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Effect of Vascular Photobiomodulation as an Adjuvant to the Treatment of Low Back Pain: Triple-blind Randomized Pilot Clinical Trial

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Abstract

This triple-blind pilot clinical trial aimed to evaluate the effect of vascular photobiomodulation combined with manual myofascial release and therapeutic exercises in the treatment of participants presenting with low back pain symptoms from the 1st to the 5th week. Participants were divided into Group 1 (placebo—inactive VPBM) and Group 2 (treatment—active VPBM), with both groups receiving myofascial release and performing therapeutic exercises. The instruments used were the Numeric Pain Scale (NPS), Oswestry Disability Index 2.0, and Roland Morris Questionnaire. Data analyses recorded intra-group and inter-group results. Statistical analysis compared data obtained both within and between groups for all questionnaires. Regarding participant disability, there was a significant difference in both intra-group and inter-group results in both questionnaires. The statistically significant value of p='0.0322' (inter-group) was found for the Oswestry Index, while for the Roland Morris Questionnaire the value was p='0.007' (inter-group). The inter-group result shown for the Numeric Pain Scale was not statistically significant, with p='0.1392.' Vascular photobiomodulation demonstrated improvement in participants' daily disability; however, regarding pain reduction, no positive result was observed.

Keywords: low-level light therapy, low back pain, photobiomodulation, myofascial release therapy, exercises.

1 Introduction

Musculoskeletal pain is one of the main causes of disability worldwide. According to the Global Burden of Disease, it ranks among the conditions with the greatest functional impact, right after mental disorders (Ferreira et al., 2022). Low back pain, in particular, is the leading cause of years lived with disability (YLD) in 126 out of 195 countries assessed and is ranked first in Brazil. It is

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also one of the most frequent complaints in emergency services in Canada (Ferreira et al., 2022; Park et al., 2024).

It is estimated that up to 80% of individuals will experience at least one episode of low back pain during their lifetime, with recurrence rates ranging from 25% to 62% within up to two years. Approximately 30% of acute cases progress to chronic pain, highlighting the magnitude of this public health issue (Yousefi-Nooraie et al., 2008). The condition is defined as pain located between L1 and L5, which may or may not include radiating pain to the lower limbs. It is classified as acute (≤ 6 weeks), subacute (7–12 weeks), or chronic (≥ 12 weeks) (Mclntosh et al., 2011; Frost et al., 2019; Oliveira et al., 2022).

Therapeutic strategies for low back pain include pharmacological, physiotherapeutic, behavioral, and surgical approaches (Cotler et al., 2015; Semrau et al., 2021). The most commonly used drugs—such as anti-inflammatory agents, opioids, antidepressants, and gabapentinoids—have significant adverse effects, including sedation, ataxia, cardiotoxicity, and respiratory depression, as well as high costs and potential complications when administered by injection (Mínobes et al., 2020; Fu et al., 2022; Binder et al., 2016; Badr et al., 2024; George et al., 2021). These limitations highlight the need for safe and effective non-pharmacological alternatives.

Low back pain can be caused by changes in the structure of the fascia, which lead to restrictions in the muscles of the back and trunk as a whole. One important concern is range of motion (ROM), referring to the ability of a joint to perform a full movement. Myofascial release and mobility can help improve ROM. The integration between muscle and fascia is genuine, and when discussing muscle shortening, fascia must also be considered. Increasing the length and width of the myofascial tissue, resulting in decreased tissue tension, are effects achieved through the use of myofascial release (Chen et al., 2021; Kim et al., 2024). Studies reveal that the myofascial release technique helps in pain reduction, restoration of shortening, improvement of muscle function, enhanced performance, and promotes patient recovery (Antohe et al., 2024). In the field of physical therapy, techniques such as myofascial release are widely used and show promising results in improving pain and function (Badr et al., 2024).

Besides manual therapy, kinesitherapy is widely used in the treatment of low back pain, since supervised physical exercises play a fundamental role. They are recommended to increase mobility, muscle strength, endurance, flexibility, greater blood supply to the muscles, joints, and intervertebral discs, functionality, and also to help improve psychological changes such as reducing anxiety. Furthermore, they contribute to the decrease of systemic inflammatory mediators, which aids in reducing low back pain (Mínobes et al., 2020). Performing physical exercise increases the neurotransmitter called Beta-endorphin (β-endorphin), which assists in decreasing pain and boosting patient motivation (Xu et al., 2023).

Photobiomodulation has also received increasing attention. Its mechanism involves the absorption of photons by the mitochondria and photodissociation of nitric oxide, which promotes

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vasodilation, increased microcirculation, and modulation of inflammatory processes (Zhang et al., 2023). Preclinical evidence shows a reduction of pro-inflammatory cytokines, such as TNF-α, IL-1β, and HIF-1α, after transcutaneous irradiation in neuropathic pain models (Hsieh et al., 2012; Cheng et al., 2021).

The evolution of the intravascular technique (ILIB) to Vascular Photobiomodulation (VPBM) has provided a non-invasive alternative applied to the radial artery, maintaining similar effects and greater safety. VPBM has been associated with immunological modulation, increased ATP production, improved microcirculation, and central and peripheral analgesic effects (Schapochnik et al., 2023; Razzaghi et al., 2021; Freitas et al., 2025). Despite its growing use in clinical practice, controlled studies evaluating its effectiveness in combination with manual therapies and exercises remain scarce.

Given this gap, this study aimed to evaluate the effect of Vascular Photobiomodulation (VPBM) associated with manual myofascial release and therapeutic exercises in reducing low back pain. As the primary outcome, the intensity of pain was measured by the Numeric Pain Scale (NPS); as secondary outcomes, the level of functional disability was measured by the Oswestry Disability Index 2.0 and the Roland-Morris Questionnaire. The central hypothesis is that VPBM acts as an effective adjuvant in reducing pain and improving the functionality of participants.
The theoretical implications of this study lie in deepening the understanding of the systemic effects of Vascular Photobiomodulation in pain modulation, providing support for new integrated therapeutic models. In practice, the findings offer clinicians a safe and effective adjuvant strategy to enhance functional recovery and reduce pain levels in patients with low back pain, optimizing rehabilitation time.

2. Methods

2.1 Study Design and Ethical Approval

This study was conducted as a randomized, triple-blind pilot clinical trial linked to the Strictu Sensu Postgraduate Program in Biophotonic Medicine at UNINOVE. The research received approval from the UNINOVE Research Ethics Committee, under opinion number 7.122.845, in accordance with resolution 466/12 of the National Health Council. All participants were fully informed about the study and signed the Free and Informed Consent Form before the procedures began. The clinical trial is registered on the World Health Organization (WHO) platform under number U111-1329-5217 and followed international recommendations for randomized clinical trials, according to the CONSORT declaration (*Consolidated Standards of Reporting Trials*).

2.2 Recruitment, Inclusion, Exclusion, and Discontinuation Criteria

2.2.1 Recruitment

The recruitment of participants was conducted through personal contact by the principal researcher. Dissemination was carried out via different channels, such as social media,

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WhatsApp, friends, and family. Those interested contacted the researcher by phone, at which time they received detailed information about the study objectives, participation criteria, and the absence of any payment for participation in the research. After eligibility was confirmed, an in-person evaluation was scheduled at the participant's home, during which additional clarifications about the study protocol were provided.

2.2.2 Inclusion Criteria

Individuals aged between 18 and 65 years who had low back pain lasting between the first and fifth week of symptoms were included.

2.2.3 Exclusion Criteria

Exclusion criteria included individuals with confirmed or under investigation for cancer, those with blood coagulation disorders, participants currently undergoing treatment for low back pain, and pregnant women.

2.2.4 Discontinuation Criteria

Discontinuation criteria included absence from two scheduled appointments, participant withdrawal, discomfort during the application of protocols, occurrence of adverse reaction, or intolerance to the laser procedure.

2.2.5 Consent and Confidentiality Procedures

Participants who agreed to take part in the study signed the Free and Informed Consent Form. All collected data were kept confidential and accessible only to the research team.

2.2.6 Blinding in the Intervention

Both the principal researcher and the participants did not know which device emitted the active red laser, since the placebo device also emitted a red light identical to the active one, with the same physical and functional characteristics. The statistician responsible for the analysis was unaware of the group assignments regarding the use of the active device.

2.3 Randomization, Allocation, and Sample

Randomization of participants into groups G1 (Placebo) and G2 (Treatment) was performed by simple drawing. Papers labeled G1 and G2 were placed in a box, and an random drawing of the volunteers was carried out, following pre-established steps in the study protocol.

As this was a pilot study, it included 20 volunteers, who were randomly allocated into two groups: Group 1 (Placebo FBMV) and Group 2 (Active FBMV), each composed of 10 participants. Participants underwent a total of 8 sessions, held twice a week at the patient's home.

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2.3.1 Measures

Data collection included the use of an assessment form containing the participants' personal information, duration of pain, skin colour, medications in use, associated pathologies, as well as the Oswestry Disability Index 2.0 and Roland Morris Disability Questionnaires, which were administered at the first and final consultation, and The Numerical Pain Scale (NPS) applied at every consultation before and after treatment by the lead researcher.

The Oswestry Disability Index Questionnaire was developed and published for the first time in 1980 with the aim of assessing the degree of functional limitation of patients in comparison with healthy individuals. Its main focus is to measure disability resulting from health conditions that affect physical performance.

The Roland Morris Questionnaire was used to assess the functional capacity of the participants. This instrument consists of 24 items describing everyday activities, such as walking, getting up, or performing household tasks, which may cause low back pain during their execution. Participants must indicate each item that causes low back pain when performed.

For pain assessment, the NPS was used, which consists of a straight line numbered from 0 (zero) to 10 (ten), where 0 indicates absence of pain and 10 represents unbearable pain (Januário et al., 2025). At every appointment, the patient reported the intensity of pain before and after treatment, which was recorded in the medical notes.

2.3.2 Interventions with Vascular Photobiomodulation, Manual Myofascial Release and Therapeutic Exercises

Group 2 (Treatment) received vascular photobiomodulation using the ILIB Plus device (Ecco Fibras, São Paulo, Brazil) with the parameters contained in Table 1. Group 1 (Placebo) underwent the application of red light (inactive FBMV) using a device with identical external characteristics to the active device. All participants used the device on their left arm, with the light beam directed at the radial artery via a specific bracelet.

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Table 1 – Dosimetric Parameters for Photobiomodulation application used in the study.

PARAMETERS	RED LASER
Wavelength	660nm
Operating Mode	Continuous
Power	100mW
Opening Diameter	0,354cm
Beam Area	0,0984cm^2
Exposure Time	1.800s
Energy	180J
Radiant Exposure	1800J/cm^2
Number of Irradiated Points	1
Application Technique	Contact
Number of Sessions	8
Treatment Frequency	2 times a week
Total Energy Radiated [J]	1440J

The participant was placed in the prone position, with a pillow under the abdomen and the upper limbs along the body, the head rotated to the patient's preferred side, providing comfort and proper alignment for the intervention. The physiotherapist activated the device and began Manual Myofascial Release using moderate hand pressure, with a neutral cream applied to improve gliding during treatment. The first movement consisted of deep horizontal gliding performed bilaterally toward the lumbar vertebrae. Next, horizontal gliding with the thumb was performed, tracing the iliac crest in the opposite direction from the vertebrae. Subsequently, the physiotherapist executed deep vertical gliding with one hand in the cranial direction (from L5 to L1), followed by deep vertical gliding with one hand in the caudal direction (from L1 to L5). Finally, the physiotherapist applied moderate pressure to the paravertebral muscles of the lumbar region with one hand for 3 seconds. The entire Manual Myofascial Release protocol lasted a total of 15 minutes.

After this procedure, the participant performed the following exercises:

1. Positioned supine, with feet on the examination table or bed, performed pelvic retroversion and anteversion movements, completing 3 sets of 10 repetitions;
2. Seated in a chair, performed 3 sets of 10 repetitions of lower limb elevation with hip and knee flexion (maximum elevation possible), alternating lower limbs with each set, maintaining maximal abdominal contraction;
3. Still seated upright, holding a stick with both hands over the thighs, performed trunk flexion (relaxed abdomen), extending the upper limbs forward as far as possible, looking straight ahead, and returning to the initial position (contracting the abdomen as much as possible)

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before returning to the initial position. This protocol was performed from the 1st to the 4th treatment session.

In sessions 5 through 8, the following exercises were added:

1) In a standing position, with the side of the body close to a wall, shoulder and elbow placed at 90 degrees of flexion, feet side by side (touching), performed maximal lateralization of the hip to the right and left alternately, completing 3 sets of 10 repetitions.
2) Pressing the hip and back against the wall, with contracted abdomen, performed shoulder flexion to approximately 180 degrees, with upper limbs extended holding a stick, and simultaneously elevated the lower limb with at least 90 degrees of hip and knee flexion, carrying out 3 sets of 15 repetitions (each lower limb, alternating them).

A 20-second interval was established between each set. The protocol lasted four weeks, with sessions held twice a week, totaling 8 appointments.

Figure 1. Manual Myofascial Release and Therapeutic Exercises

3. Results

3.1 Recruitment

Care for eligible participants was provided between December 2024 and August 2025, totaling 23 participants who completed the Physical Therapy Assessment Form. However, during the medical history interview, one patient did not report specific pain in the lumbar region, another was undergoing concurrent physical therapy treatment, and a third could not complete the four consecutive weeks of the protocol due to a personal trip; thus, 20 participants remained eligible for the study.

All included participants completed the Physical Therapy Assessment Form as well as the END, Roland Morris, and the Oswestry Disability Index 2.0 questionnaires, which were used for statistical analysis of the collected data, as described in subsection 4.5.
The analysis of demographic averages (age, sex, and phototype variables) showed no significant differences.

3.2 Statistical Analysis and Data Analysis

Descriptive analysis was carried out for quantitative and categorical variables. Initial comparisons between groups used the Student's t-test or models with Poisson distribution, after

checking normality using the Shapiro-Wilk test. Associations between categorical variables were assessed using the Chi-square test.

The variables VAS, Oswestry, and Roland-Morris were analyzed using repeated measures models, considering the group × time interaction, with adjustment in Poisson distribution and the Wald test for multiple comparisons. The Oswestry classification was compared between groups only at the pre- and post-intervention moments.

A significance level of 5% was adopted. Analyses were performed in SAS 9.4.

3.3 Figure 2 - Flowchart

The study methodology was structured as a controlled clinical trial, with a total sample of 20 participants divided equally between the control group (G1 - Placebo) and the experimental group (G2 - Treatment). The flowchart below details the assessment steps, the instruments used, and the intervention protocol carried out over eight sessions.

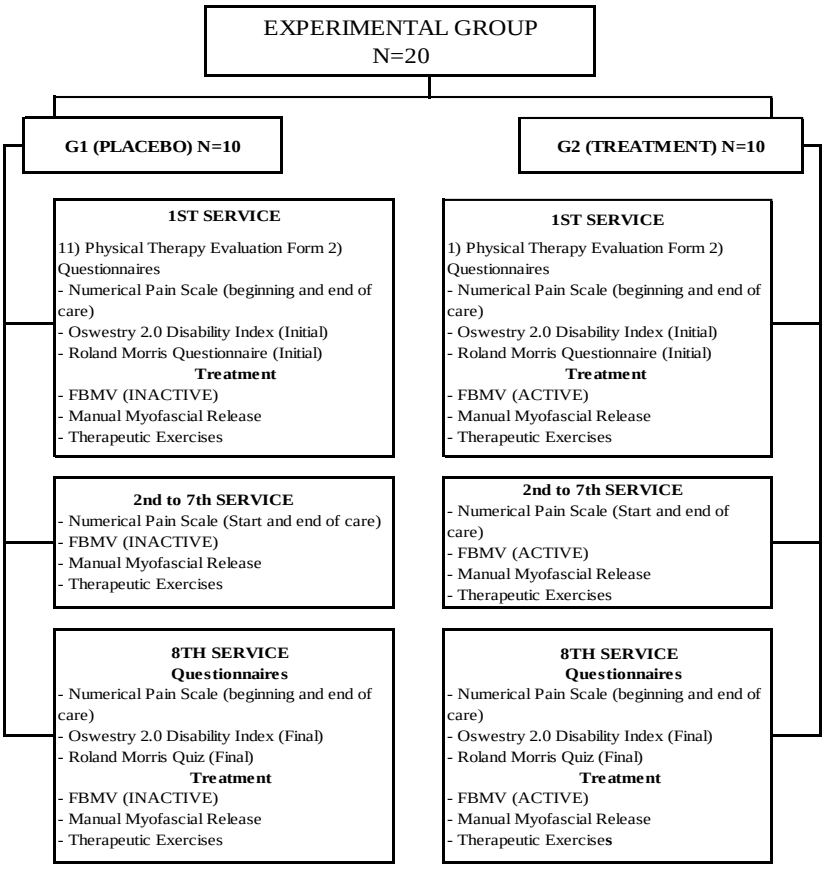

Figure 2. Flowchart

3.4 Reference Data

As shown in Table 2, Group 1 (Placebo) had a sample with low dispersion, while Group 2 (Treatment) exhibited greater age diversity, evidenced by a higher standard deviation. No statistically significant differences were observed between the groups regarding age range (p = 0.189).

Table 2 - Comparative analysis of mean values for the Age variable: G1 and G2

Variables	Groups	N	Average	Standard Deviation	Median	Q1	Q3	p-value	p-value[1]
Age	**G1**	10	44.3	5.5	43.5	41	48	**0.189***	**0.2115**
	G2	10	38.6	11.77	40.5	27	45		

Note. [1] p-value referring to the Shapiro-Wilk test.

Regarding gender, Group 1 (Table 3) consisted of 70% female participants and 30% male, while Group 2 had approximately 80% female and only 20% male participants. Thus, there was a predominance of females in both groups, with no statistically significant difference observed (p-value 0.06056).

Table 3 - Comparative analysis of mean values for the Gender variable: G1 and G2

Gender	G1		G2		Total		p-value
	Qty.	%	Qty.	%	Qty.	%	
Masculine	3	30	2	20	05	25	0.6056
Feminine	7	70	8	80	15	75	
Total	10		10		20		

The Fitzpatrick Scale, a recognized tool for assessing skin tone, was used as an instrument to analyze possible differences between phototypes regarding sensitivity to the use of FBMV.
The analysis (Table 4) revealed a predominance of phototype 3 (light brown) in both groups, totaling 50% of the sample. There were no participants with phototypes 5 or 6. The “p” value for this scale did not show statistical significance. Additionally, among the phototypes evaluated, no change in skin sensitivity was observed, such as redness, edema, or reports of a burning sensation during the application of FBMV.

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Table 4 - Association between Phototype (Fitzpatrick Scale) and groups.

Fototype	G1		G2		Total		p-value
	Qty.	%	Qty.	%	Qty.	%	
I	0	0	1	10	1	5	
II	3	30	3	30	6	30	
III	5	50	5	50	10	50	
IV	2	20	1	10	3	15	0.7212
V	0	0	0	0	0	0	
VI	0	0	0	0	0	0	
Total	10		10		20		

It was observed (Table 5) that the mean values for the days with pain were similar in both groups; however, the high standard deviation indicates heterogeneity in the samples of both groups. Based on these results, it was found that the p-value obtained was not statistically significant.

Table 5 – Comparison of means for the quantitative variable related to Days with Low Back Pain

Variables	Groups	N	Average	Standard Deviation	Median	Q1	Q3	p-value	p-value[1]
Days WITH pain	G1	10	13.9	8.25	11.5	8	18	0.9523**	<0,0001
	G2	10	14	8.01	12.5	6	20		

The data from the Oswestry Disability Index Questionnaire (Table 6) revealed a favorable progression in both groups:

1) Placebo Group (G1): By the end of follow-up, all participants (100%) progressed from the initial moderate disability level (21% to 40%) to the minimal disability category (0% to 20%).
2) Treatment Group (G2): The two participants initially classified with severe disability (61% to 80%) showed significant improvement. After the intervention, one individual moved to the moderate disability category (21% to 40%), while the other reached the minimal-excellent disability level (0% to 20%).
3) The reclassification of the second individual in G2 represents a clinically relevant evolution, given the progression of two levels on the Oswestry Disability Index scale."

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Table 6 - Association between the Oswestry classification and Groups at Pre- and Post-Treatment Moments

Oswestry	Pre							Post						
	Inicial Assesment	G1		G2		Total		Final Assesment	G1		G2		Total	
		Qty.	%	Qty.	%	Qty.	%		Qty.	%	Qty.	%	Qty.	%
0% a 20%	Minimum disability	**4**	**40**	**2**	**20**	**6**	**30**	Excellent	**10**	**100**	**9**	**90**	**19**	**95**
21%a 40%	Moderade disability	**6**	**60**	**6**	**60**	**12**	**60**	Good	0		**1**	**10**	**1**	**05**
41% a 60%	Intense disability	0	0	**2**	**20**	**2**	**10**	Unchanged	0		0		0	
61% a 80%	Crippled	0		0		0		Get Worsed	0		0		0	
81% a 100%	Invalid	0		0		0		Get Worsed	0		0		0	
Total		**10**		**10**		**20**			**10**		**10**		**20**	

Initial analysis showed that, in both disability questionnaires (Oswestry and Roland Morris), the Treatment Group (G2) began follow-up with a higher mean disability index and a high standard deviation, suggesting greater heterogeneity and baseline severity of symptoms in G2 (Table 7).
The results of the statistical analysis for each instrument were:

1) Oswestry Questionnaire - the tests revealed significant intergroup differences (lowercase letters) both at the pre-treatment time point ($p=0.0061$) and at the post-treatment time point ($p=0.04$). The intragroup differences between the pre- and post-treatment time points were highly significant (uppercase letters) for G1 ($p<0.0001$) and for G2 ($p<0.0001$). Additionally, the p-value of 0.0322 confirms a statistically significant difference between the groups over time (Group X Time Point interaction). Although both groups showed significant differences, G2 (treatment) included participants with severe disability, while G1 (placebo) presented only moderate and minimal disability. Specifically, in group G2, 1 participant progressed to a good level and 1 participant progressed to an excellent level after treatment. These results reinforce the positive impact of the treatment, especially given the greater initial severity presented by G2.
2) Roland Morris Questionnaire - similarly, the results indicated significant intergroup differences (lowercase letters) at pre-treatment ($p=0.0407$) and post-treatment ($p=0.0014$) time points. The intragroup differences between pre- and post-treatment time points were equally significant (uppercase letters) for both groups (G1: $p<0.0001$; G2: $p<0.0001$).

The repeated measures model analysis for the Oswestry and Roland Morris scores confirms a statistically significant effect of both the time factor (improvement between pre- and post-treatment) and the Group factor (difference between G1 and G2). However, it is important to highlight that G2 (treatment) initially presented a higher level of disability than G1 (placebo) and yet still achieved a significant improvement. These findings suggest that vascular photobiomodulation promoted a relevant reduction in disability.

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Table 7 - Comparison of means for the Oswestry and Roland Morris questionnaires at Pre- and Post-Treatment Moments for the Groups

Variables	Moments	G1				G2				p-value	p-value		
		N	Average	SD	Median	N	Average	SD	Median		Group	Moments	Interaction
Oswestry	Pre	10	22.04aA	8.07	24.22	10	33.77bA	12.41	38.85	0,0061	0.0322	0.0001	0.4724
	Post	10	7.11aB	6.2	7	10	13.67bB	9.93	12	0,04			
Roland Morris	Pre	10	9.1aA	4.75	9	10	13.7bA	5.68	16	0,0407	0.007	0.0003	0.0542
	Post	10	2.1aB	2.08	1.5	10	6.6bB	4.43	8	0,0014			

Note. Repeated measures model; p-value: Adjustment using Poisson distribution, Wald's Multiple Comparison Test. Means followed by the same lowercase letter (fixing time point and testing groups) do not differ at the 5% significance level; means followed by the same uppercase letter (fixing group and testing time points) do not differ at the 5% significance level; p-values were obtained by fitting a repeated measures model considering groups, time points, and the interaction between groups and time points.

Analysis of the variation in mean scores across consultations (Figure 3) revealed that only in the first consultation did both groups (G1 and G2) present significant mean values ($p < 0.05$), as indicated by the symbols (∗#). Although the Treatment Group (G2) started with a higher mean value than the Placebo Group (G1), a convergence of means was observed at the pre-treatment point of the eighth consultation, where the mean values became statistically similar between the groups.

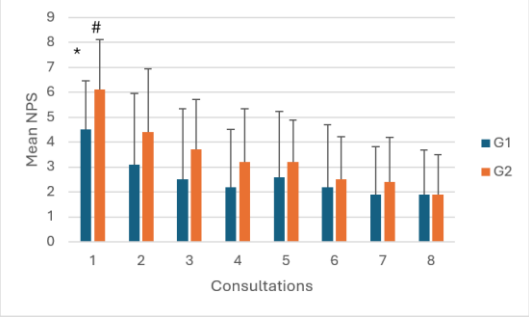

Figure 3. Mean and SD for NPS for G1 and G2 at the Pre-Test Time Point

Analysis of mean post-treatment pain scores (Figure 4) revealed distinct response patterns:

1) Placebo Group (G1): The mean post-treatment pain score at Consultations 6, 7, and 8 showed a statistically significant difference compared to the mean pain score at the initial and intermediate consultations ($p < 0.05$), as indicated by the asterisk (*).
2) Treatment Group (G2): The reduction in post-treatment pain was significantly greater at Consultations 4, 5, 6, 7, and 8 compared to the other consultations ($p < 0.05$), as indicated by the hash symbol (#).

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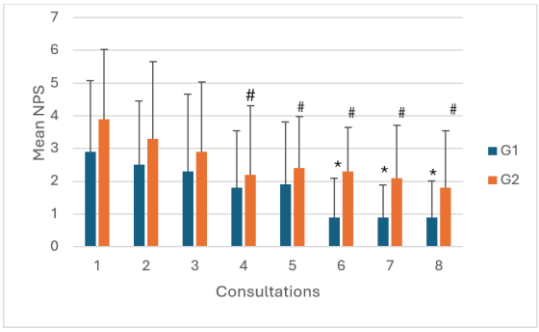

Figure 4. Mean and standard deviation for the NPS for G1 and G2 at the Post-Treatment Time

In the Placebo Group, the analysis revealed a statistically significant reduction in pain intensity, as measured by the Numerical Pain Scale (NPS), in Visits 1, 5, 6, 7, and 8 ($p<0.05$). In contrast, no significant change in pain intensity was observed in the remaining visits. Detailed results (indicated by (*)) are illustrated in Figure 5.

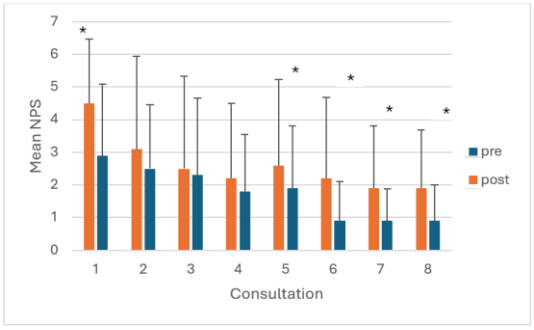

Figure 5. Mean and standard deviation for NPS at Pre and Post Moments for Group 1 (Placebo)

As can be seen, Figure 6 illustrates that Group 2 (G2, intervention) showed a statistically significant difference ($p<0.05$) between the pre- and post-treatment moments, specifically in the initial consultations, as indicated by the asterisks, suggesting that in the initial consultations there was control of the inflammatory process, one of the effects of FBMV.

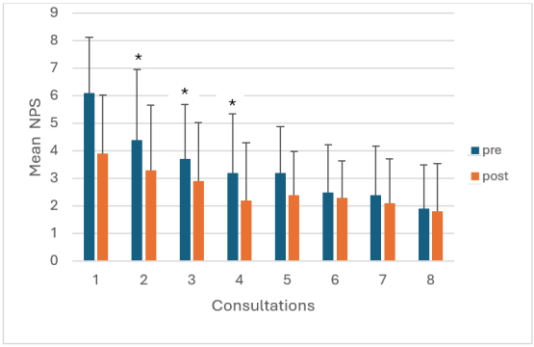

Figure 6. Mean and SD for NPS at Pre and Post Moments for Group 2

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The repeated measures model adjustment, using a Poisson distribution and Wald's multiple comparison test, revealed a significant effect only for the "times" factor (pre- and post-intervention assessment). The "groups" factor showed a borderline p-value of 0.06 (6%), suggesting a trend that, however, did not reach conventional statistical significance ($\alpha = 0.05$). Multiple comparisons corroborated this finding. Specifically, the comparison between groups at baseline was $p = 0.06$ and at the final time point was $p = 0.14$. On the other hand, intragroup comparisons (pre versus post) were statistically significant for both G1 and G2 (Table 8).

Table 8 - Comparison between Groups and Moments for the NPS

	G1	G2	
NPS*	Average ± SD	Average ±SD	p-value (groups)
Initial	4,5 ±1,96	6,1 ± 2,02	0.0639
Final	0,9 ± 1,1	1,8 ± 1,75	0.1392
p-value (Moments)	<0.0001	0.0002	

Note. * Fitting the repeated measures model using Poisson: p-value for groups = 0.0678; p-value for moments = 0.0002; p-value for group*moment interaction = 0.4383.

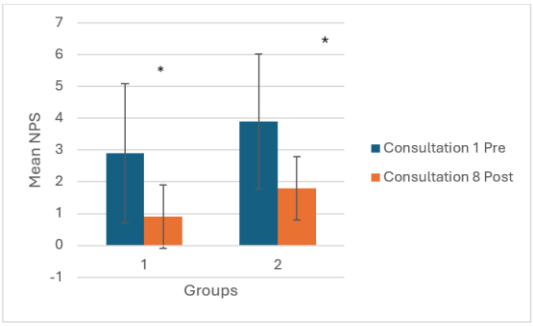

Figure 7 - Mean and SD for NPS in Consultation 1 pre and Consultation 8 post for Groups 1 and 2

Discussion and Conclusion

Low back pain remains a significant public health challenge, widely associated with functional limitations, psychosocial changes, and high utilization of therapeutic resources, including medications with potential adverse effects. In this scenario, non-pharmacological and lower-risk approaches have become essential to expand access and reduce complications associated with pain management. Vascular Photobiomodulation (VPM) has stood out as a promising intervention, given its ability to modulate cellular and hemodynamic processes, resulting in analgesic, anti-inflammatory, and tissue metabolism regulatory effects (Schapochnik et al., 2023; Razzaghi et al., 2021; Freitas et al., 2025).

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In the present study, the combination of VPM with myofascial release and therapeutic exercises resulted in a significant improvement in functional disability between the 1st and 5th week of low back pain. Although the comparison between groups did not show a statistically significant difference in pain intensity, a consistent intragroup improvement was observed. Furthermore, at the end of treatment, the placebo group presented a lower average pain level than the treated group, suggesting that non-specific factors, such as patient expectations and the natural progression of the condition, may also have influenced this outcome.

The functional improvement observed in our study is aligned, albeit partially, with the findings of Tantawy et al. (2019), who demonstrated a significant reduction in pain and functional improvement after local photobiomodulation associated with exercise, compared to therapeutic ultrasound. The discrepancy between the pain results may be related to substantial methodological differences, including the application method (local versus systemic), the wavelength used (808 nm), the greater number of sessions (16 treatments), and the higher weekly frequency of exercise.

Ahmed et al. (2022) also reported superior benefits of local photobiomodulation (830 nm) compared to exercise alone in patients with discogenic lumbar radiculopathy, highlighting significant improvement in pain and functionality. As in the study by Tantawy et al., the longer duration of the protocol (18 sessions) and the local nature of the application may explain the greater magnitude of the effects, in contrast to the present study, which used only eight sessions of systemic application.

Similarly, Abdelbasset et al. (2020) compared low- and high-intensity laser in combination with exercise over 12 weeks, observing significant improvement in all groups, although without differences between the types of lasers. In this case, again the longer intervention time and the inclusion of patients with chronic pain, a condition recognized as more persistent, constitute methodological factors that make direct comparisons with our findings difficult.

Additional evidence of the potential anti-inflammatory effect of FBMV was reported by Su et al. (2024), who observed a reduction in IL-1β and IL-13 after ILIB in patients with osteoarthritis, supporting the role of the technique in the systemic modulation of the inflammatory response. These data offer a possible physiological explanation for the initial reduction in the pain threshold observed in the treated group in our study.

During clinical follow-up, a greater use of analgesic and/or anti-inflammatory medication was observed in the G2 treated group (n=8) compared to the G1 placebo group (n=4). Part of this use, however, was related to conditions not associated with low back pain, such as sinusitis or sore throat, constituting a possible confounding factor in the interpretation of the analgesic effects attributed to the treatment.

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The assessment of pain using the Numerical Pain Scale (NPS) represents an inherent limitation, given the subjective nature of the pain experience and its interindividual variability. Still, it is a widely validated and quick-to-apply instrument, justifying its use in clinical studies. Another important point refers to the breadth of the categories of the Oswestry Disability Index, whose wide percentage ranges may reduce the sensitivity to capture small functional changes.

Despite these limitations, the results demonstrated that the combined treatment (FBMV + conventional physiotherapy) was superior to placebo in restoring functionality, a clinical outcome of high relevance for patients with low back pain. Although the reduction in pain intensity, as measured by the END, did not reveal a statistically significant difference between the groups (intergroup difference), functional improvement represents a more relevant clinical outcome.

Considering the small sample size and limited number of sessions, future studies with larger samples and greater control of confounding variables are recommended to consolidate the findings and improve statistical power. Still, the results presented position FBMV as a promising adjuvant strategy in the management of low back pain, especially with regard to improving functionality.

This study has limitations inherent to its pilot design and small sample size (n=20), distributed in two groups of ten participants. The limited number of subjects reduces statistical power and restricts the generalization of findings to larger populations. In addition, the short follow-up period does not allow for the assessment of the durability of the observed effects of photobiomodulation on low back pain. Individual factors, such as variations in pain threshold, concomitant use of analgesics, and differences in lifestyle, may also have influenced the responses to treatment. Although the sample size of this pilot study was small, it is considered that it contributes to future work with larger samples, guiding clinical protocols that use multimodal approaches and can contribute to the treatment of patients with low back pain, and consequently, their quality of life.

The results of this study demonstrate that there was no difference between the placebo group and the treatment group in relation to low back pain, but the intragroup result showed a statistically significant difference, suggesting that the use of FBMV in conjunction with myofascial release and therapeutic exercises may be beneficial in reducing low back pain. Regarding the daily functionality of the participants, a statistically significant difference was found between the groups, indicating an improvement in the participants' ability to move. As this is a pilot study, it was concluded that the method used is suitable for conducting a clinical trial with a larger sample size, proving to be feasible from a methodological and analytical point of view.

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