Effects of 660-nm Photobiomodulation Therapy on Pain and Healing of Nipple Trauma in Lactating Women: A Pilot Randomized Double-Blind Controlled Trial

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Abstract

Objective

To evaluate the effects of PBMT (λ = 660 nm) on pain, breastfeeding quality, and healing of nipple injuries.

Method

This randomized, double-blind, controlled pilot trial included 20 lactating postpartum women with nipple trauma. Participants were divided into PBMT (standard care + active PBMT) and Placebo (standard care + sham) groups. Interventions occurred up to seven sessions over 15 days. PBMT parameters: 660 nm, 40 mW, 10 J/cm², and 0.4 W/cm² for 10s per point (one central and four peripheral points). Assessments included the Visual Analogue Scale (VAS), LATCH Scale, Nipple Trauma Score (NTS), and photogrammetry.

Results

Most participants (90%) presented bilateral excoriations or fissures. The PBMT group showed significantly greater pain reduction from the third session onward ($p < 0.05$), achieving total analgesia by the seventh, whereas the Placebo group maintained higher VAS scores. Although both groups improved their breastfeeding technique, the PBMT group showed superior post-intervention LATCH scores. Furthermore, PBMT significantly accelerated tissue repair from the third session onward. The PBMT group reached complete lesion regression (NTS = 0), while the Placebo group maintained residual trauma (NTS = 1).

Conclusion

PBMT combined with clinical management is effective for pain relief, tissue repair, and improving breastfeeding quality. It serves as a promising adjuvant resource to prevent complications and support the maintenance of exclusive breastfeeding.

1. Introduction

Nipple trauma is characterized by lesions arising from breastfeeding dynamics that disrupt cutaneous integrity, ranging from superficial epidermal damage to deep dermal involvement. These injuries clinically manifest as fissures, erosions, or excoriations [1–3]. Such conditions are frequently exacerbated by incorrect infant latching or the inadequate use of breast pumps, resulting in a painful process that predisposes lactating women to secondary complications, including puerperal mastitis and breast abscesses due to bacterial colonization [4, 5]. Within this scenario, prompt clinical interventions

are vital to promote wound healing and alleviate maternal distress, thereby mitigating the risk of premature weaning [6–8].

In this context, Photobiomodulation Therapy (PBMT) has emerged as a prominent non-invasive adjuvant resource [7, 8]. PBMT utilizes monochromatic and coherent radiation to induce specific cellular biological responses; specifically, lasers within the red spectrum (λ = 660 nm) demonstrate high efficacy in treating superficial lesions and promoting tissue repair [7–10]. The underlying mechanism of action is based on the stimulation of mitochondrial membranes and the subsequent upregulation of adenosine triphosphate (ATP) synthesis [9]. This process accelerates cellular metabolism, enhances revascularization, and stimulates collagen synthesis—elements fundamental to skin regeneration [9–11].

The therapeutic effects of laser therapy, including the reduction of pro-inflammatory cytokines, resolution of edema, and the release of endogenous endorphins, provide a synergistic triple action: analgesic, anti-inflammatory, and regenerative [10, 11]. However, literature reviews indicate that, despite its increasing clinical use, a significant gap remains regarding the standardization of protocols. Specifically, there is a lack of consensus on precise dosimetry, the optimal number of sessions, and well-designed sham-controlled trials to consolidate its clinical efficacy during lactation [7, 8, 12, 13]. Consequently, investigating these specific PBMT parameters is essential to establish a more standardized, evidence-based approach for clinical practice.

The present study aims to analyze the effects of PBMT (λ = 660 nm) on pain intensity, breastfeeding quality (via the LATCH scale), and the cicatricial evolution of nipple lesions. By elucidating the benefits and limitations of this technology, this research seeks to support clinical protocols that optimize the management of nipple trauma. Ultimately, the integration of PBMT into postpartum care may represent a valuable advancement in the treatment of nipple fissures, offering a more efficient and supportive approach for lactating women. Consequently, this intervention has the potential to foster prolonged breastfeeding and generate positive impacts on maternal and child public health.

2. Methods

1.1 Study Design

This is a prospective, randomized (pilot), double-blind, controlled clinical trial (involving both participants and outcome assessors) conducted to evaluate the efficacy of PBMT in the treatment of nipple trauma.

1.2 Participant Selection and Sampling

The study population comprised postpartum women with a clinical diagnosis of nipple trauma, recruited from reference centers in Diamantina, Minas Gerais: the *Hospital Nossa Senhora da Saúde* (HNSS), the *Casa da Gestante e da Puérpera* (CAGEP), and Basic Health Units (*Unidades Básicas de Saúde* - UBS).

Recruitment was conducted using a sequential, convenience sampling approach. Although the *a priori* sample size calculation, targeting a statistical power of 95%, a significance level of 5%, and the detection

of a minimum clinically important difference of 1 point on the Visual Analog Scale (VAS), indicated a requirement of 37 patients per group (total N = 74), this study was executed as an exploratory pilot trial. Consequently, the final sample consisted of 20 participants (n = 10 per group) to prioritize clinical feasibility. For this sample size, the achieved statistical power was 80% (β = 0.20) to detect a large effect size (Cohen's d ≈ 1,25).

1.3 Eligibility Criteria

Inclusion Criteria:

Lactating postpartum women presenting with nipple trauma (fissures, abrasions, or erosions) in at least one nipple, associated with complaints of pain, and who signed the Informed Consent Form (ICF).

Exclusion Criteria:

Presence of mastitis or nipple candidiasis; age under 18 years; history of malignant pathologies; photosensitivity; current pregnancy; breast implants; use of topical therapies (lanolin, antifungals, corticosteroids) or systemic therapies (antibiotics, anti-inflammatory drugs); comorbidities that impair wound healing (e.g., Cushing's Syndrome) or a predisposition to keloids; and cognitive deficit.

1.4 Ethical Considerations

The study protocol was approved by the Research Ethics Committee of the *Universidade Federal dos Vales do Jequitinhonha e Mucuri* (UFVJM) (Opinion No. 6,768,049; CAAE No. 77707024.9.000.5108), in compliance with Resolution No. 466/2012 of the Brazilian National Health Council. All volunteers signed the ICF and the Image Use Authorization Form.

1.5 Randomization and Blinding

The random allocation sequence was generated by an independent researcher using [appropriate software]. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes. Participants and outcome assessors were blinded to group allocation; the therapist responsible for device application was/was not blinded. Participants were randomly allocated to either the PBMT group (standard care + active laser) or the Placebo group (standard care + sham laser) using sealed, opaque brown envelopes prepared by a researcher who was not involved in data collection.

Blinding was ensured by using two visually identical Twin Flex® devices (MMOptics, Brazil). In the placebo device, light emission was blocked internally with electrical tape, according to the manufacturer's protocols. Both devices emitted identical acoustic signals and luminous indicators (blue control LED), rendering the active and sham therapies indistinguishable to both patients and the outcome assessor.

1.6 Intervention Protocol

Interventions were performed in either home or hospital environments. Standard clinical management was established for both groups, including verbal and written guidance (brochures) regarding latch technique, positioning, comfort pumping, and moist wound healing (using the mother's own breast milk).

PBMT was applied using an InGaAlP laser (660 nm), 3 times a week on alternating days, for up to 15 days (maximum of 7 sessions). The protocol consisted of application in contact mode (90º) after previously cleansing the lesion with 0.9% normal saline. Five points per breast were used: one central point over the lesion and four peripheral points on the areola (spaced 2 cm apart) (Appendix 1). Detailed parameters included: power of 40 mW, energy density of 4 J/cm², and irradiance of 0.4 W/cm², with an exposure time of 10 seconds per point (totaling 50 seconds per session). Biosafety was maintained using disposable PVC wrap on the handpiece and protective goggles. The parameters and management guidelines were developed based on previous studies [4, 14]. Complete dosimetry table (appendix 11).

1.7 Outcome Assessment

- Primary Outcomes:

Pain intensity was measured pre-intervention in all sessions using the Visual Analog Scale (VAS, 0–10). Breastfeeding quality was assessed on the first and last days using the LATCH score (Portuguese-validated version).

- Secondary Outcomes:

Lesion severity was classified in all sessions using the Nipple Trauma Score (NTS, 0–5). Healing was quantified by photogrammetry (Xiaomi Note 11, 50 MP) during sessions 1, 3, 5, and 7. The images, standardized with a caliper for scaling, were analyzed using the Quantikov software, allowing for the automated calculation of the lesion area in mm² via pixel counting (Appendix 2).

- Participant Perception:

At the end of the study, a structured questionnaire was administered to evaluate satisfaction and potential adverse effects.

1.8 Statistical Analysis

Data were organized into spreadsheets and analyzed for normality using the Shapiro-Wilk test. Intragroup comparisons (LATCH) were performed using the Wilcoxon test, while intergroup comparisons were conducted using the Mann-Whitney test or Student's t-test. The progression of trauma (NTS) was analyzed via Two-Way Analysis of Variance (Two-Way ANOVA) with Bonferroni post-hoc test. For longitudinal variables (pain and lesion area), a Mixed-Effects Model was utilized. The significance level was set at 5% ($p < 0.05$), and results were expressed as mean and standard deviation or median (95% CI).

3. Results

3.1 Characteristics of the participants

A total of thirty postpartum women presenting with nipple trauma were sequentially recruited between May and November 2024; however, only 20 participants completed the study due to dropouts or other reasons that limited the study's progression (Fig. 1).

[insert Fig. 1]

Consequently, the final sample consisted of 20 postpartum women residing in the city of Diamantina, with a total of 38 affected breasts (n = 38). Table 1 presents the socioeconomic characteristics of the participants.

Table 1
Participants' characteristics

Variable	PBMT Group (n = 10)	Placebo Group (n = 10)
Age (years)	29.5 (± 5.8)*	32.1 (± 5.1)*
Ethnicity		
White	4 (40%)	2 (20%)
Brown (Parda)	4 (40%)	7 (70%)
Black	1 (10%)	1 (10%)
Asian (Amarela)	1 (10%)	0 (0%)
Educational Level		
Incomplete high school	1 (10%)	0 (0%)
Complete high school	4 (40%)	6 (60%)
Complete higher education	5 (50%)	4 (40%)
Monthly Income		
No income	3 (30%)	1 (10%)
Up to two minimum wages	5 (50%)	7 (70%)
3 to 5 minimum wages	2 (20%)	1 (10%)
More than 5 minimum wages	0 (0%)	1 (10%)
Marital Status		
Married / Stable union	8 (80%)	7 (70%)
Single	2 (20%)	3 (30%)
Number of Children		
Primiparous	8 (80%)	7 (70%)
Multiparous	2 (20%)	3 (30%)
**Mean (± SD), SD: standard deviation, %: percentage. Source: Authors, 2025.*		

[insert Table 1*]*

The obstetric and clinical characteristics of the participants demonstrated high homogeneity between the study groups at baseline (Table 2). All patients in both the PBMT and Placebo groups attended prenatal care, and the vast majority reported having received prior guidance on breastfeeding. Regarding the delivery profile, a cesarean section was the predominant route in both groups (70% each), with mean

gestational ages of approximately 38 weeks. The participants were evaluated during the early postpartum period, presenting a mean time of 5.8 (4.1) days in the active group and 8.5 (4.6) days in the placebo group. Notably, bilateral nipple involvement was the most frequent clinical presentation, affecting 90% of the sample in both groups.

Table 2
Characterization of participants' obstetric clinical data

Variable	PBMT Group (n = 10)	Placebo Group (n = 10)
Prenatal Care		
Yes	10 (100%)	10 (100%)
No	0 (0%)	0 (0%)
Prior Orientation		
Yes	10 (100%)	9 (90%)
No	0 (0%)	1 (10%)
Delivery Type		
Cesarean	7 (70%)	7 (70%)
Vaginal	3 (30%)	3 (30%)
Gestational age (weeks)	38.5 (± 1.3)*	38.7 (± 0.9)*
Postpartum time (days)	5.8 (± 4.1)*	8.5 (± 4.6)*
Infant Sex		
Female	2 (20%)	7 (70%)
Male	8 (80%)	3 (30%)
Birth weight (kg)	3.08 (± 0.427)*	3.07 (± 0.309)*
Affected Nipple		
Both nipples	9 (90%)	9 (90%)
Right nipple only	0 (0%)	1 (10%)
Left nipple only	1 (10%)	0 (0%)
**Mean (± SD), SD: standard deviation, %: percentage. Source: Authors, 2025.*		

[insert Table 2*]*

3.2 Characteristics of the breasts/nipples

Regarding breast and nipple characteristics, flaccid breasts were the most prevalent presentation in both study arms, followed by turgid or engorged breasts (Table 3). Protruding nipples were predominant among the participants, particularly in the Placebo group. In terms of wound classification, excoriation was the most frequent type of injury observed across both groups, followed by isolated fissures. Notably, in both groups, there were patients with lesions affecting only a single breast. Regarding the baseline duration of the lesion, it was identical between the groups, with a mean of 2.6 (1.0) days for the PBMT group and 2.6 (1.1) days for the Placebo group, reflecting a highly synchronized timing of intervention relative to the onset of injury.

Table 3
Breast and nipple characteristics of participants

Variable	PBMT Group (n = 19)	Placebo Group (n = 19)
Breast Condition		
Flaccid	11 (~ 58%)	13 (~ 68%)
Turgid / Engorged	8 (~ 42%)	6 (~ 32%)
Nipple Classification		
Protruded	8 (~ 42%)	13 (~ 68%)
Semi-protruded	7 (~ 37%)	6 (~ 32%)
Pseudo-inverted / Flat	4 (~ 21%)	0 (0%)
Wound Classification		
Fissure	3 (~ 16%)	4 (~ 21%)
Excoriation	13 (~ 68%)	14 (~ 74%)
Fissure and excoriation	3 (~ 16%)	1 (~ 5%)
Lesion duration (days)	2.6 (± 1.0)*	2.6 (± 1.1)*
**Mean (± SD), SD: standard deviation, ~: approximately, %: percentage.*		

[insert Table 3*]*

3.3 Pain

The longitudinal analysis of self-reported pain intensity revealed a progressive and distinct reduction in scores between the study groups over the seven follow-up sessions (Fig. 2, Appendix 3). At baseline (Session 1), mean pain scores were statistically similar, confirming initial sample homogeneity ($p > 0.9999$). Although a slight, non-significant reduction in pain was observed in the PBMT group during the second session, a significantly greater pain relief was achieved in this group by Session 3 ($p = 0.0174$). While intergroup differences did not reach statistical significance during Sessions 4 and 5 ($p = 0.2571$

and p = 0.0799, respectively), a sustained trend toward descriptive pain reduction remained evident in the active group. Statistical significance emerged again at Session 6 (p = 0.0159) and became highly pronounced by Session 7 (p = 0.0006). At this final timepoint, the PBMT group achieved complete pain resolution (mean score = 0.000), whereas the Placebo group still reported residual pain.

[insert Fig. 2*]*

3.4 LATCH

Regarding the quality of breastfeeding, although the PBMT group had lower baseline LATCH scores, it demonstrated a greater numerical improvement after the intervention. However, this result should be interpreted with caution, as baseline imbalance may have influenced the magnitude of the change. Notably, after the intervention, both groups showed improved scores, with the PBMT group outperforming the placebo group, as illustrated in Fig. 3 and Appendix 4.

[insert Fig. 3*]*

3.5 NTS

Moreover, lesion severity was measured using the NTS across seven follow-up sessions (Appendix 5, Appendix 6). In the initial sessions (1 and 2), no statistically significant differences were observed between the arms, with both groups presenting similar clinical means (p > 0.9999). However, from the third session onward, a significantly greater redu

ction in NTS scores was achieved in the PBMT group (p = 0.0002). This pattern of more pronounced and consistent clinical improvement was sustained throughout all subsequent sessions. Notably, the sample size (N) decreased progressively in both groups over time; however, this reduction was sharply accelerated in the PBMT group from the fourth session onward due to early clinical healing (discharge upon complete resolution of the injury). By the seventh session, the PBMT group reached a null mean score (0.000 (0.000); p = 0.0213), representing total lesion resolution for all remaining participants, whereas the Placebo group maintained a residual mean score of 1.000 (0.296).

3.6 Area of the lesion

This study also aimed to evaluate the clinical efficacy of the PBMT device on nipple wound closure. As demonstrated by the longitudinal data in Appendix 7, descriptive analyses showed that the lesion area decreased more rapidly in the PBMT group, with significant within-group reductions between sessions 1 and 3, as well as sessions 1 and 5. However, intergroup comparisons for lesion area did not reach statistical significance, likely due to the small sample size and informative attrition caused by early healing.

In addition, a progressive reduction in lesion area was observed in both study arms across the sessions, reflecting the positive therapeutic impact of both standard care (breastfeeding guidance and the application of breast milk) and photobiomodulation. However, the two groups exhibited distinct kinetic

profiles. The Placebo group displayed a gradual healing trajectory that failed to match the magnitude of tissue repair observed in the active group, maintaining a measurable residual lesion area by the end of the study. Conversely, the PBMT group demonstrated a significantly accelerated and pronounced contraction of the wound surface. This superior performance became evident from the third session onward, with the mean lesion area steadily declining until achieving complete clinical epithelialization by the seventh session, at which point the wound area asymptotically approached zero (0 mm^2).

Furthermore, baseline lesion areas were statistically similar between groups ($p > 0.9999$), confirming initial sample homogeneity (Appendix 8). From the third session onward, the PBMT group displayed a descriptive reduction in mean lesion area and achieved complete wound closure by the end of the follow-up. Although intergroup comparisons at the final sessions did not reach statistical significance ($p > 0.9999$), this was driven by a progressive sample size (N) reduction in the active group; this attrition represents a positive clinical outcome, as participants achieved early healing and were discharged before completing the seven scheduled sessions, whereas the Placebo group required prolonged monitoring. Intragroup analysis confirmed an accelerated early healing rate for the PBMT group, with significant tissue contraction between sessions 1 vs. 3 ($p = 0.0002$) and 1 vs. 5 ($p = 0.0023$) (Appendix 9). The subsequent lack of significance in later sessions reflects both a clinical plateau effect and the reduced sample size from early discharges. Conversely, the Placebo group exhibited a more gradual, smaller contraction, reaching statistical significance only over an extended timeframe (sessions 1 vs. 5; $p = 0.0157$). This contrast supports the role of laser therapy in accelerating tissue repair, while the common clinical management explains the gradual improvement observed in both arms.

3.7 Satisfaction and adverse events

Upon treatment completion, all participants completed a self-perception questionnaire (Appendix 10). The therapeutic approach was overwhelmingly rated as excellent, encompassing 100% of the PBMT group and 90% of the Placebo group. While all participants in both study arms reported pain reduction, 100% of the women in the PBMT group strongly agreed that this relief was directly associated with laser therapy, compared to 70% in the Placebo group. Furthermore, breastfeeding maintenance was successfully achieved by all participants in both groups, with a high proportion of respondents acknowledging the positive influence of the intervention on lactation continuity. Lastly, no adverse effects were reported in the active PBMT group.

4. Discussion

PBMT showed promising effects on pain reduction and tissue repair in this pilot randomized controlled trial. While both groups achieved progressive clinical improvement due to standardized breastfeeding education and correct positioning, the PBMT group exhibited a statistically significant reduction in pain intensity starting from the third session, culminating in complete pain eradication by the seventh session. This rapid, multi-session response corroborates a cumulative therapeutic effect, consistent with previous studies [15, 16].

Mechanistically, while traditional practices like using breast milk offer mild antimicrobial benefits, they lack potent analgesic properties [6, 7]. In contrast, PBMT modulates the inflammatory response, downregulates pro-inflammatory cytokines, and decreases mitochondrial membrane potential to interrupt nociceptive signaling while increasing endogenous beta-endorphins [17]. This robust biochemical action explains the superiority of our multi-session protocol over single-application designs in the literature that failed to detect significant pain reduction [18, 19].

Parallel to pain management, PBMT significantly expedited structural tissue regeneration, with the intervention group requiring substantially fewer clinical sessions (3.3 (1.3)) than the control group (5.4 (1.6)) due to early wound resolution. Intragroup analysis revealed rapid lesion area reduction between the first and third sessions, mirroring cell-culture and animal models where PBMT stimulates keratinocyte and fibroblast proliferation, increases ATP production, and activates the TGF-β signaling pathway to accelerate wound contraction [10, 11, 14]. Our results corroborate previous clinical trials [15, 18, 20] confirming that laser therapy dramatically reduces healing time compared to conventional wet dressing and educational management alone. Although the sample size in the PBMT group decreased in the final sessions due to early discharge, temporarily reducing statistical power, the clinical evidence of faster healing remains evident and consistent.

The clinical relevance of these findings is underscored by a nearly perfect positive correlation found between nipple lesion area, the Nipple Trauma Score, and self-reported pain intensity ($r = 0.985$ in the PBMT group). This strong association confirms that local tissue degradation directly governs maternal discomfort, creating a high-risk scenario for early weaning if left unaddressed [16]. By rapidly improving the LATCH 'Comfort' domain through simultaneous tissue repair and analgesia, PBMT directly enhanced maternal comfort and infant sucking performance. This synergistic clinical improvement acted as a major pillar for maintaining exclusive breastfeeding, validating PBMT not only as a tissue-healing device but as a critical psychological and behavioral intervention that empowers women to sustain lactation despite initial adversity [2, 13, 16, 17].

These positive clinical outcomes were achieved within a baseline sample of young-adult, predominantly primiparous, and sociodemographically vulnerable postpartum women. Sociodemographic and obstetric characteristics, such as maternal age (mean 30.8 (5.6) years), gestational age (38.6 weeks), and newborn birth weight (3,077g), aligned with normal biological baselines and national demographic trends [21]. Crucially, the small age variance between groups had no physiological impact on tissue repair, ensuring baseline comparability since wound-healing mechanisms remain preserved up to approximately 40 years of age [22]. Although international literature suggests that lower maternal education, primiparity, and lighter skin tones increase susceptibility to nipple trauma [23, 24], our data showed a predominance of lesions among brown (mixed-race) women with high school or higher education. This discrepancy highlights that while structural awareness drives educated women to seek advanced therapies like PBMT [25], baseline clinical counseling alone is often insufficient to prevent trauma without continuous, hands-on breastfeeding technique corrections post-birth [2, 4, 6].

Finally, the success of the patient-blinding protocol was supported by the high treatment satisfaction observed in both groups, as even participants in the control arm attributed their gradual improvement to the simulated laser application. Furthermore, no adverse effects were reported. In developing countries such as Brazil, where low-income populations often face barriers to specialized postpartum care, expanding access to this technology may be particularly relevant. Although the *Sistema Único de Saúde* (SUS) (Brazilian Unified Health System) currently reimburses laser therapy only for the management of oral mucositis, our findings support the potential inclusion of PBMT for postpartum nipple trauma within public healthcare policies. The incorporation of this low-cost, evidence-based intervention into primary care services could help reduce socioeconomic disparities in maternal care, promote breastfeeding continuity, and potentially decrease premature weaning rates among vulnerable populations.

4.1 Limitations

Although this study provides valuable insights into the clinical utility of photobiomodulation, several limitations must be acknowledged. First, despite a *priori* sample size calculation indicating a requirement of 74 patients to achieve maximum statistical power, this study was executed as a small-scale exploration pilot trial with a final sample of 20 participants. While this sample provided an 80% statistical power to detect large effect sizes, the small cohort limits the generalizability of the findings to a broader population of lactating women. Second, a progressive reduction in sample size occurred across the follow-up sessions. Although this attrition was driven by a positive clinical outcome, specifically, early wound healing and subsequent discharge of participants in the active PBMT group, the declining number of remaining participants over time reduced statistical power in the final sessions, precluding the detection of significant intergroup differences in lesion area at the end of the study. Lastly, because the trial was restricted to reference centers within a single municipality, the findings may reflect specific local breastfeeding support practices, highlighting the need for multi-center studies with larger, more diverse cohorts to validate these parameters and standardize clinical guidelines

5. Conclusion

In this pilot randomized, double-blind, placebo-controlled trial, 660-nm PBMT associated with standard breastfeeding management showed promising effects on pain reduction, nipple trauma severity, and breastfeeding quality among lactating women with nipple trauma. The findings suggest that PBMT may be a useful adjunctive therapy; however, larger adequately powered trials, with participant-level analyses and standardized dosimetric reporting, are needed to confirm its clinical effectiveness.

Declarations

Competing interests:

No, I declare that the authors have no competing interests or other interests that might be perceived to influence the results and/or discussion reported in this paper.

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Author Contribution

B.H.M.M. and D.M.X. conceived and designed the study, coordinated the clinical interventions, collected and processed the primary data, performed the photogrammetry and statistical analysis, and drafted the main manuscript text. H.C.R. and M.S.F.M. participated in the protocol implementation, baseline clinical evaluations, and data extraction. V.S.B. and M.X.O. provided critical administrative, material, and logistical support, supervised the research project, and performed critical revisions of the manuscript for intellectual content. All authors reviewed, edited, and approved the final version of the manuscript.

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Data Availability

All data supporting the findings of this study are available within the paper and its Supplementary Information.

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Figures

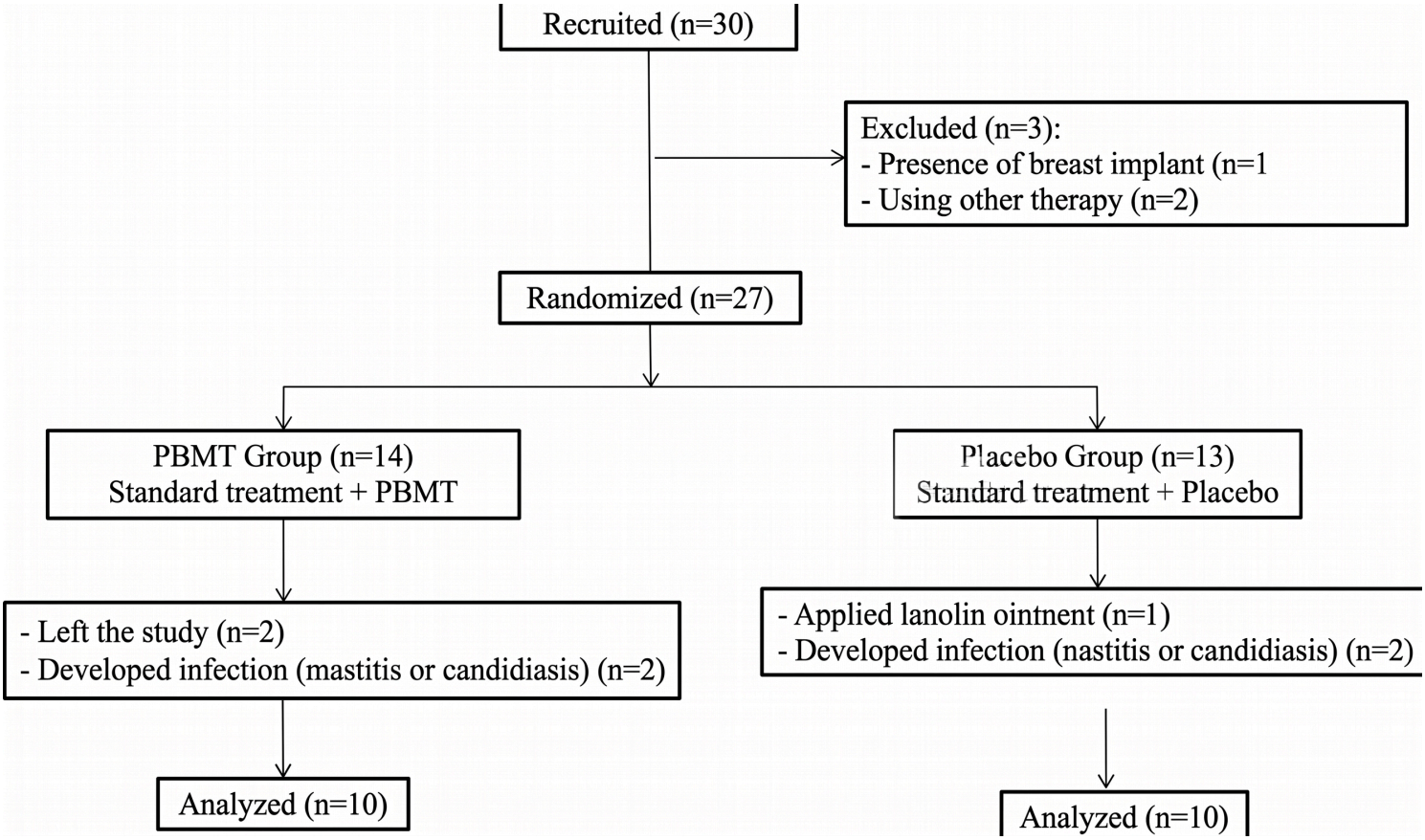

Figure 1

Legend not included with this version

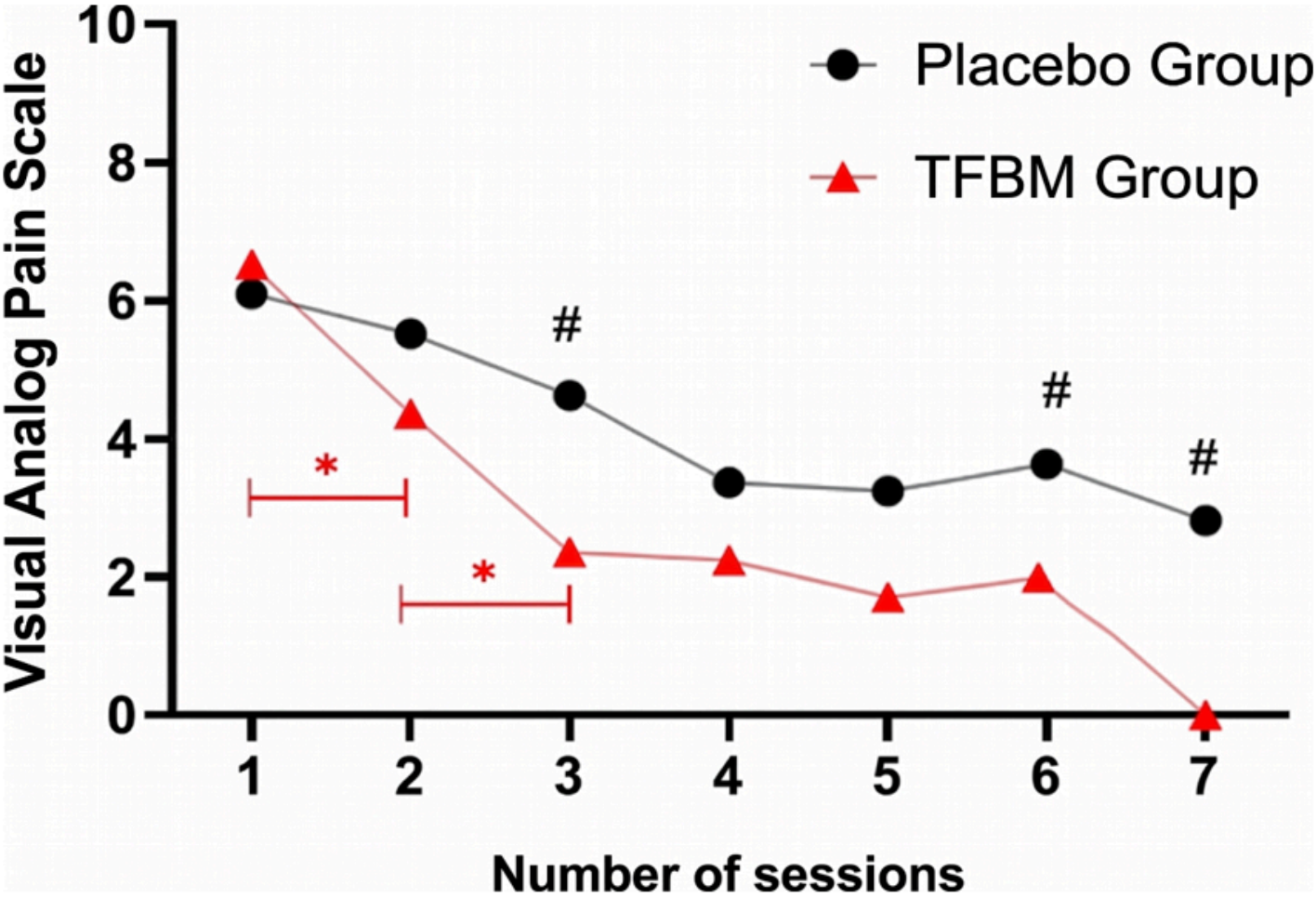

Figure 2

Comparison of pain evolution over time

Legend: # Statistically significant difference between groups. * Statistically significant intragroup difference (comparison between sessions within the group in relation to the previous session; $p<0.005$. Source: Authors, 2025.

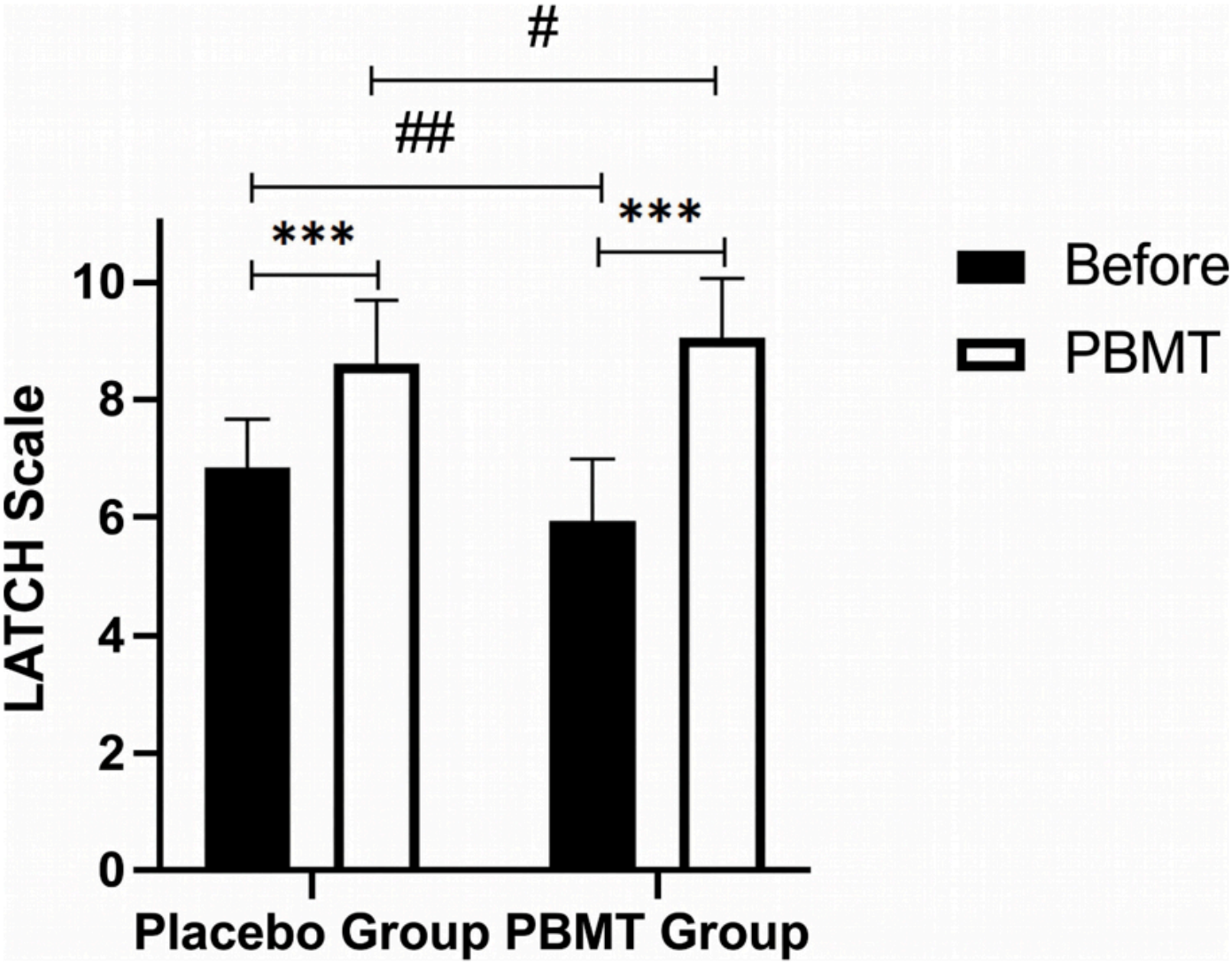

Figure 3

Comparison of the evolution of breastfeeding quality before and after the intervention, assessed by the LATCH scale, in the placebo and TFBM groups

Legend: *Intragroup statistical difference (before and after) # Intergroup statistical difference (before vs. after) Source: Authors (2025)

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Appendix3.docx
- Appendix5.docx
- Appendix4.docx
- APPENDIX1.docx

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