 Nm Wavelength: World Association for Laser Therapy. 2010. Available online: https://waltpbm.org/documentation-links/recommendations/dosage-recommendations (accessed on 24 November 2026).
28. Huang, Y.-Y.; Sharma, S.K.; Carroll, J.; Hamblin, M.R. Biphasic Dose Response in Low Level Light Therapy—An Update. *Dose-Response* **2011**, *9*, 602–618. [CrossRef] [PubMed]
29. Hamblin, M.R. Photobiomodulation or Low-level Laser Therapy. *J. Biophotonics* **2016**, *9*, 1122–1124. [CrossRef] [PubMed]
30. Hermens, H.J.; Freriks, B.; Disselhorst-Klug, C.; Rau, G. Development of Recommendations for SEMG Sensors and Sensor Placement Procedures. *J. Electromyogr. Kinesiol.* **2000**, *10*, 361–374. [CrossRef] [PubMed]
31. Merletti, R.; Cerone, G.L. Tutorial. Surface EMG Detection, Conditioning and Pre-Processing: Best Practices. *J. Electromyogr. Kinesiol.* **2020**, *54*, 102440. [CrossRef] [PubMed]
32. Naro, A.; Leo, A.; Russo, M.; Casella, C.; Buda, A.; Crespantini, A.; Porcari, B.; Carioti, L.; Billeri, L.; Bramanti, A.; et al. Breakthroughs in the Spasticity Management: Are Non-Pharmacological Treatments the Future? *J. Clin. Neurosci.* **2017**, *39*, 16–27. [CrossRef] [PubMed]
33. de Oliveira, A.F.S.S.; da Silva, J.L.; Camillo, C.A.M.; Andraus, R.A.C.; Maia, L.P. Does Photobiomodulation Improve Muscle Performance and Recovery? A Systematic Review. *Rev. Bras. Med. Esporte* **2023**, *29*, e2021_0412. [CrossRef]

34. Oliveira, M.X.; Toma, R.L.; Jones, B.J.L.; Cyprien, T.P.; Tier, M.R.; Wallace, C.A.; Renno, A.C.M.; Sabapathy, S.; Laakso, E.-L. Effects of Photobiomodulation Therapy (Pulsed LASER 904 Nm) on Muscle Oxygenation and Performance in Exercise-Induced Skeletal Muscle Fatigue in Young Women: A Pilot Study. *Mech. Photobiomodulation Ther. XII* **2017**, *10048*, 80–88. [CrossRef]
35. Miranda, E.F.; Vanin, A.A.; Tomazoni, S.S.; Dos Santos Grandinetti, V.; De Paiva, P.R.V.; Dos Santos Monteiro Machado, C.; Monteiro, K.K.D.S.; Casalechi, H.L.; De Tarso Camillo De Carvalho, P.; Leal-Junior, E.C.P. Using Pre-Exercise Photobiomodulation Therapy Combining Super-Pulsed Lasers and Light-Emitting Diodes to Improve Performance in Progressive Cardiopulmonary Exercise Tests. *J. Athl. Train.* **2016**, *51*, 129–135. [CrossRef] [PubMed]
36. Trompetto, C.; Marinelli, L.; Mori, L.; Pelosin, E.; Currà, A.; Molfetta, L.; Abbruzzese, G. Pathophysiology of Spasticity: Implications for Neurorehabilitation. *BioMed Res. Int.* **2014**, *2014*, 354906. [CrossRef] [PubMed]
37. Raghavan, P. Muscle Physiology in Spasticity and Muscle Stiffness. *Toxicon* **2025**, *259*, 108350. [CrossRef] [PubMed]
38. Bissolotti, L.; Villafañe, J.H.; Gaffurini, P.; Orizio, C.; Valdes, K.; Negrini, S. Changes in Skeletal Muscle Perfusion and Spasticity in Patients with Poststroke Hemiparesis Treated by Robotic Assistance (Gloreha) of the Hand. *J. Phys. Ther. Sci.* **2016**, *28*, 769–773. [CrossRef] [PubMed]
39. Mazzoli, D.; Basini, G.; Prati, P.; Galletti, M.; Mascioli, F.; Rambelli, C.; Zerbinati, P.; Campanini, I.; Merlo, A. Indices of Loading and Propulsive Ability in the Gait of Patients with Chronic Stroke with Equinus Foot Deviation: A Correlation Study. *Front. Hum. Neurosci.* **2022**, *15*, 771392. [CrossRef] [PubMed]
40. Nourizadeh, M.; Shadgan, B.; Abbasidezfouli, S.; Juricic, M.; Mulpuri, K. Methods of Muscle Spasticity Assessment in Children with Cerebral Palsy: A Scoping Review. *J. Orthop. Surg. Res.* **2024**, *19*, 401. [CrossRef] [PubMed]
41. Leal-Junior, E.C.P.; Vanin, A.A.; Miranda, E.F.; Carvalho, P.d.T.C.d.; Corso, S.D.; Bjordal, J.M. Effect of phototherapy (low-level laser therapy and light-emitting diode therapy) on exercise performance and markers of exercise recovery: A systematic review with meta-analysis. *Lasers Med. Sci.* **2013**, *30*, 925–939. [CrossRef] [PubMed]
42. Linares, S.N.; Beltrame, T.; Galdino, G.A.M.; Frade, M.C.M.; Milan-Mattos, J.C.; Gois, M.O.; Borghi-Silva, A.; de Biase, P.F.; Manchado-Gobatto, F.B.; Bagnato, V.S.; et al. Dose Response Effect of Photobiomodulation on Hemodynamic Responses and Glucose Levels in Men with Type 2 Diabetes: A Randomized, Crossover, Double-Blind, Sham-Controlled Trial. *Photonics* **2022**, *9*, 481. [CrossRef]
43. Borsa, P.A.; Larkin, K.A.; True, J.M. Does Phototherapy Enhance Skeletal Muscle Contractile Function and Postexercise Recovery? A Systematic Review. *J. Athl. Train.* **2013**, *48*, 57–67. [CrossRef] [PubMed]
44. Gal, O.; Baude, M.; Deltombe, T.; Esquenazi, A.; Gracies, J.; Hoskovcova, M.; Rodriguez-Blazquez, C.; Rosales, R.; Satkunam, L.; Wissel, J.; et al. Clinical Outcome Assessments for Spasticity: Review, Critique, and Recommendations. *Mov. Disord.* **2025**, *40*, 22–43. [CrossRef] [PubMed]
45. Pandyan, A.D.; Johnson, G.R.; Price, C.I.M.; Curless, R.H.; Barnes, M.P.; Rodgers, H. A Review of the Properties and Limitations of the Ashworth and Modified Ashworth Scales as Measures of Spasticity. *Clin. Rehabil.* **1999**, *13*, 373–383. [CrossRef] [PubMed]
46. Cheung, J.; Rancourt, A.; Di Poce, S.; Levine, A.; Hoang, J.; Ismail, F.; Boulias, C.; Phadke, C.P. Patient-Identified Factors That Influence Spasticity in People with Stroke and Multiple Sclerosis Receiving Botulinum Toxin Injection Treatments. *Physiother. Can.* **2015**, *67*, 157–166. [CrossRef] [PubMed]
47. Phadke, C.P.; Balasubramanian, C.K.; Ismail, F.; Boulias, C. Revisiting Physiologic and Psychologic Triggers That Increase Spasticity. *Am. J. Phys. Med. Rehabil.* **2013**, *92*, 357–369. [CrossRef] [PubMed]
48. Rekand, T. Clinical Assessment and Management of Spasticity: A Review. *Acta Neurol. Scand.* **2010**, *122*, 62–66. [CrossRef] [PubMed]
49. Bohannon, R.W.; Smith, M.B. Interrater Reliability of a Modified Ashworth Scale of Muscle Spasticity. *Phys. Ther.* **1987**, *67*, 206–207. [CrossRef] [PubMed]
50. Mutlu, A.; Livanelioglu, A.; Gunel, M.K. Reliability of Ashworth and Modified Ashworth Scales in Children with Spastic Cerebral Palsy. *BMC Musculoskelet. Disord.* **2008**, *9*, 44. [CrossRef] [PubMed]

Disclaimer/Publisher's Note: The statements, opinions and data contained in all publications are solely those of the individual author(s) and contributor(s) and not of MDPI and/or the editor(s). MDPI and/or the editor(s) disclaim responsibility for any injury to people or property resulting from any ideas, methods, instructions or products referred to in the content.