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Early photobiomodulation in nipple pain and injury during breastfeeding: pilot double-blind randomized clinical trial

Fotobiomodulação precoce na dor e lesão mamilar na amamentação: piloto de ensaio clínico randômico duplo-cego

Fotobiomodulación temprana en el dolor y la lesión del pezón durante la lactancia: ensayo clínico piloto aleatorizado, doble ciego

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ABSTRACT

Objective: To verify the feasibility of a randomized clinical trial to test the effects of early photobiomodulation on nipple pain and injury resulting from breastfeeding.

Method: External pilot study for a randomized clinical trial, conducted between June and December 2023. Postpartum women with a gestational age ≥ 37 weeks, admitted to the shared rooms of two maternity hospitals in Paraná, Brazil, were included. Participants were randomly allocated by lottery to Groups: A (local photobiomodulation); B (Intravenous Laser Irradiation of Blood – systemic); C (local and systemic photobiomodulation) or D (control group), received two sessions of the intervention, were followed up in the first month postpartum, and data were collected at five time points.

Results: 58 postpartum women started the study, with a loss to follow-up of 20%. The pilot study reinforced the feasibility of the large-scale clinical trial and allowed for the adaptation of the protocol, the adjustment of the sample estimate, and the standardization of guidelines.
Conclusion: Conducting a large-scale clinical trial is feasible and viable from a methodological and operational standpoint, with the potential to generate robust evidence on the role of photobiomodulation in the early management of nipple pain and injury, contributing to the reduction of maternal distress resulting from pain and injury, and preventing early weaning.
Descriptors: Low-level light therapy; Breastfeeding; Pain management; Wounds and injuries; Nipples.

RESUMO
Objetivo: verificar a viabilidade de um ensaio clínico randômico para testar os efeitos da fotobiomodulação precoce na dor e lesão mamilar decorrentes da amamentação.
Método: Estudo-piloto do tipo externo para ensaio clínico randômico, realizado entre junho e dezembro de 2023. Foram incluídas puérperas com idade gestacional ≥ 37 semanas, internadas nos alojamentos conjuntos de duas maternidades do Paraná, Brasil. As participantes foram alocadas aleatoriamente por sorteio nos Grupos: A (fotobiomodulação local); B (*Intravenous Laser Irradiation of Blood* – sistêmico); C (fotobiomodulação local e sistêmica) ou D (grupo controle), receberam duas sessões da intervenção, foram acompanhadas no primeiro mês pós-parto e os dados coletados em cinco momentos.
Resultados: 58 puérperas iniciaram a pesquisa, com perda de seguimento de 20%. O estudo-piloto reforçou a viabilidade do ensaio clínico de grande escala e possibilitou a adequação do protocolo, o ajuste da estimativa amostral e a padronização das orientações.
Conclusão: a realização do ensaio clínico de grande escala é factível e viável do ponto de vista metodológico e operacional, com potencial para gerar evidências robustas sobre o papel da fotobiomodulação no manejo precoce da dor e lesão mamilar, contribuindo para a redução do sofrimento materno decorrente da dor e lesão, evitando o desmame precoce.
Descritores: Terapia com luz de baixa intensidade; Aleitamento materno; Manejo da dor; Ferimentos e lesões; Mamilos.

RESUMEN
Objetivo: Verificar la viabilidad de un ensayo clínico aleatorizado para evaluar los efectos de la fotobiomodulación temprana en el dolor y las lesiones del pezón derivadas de la lactancia materna.
Método: Estudio piloto externo para un ensayo clínico aleatorizado, realizado entre junio y diciembre de 2023. Se incluyeron mujeres en posparto con una edad gestacional ≥ 37 semanas, ingresadas en habitaciones compartidas de dos maternidades en Paraná, Brasil. Las participantes fueron asignadas aleatoriamente por sorteo a los Grupos: A (fotobiomodulación local); B (Irradiación Láser Intravenosa de Sangre – sistémica); C (fotobiomodulación local y sistémica) o D (grupo control). Recibieron dos sesiones de la intervención, se les realizó seguimiento durante el primer mes posparto y se recopilaron datos en cinco momentos.
Resultados: 58 mujeres en posparto iniciaron el estudio, con una pérdida de seguimiento del 20 %. El estudio piloto reforzó la viabilidad del ensayo clínico a gran escala y permitió la adaptación del protocolo, el ajuste de la estimación de la muestra y la estandarización de las directrices.
Conclusión: Realizar un ensayo clínico a gran escala es factible y viable desde un punto de vista metodológico y operativo, con el potencial de generar evidencia sólida sobre el papel de la fotobiomodulación en el manejo temprano del dolor y las lesiones del pezón, contribuyendo a la reducción del sufrimiento materno derivado del dolor y las lesiones, y previniendo el destete precoz.

Descriptores: Terapia de luz de baja intensidad; Lactancia materna; Manejo del dolor; Heridas y lesiones. Pezones.

INTRODUCTION

Due to its immunomodulatory and protective properties, breastfeeding (BF) has a positive impact on maternal and child health, and its promotion and protection are essential to achieving the World Health Organization's Sustainable Development Goals by 2030[1]. Scientific evidence demonstrates that prolonged BF is associated with a significant reduction in the incidence of moderate to severe respiratory infections, gastrointestinal infections, otitis media, asthma, childhood obesity, allergic rhinitis, type 1 diabetes, and infant mortality[2,3].

Breastfeeding is therefore considered the gold standard food, ideally starting in the delivery room, exclusively until six months and maintained for two years or more[3]. Globally, in 2024, 48% of babies under six months were exclusively breastfed[4]. Brazil, however, presented exclusive breastfeeding (EBF) rates averaging only 45.8% among children under six months, and the median duration of EBF was only three months, according to the report from the National Study of Infant Feeding and Nutrition (ENANI). The goal is to reach 70% EBF by 2030[4,5]. Given the numerous benefits, with increasingly robust evidence demonstrating its importance, it is essential to strengthen public policies and strategies that promote and protect breastfeeding, as well as to foster continuous and updated research on the subject to improve the incidence, especially of EBF[1-4].

However, there are significant predictive factors for breastfeeding interruption, such as pain and nipple injury, common in the first few days postpartum, often caused by inadequate positioning and latch of the infant[6-8]. Pain during breastfeeding can signal the onset of nipple injury that is not yet visible, which, if not identified early, can worsen[8,9]. A Spanish study showed that 97% of 58 breastfeeding mothers experienced nipple pain in the first 48 hours postpartum[10]. A prospective cohort identified that 66.8% of postpartum women presented nipple injury, and nipple pain increased the chance of injury appearing within the first ten days by 59%[11]. A scoping A review published in 2024 investigated the reasons for discontinuation of exclusive breastfeeding and identified in 15 of the 17 studies analyzed that the main factors associated with weaning included nipple pain, nipple injuries, breast engorgement, among others[12].

As this period is critical for establishing breastfeeding, rooming-in is a strategic setting for professional intervention focused on the proper management of breastfeeding. In this regard,

to offer comfort measures to women in the first postpartum days, photobiomodulation (PBM) with low-intensity laser and/or Intravenous Laser Irradiation of Blood (ILIB) associated with clinical care may be effective complementary therapies for pain and injury resulting from breastfeeding, due to their analgesic, anti-inflammatory, and immune response properties[13,14].

Photobiomodulation is characterized by the use of light to modulate biological processes, promoting three main effects: cell regeneration and healing process, with increased cell activity and tissue oxygenation; modulation of the inflammatory process by activating defense cells, and analgesia through blocking the action potential and controlling inflammation, which generates less pain sensation[15].

A systematic review with meta-analysis published in 2025 evaluated seven randomized clinical trials and concluded that PBM is associated with a significant reduction in breastfeeding pain, accelerated healing of nipple fissures, and improved quality of life for breastfeeding mothers[14]. Evidence suggests that PBM has effective results for the treatment of established nipple pain and injury, but research evaluating its effectiveness in early intervention and/or even before the onset of nipple pain and injury is lacking[13,16-18].

From this perspective, the protocol on which this pilot study is based seeks to test the hypothesis that women undergoing early PBM sessions have significantly lower pain scores compared to those who do not receive the intervention.

Pilot studies can be defined as a subset of feasibility studies that specifically analyze a proposed design feature for the main trial, conducted on a smaller scale. For clinical interventions, pilot studies can identify possible adjustments to the intervention or test preliminary study effects[19]. Feasibility assessment is a crucial step in planning a large-scale randomized clinical trial (RCT), particularly when proposing the application of interventions in a healthcare setting.

In the case of photobiomodulation (PBM) applied to breastfeeding, it is necessary to previously evaluate aspects such as acceptability, adherence to the protocol, and the adequacy of the assessment instruments. Thus, the objective of this pilot study is to verify the feasibility of an RCT that aims to investigate the effects of PBM in the early treatment of nipple pain and injury resulting from breastfeeding.

METHOD

Study design

A double-blind, external RCT pilot study conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT)[20] and SPIRIT[21]. Pilot studies are essential for verifying feasibility, selecting appropriate participants, adjusting data collection instruments, assessing protocol adequacy, and obtaining data for sample size calculation[19,22].

Study setting and period

The study was conducted in two maternity hospitals designated as referral centers for low-risk pregnancies and affiliated with the Baby-Friendly Hospital Initiative (BFHI), located in a medium-sized city in Paraná, Brazil, where full-term births predominate. The rooming-in unit was the sector where patients were approached, and the research took place between June and December 2023.

Eligibility criteria

The study population consisted of postpartum women during their postpartum hospitalization period. Inclusion criteria were: patients admitted to the shared rooms of participating maternity hospitals, with a gestational age of 37 weeks or more, who were breastfeeding their babies and had a smartphone for research monitoring. Exclusion criteria were: twin pregnancy; contraindication to breastfeeding; lack of intention to breastfeed; child with clinical conditions that could impair breastfeeding during the research; breast and/or nipple anomalies; contraindications to breast milk production; history of malignant pathology; and photosensitivity before photobiomodulation. Patients who refused to continue the research and those who could not be located for follow-up were considered lost to follow-up.

Recruitment procedures

Led by the main investigator, the recruitment and selection of participants were carried out within the first 24 hours after the baby's birth. Obstetric and perinatal data were evaluated using medical records to verify compliance with the established inclusion criteria. Eligible postpartum women were then approached, at which time the study was presented to them clearly, with an explanation of its objectives and procedures. After agreement and signing of the Informed Consent Form, the procedures for allocation to groups and data collection using a semi-structured instrument began.

Randomization, allocation, and blinding

A collaborator not involved in the study performed an electronic draw to generate an irreproducible list of random numbers in four blocks[23]. To conceal the randomization sequence, opaque, dark-colored, sealed, and numbered envelopes were used, which contained the corresponding allocation groups inside.

Each allocation group received a specific intervention: Group A: Local PBM; Group B: Transcutaneous ILIB; Group C: Both interventions (Local PBM + ILIB); and Group D: Control (placebo for local PBM with inactivated equipment).

The postpartum women and the data analyst were blinded and had no knowledge of whether the device was active or a placebo; only the recruiters and researchers knew about it. Both devices used were of the same model and manufacturer and identical in their characteristics, ensuring randomization and blinding of the participants. One of them had been previously modified by the manufacturer's clinical engineering department so that it would not emit radiation for treatment.

Implementation of the intervention

The intervention consisted of applying two sessions of PBM with low-intensity laser, with an average interval of 24 hours between sessions, in the four groups, according to randomization, along with guidance on the management of BF.

Identical low-power devices were used, with an infrared wavelength of 880nm and a red wavelength of 660nm. Both were identified with labels A and B, the latter being the placebo device.

The dosimetry, application points and therapy time used in this study were defined based on technical recommendations and clinical protocols, combined with the knowledge and expertise of the researchers[24].

The researchers responsible for applying the PBM have a background in nursing and were trained and qualified by the principal researcher to perform the technique and data collection procedures.

Initially, 4J of infrared light was applied to three points near the axillary lymph node network to promote photoactivation and lymphatic drainage. Then, 4J of infrared light was applied to the four cardinal points around the areola, perpendicularly and in contact with the skin, for analgesia, followed by 4J of red light in the center of the nipple or lesion, in a punctual manner, perpendicularly and in contact with the skin, totaling 10 seconds per joule.

In transcutaneous ILIB procedure, infrared light was used in the "ILIB 2 mode" configuration, applied through a specific wristband on the participant's wrist, directing the light to the radial artery, for 30 minutes.

The participants were followed up during the first month postpartum, and data were collected at five time points: within the first 24 hours after delivery; between 6 and 12 hours after the first application of the PBM, via WhatsApp or phone call; on the 2nd day postpartum,

before discharge; between 7 and 10 days postpartum, via WhatsApp or phone call; and between 30 and 35 days postpartum, also via WhatsApp or phone call.

At Moment 1 (M1), after recruitment, selection and acceptance of participants, information regarding sociodemographic, obstetric and perinatal data was collected, and opportunely, the researcher asked the postpartum woman to put the baby to the breast. The participants were observed during breastfeeding and received similar, detailed and systematized guidance on breastfeeding management. The LATCH instrument[25], used to assess the performance of the mother and baby during breastfeeding, was completed during observation, and nipple pain was assessed using the Numerical Verbal Scale (NVS)[26].

After breastfeeding, participants underwent the first PBM session according to the allocation group. Subsequently, in the presence of nipple injury, assessment and classification were carried out using the Nipple Trauma Score (NTS)[27]. Fifteen minutes after the end of the therapy, the postpartum woman was again asked about the intensity of the pain at that moment, using the NVS.

At Moment 2 (M2), via telephone, questions were asked about the intensity of the pain and the response time regarding pain improvement after laser application.

Phase 3 (M3) followed the same approach as M1 and included assessment of breastfeeding using the LATCH scale, pain assessment with the numerical verbal scale (NVS) during breastfeeding, **a** second session of photobiomodulation (PBM), followed by classification using the National Stroke Test (NST), and, in the presence of injury, NVS 15 minutes after PBM. Finally, an assessment of maternal self-efficacy for breastfeeding was added using the Breastfeeding Self-Efficacy Scale – Short Form (BSES-SF)[28]. The use of this scale allows professionals to identify the weaknesses in self-efficacy and confidence of postpartum women to breastfeed, enabling the implementation of care and breastfeeding promotion strategies, which can help reduce early weaning rates[28].

In the fourth phase (M4), participants were asked via telephone about possible additional interventions used in the period after discharge up to 7 to 10 days postpartum, the type of feeding the baby received, and the existence of injuries and/or pain.

At Moment 5 (M5), also by telephone, questions were asked regarding the type of feeding the baby was receiving at 30 days of age; occurrence of weaning; persistence of nipple pain and appearance of nipple lesions between the fourth and fifth moments.

During the contacts made at M4 and M5, if the participants reported difficulties, persistent pain, continued nipple injury, or any other breastfeeding-related issue, the researchers offered initial guidance by telephone and, when necessary, the postpartum women were referred

to the Human Milk Bank of Universidade Estadual de Londrina for evaluation and follow-up, to ensure continuing breastfeeding.

Table 1 presents the outline of the interventions carried out in the pilot study.

Table 1 - Diagram of the interventions planned in the study. Londrina, Paraná, Brazil, 2025

PROCEDURES				
Moment 1 (<24 hours) (postpartum)	**Phase 2** (6 - 12 h) after PBM)	**Moment 3** (2nd day) (postpartum)	**Stage 4** (7-10 days) (postpartum)	**Stage 5** (30-35 days) (postpartum)
Allocation within the Group ⬇ Assessment of breastfeeding (LATCH*), guidance and assessment of pain (NVS**) ⬇ Application of the intervention (depending on the group) ⬇ Nipple injury classification (NTS***) ⬇ Pain assessment (NVS**) 15 minutes after the intervention	Telephone contact ⬇ Pain assessment (NVS**)	Assessment of breastfeeding (LATCH*), guidance and assessment of pain (NVS**) ⬇ Application of the intervention (depending on the group) ⬇ Nipple injury classification (NTS***) ⬇ Self-efficacy assessment (BSES-SF****) ⬇ Pain assessment (VAS**) 15 minutes after the intervention	Telephone contact ⬇ Evolution of pain/injury. Interventions performed.	Telephone contact ⬇ Assessment of infant feeding, pain, and nipple injury.

Source: Authors, 2025
*LATCH = Tool for assessing performance during breastfeeding[25]
**NVS = Numerical Verbal Scale of Pain[26]
***NTS = Nipple Trauma Score[27]
****BSES-SF = *Breastfeeding Self-Efficacy Scale – Short Form*[28]

Outcomes assessed

The primary outcome was the incidence rate of pain and the intensity of nipple pain measured by the VAS (Visual Analogue Scale). The secondary outcome was the incidence rate of nipple injury.

Sample size calculation

As this is a pioneering RCT for evaluating early PBM in nipple pain and injury, a sample size calculation for clinical trials with multiple arms was performed to test the hypothesis of this study[29]. For the calculation, the intensity of pain after the PBM session was used as the baseline parameter, with a significance level of 5% ($\alpha = 0.05$) and a study power of 98% ($1 - \beta = 0.98$), considering three arms ($k=3$), which will be compared to the control group, with an allocation rate between groups equal to 1. As one of the admitted hypotheses is that Group C is superior to the others, a mean and standard deviation corresponding to one point below the best treatment were considered. For this group, a mean of 2.74 and the respective standard deviation for this intervention were assumed, in addition to a dropout rate of 30%. Thus, the estimated sample was 59 patients per group, totaling 236 participants in the RCT itself. For this pilot study, a sample of approximately 25% of the main study sample was chosen, totaling 59 postpartum women. Because this is an external pilot study, the data obtained will not be used in the main RCT.

Study variables

The variables planned for this pilot study were examined and evaluated as described in Table 2:

Table 2 - Variables of the pilot study. Londrina, Paraná, Brazil, 2025

Variables	Categories	Source	Nature
Baseline			
Maternal age	-	Interview	Discreet
Marital status	Without a partner; with a partner	Interview	Nominal
Education (years)	<8; ≥ 8	Interview	Ordinal
Family income (minimum wage)	≤ 2; >2	Interview	Ordinal
Maternal occupation	Paid work; homemaker	Interview	Nominal
Previous pregnancy(ies)	No; yes	Medical Record	Nominal
Number of prenatal visits	<6 queries; ≥ 6 queries	Medical Record	Ordinal
Delivery method	Vaginal; Cesarean section	Medical Record	Nominal
She received guidance on breastfeeding during prenatal care.	Yes; no	Interview	Nominal
She performed nipple preparation during prenatal care.	Yes; no	Interview	Nominal

Gestational age	37s to 38s6d; 39s to 41s6d	Medical Record	Ordinal
Apgar ≥ 7 in 5 minutes	Yes; no	Medical Record	Nominal
Birth weight	Ordinal number	Medical Record	Discreet
Skin-to-skin contact was established within the first hour of life.	Yes; no	Interview	Nominal
BF in the first hour of life	Yes; no	Interview	Nominal
Previous breastfeeding	Yes; No/Not applicable	Interview	Nominal
Nipple pain in previous breastfeeding	Yes; No/Not applicable	Interview	Nominal
Nipple injury in previous breastfeeding	Yes; No/Not applicable	Interview	Nominal
LATCH scale note*	Ordinal Number (0-10)	Interview	Discreet
Presence of pain**	No; yes	Interview	Nominal
Rating of pain intensity at the moment the baby latches on**	None; mild; moderate; intense	Interview	Ordinal
NTS nipple trauma score***	Score 0; score 1; score 2; score 3; score 4; score 5	Interview	Ordinal
Outcomes			
M1^			
Presence of pain	No; yes	Interview	Nominal
Rating of pain intensity at the moment the baby latches on.	None; mild; moderate; intense	Interview	Ordinal
Presence of nipple lesion	No; yes	Interview	Nominal
M2^^			
Presence of pain**	No; yes	Interview	Nominal
Rating of pain intensity at the moment the baby latches on	None; mild; moderate; intense	Interview	Ordinal
Pain relief after the interventions were applied.	No; yes	Interview	Nominal
M3^^^			
Presence of pain**	No; yes	Interview	Nominal
Rating of pain intensity at the moment the baby latches on.	None; mild; moderate; intense	Interview	Ordinal
Presence of nipple lesion	No; yes	Interview	Nominal
Scale rating *Breastfeeding Self-Efficacy Scale – Short Form*****	Ordinal number (score 14-70)	Interview	Discreet
Rating of pain intensity at the moment the baby latches on**	None; mild; moderate; intense	Interview	Ordinal
Presence of nipple lesion	No; yes	Interview	Nominal
M4^^^^			
Presence of pain**	No; yes	Interview	Nominal
Rating of pain intensity at the moment the baby latches on.	None; mild; moderate; intense	Interview	Ordinal
Presence of nipple lesion	No; yes	Interview	Nominal
EBF	No, yes	Interview	Nominal
M5^^^^^			
EBF	No; yes	Interview	Nominal

Source: Authors, 2025

*LATCH = Tool for assessing performance during breastfeeding[25]
**Measured by the NVS = Numerical Verbal Scale of pain[26]
***NTS = Nipple Trauma Score[27]
****BSES-SF = *Breastfeeding Self-Efficacy Scale – Short Form*[28]
^M1= Moment 1: first 24 hours postpartum
^^M2 = Moment 2: 6 - 12 hours after PBM
^^^M3 = Moment 3: 2nd day postpartum
^^^^M4 = Moment 4: 7-10 days postpartum
^^^^^ M5: Moment 5: 30-35 days postpartum

Statistical analysis

The data obtained in the pilot study were archived in the Open Data Kit (ODK) program and transferred for statistical analysis at the Package for the Social Sciences (SPSS), version 22.0. Initially, the Shapiro-Wilk test was applied to verify the normality of the quantitative variables. Subsequently, descriptive statistics were used, with measures of central tendency (mean and standard deviation) for variables with normal distribution and 25th (P25) and 75th (P75) percentiles for skewed distributions, in addition to absolute (n) and relative (%) frequencies for qualitative variables.

For comparison between groups regarding baseline and follow-up characteristics, Fisher's exact test was used for qualitative variables and one-way analysis of variance (ANOVA) or the Kruskal-Wallis test for quantitative variables, according to the data distribution, adopting a significance level of 5% (p -value < 0.05).

Ethical considerations

The project was approved by the Research Ethics Committee (CEP) of the State University of Londrina (Protocol No. 5.673.715; CAAE 63168922.0.0000.5231). All participants signed the Informed Consent Form (TCLE) and, when under 18 years of age, the assent form, concurrently with obtaining the consent of their legal guardian. The researchers signed a confidentiality and non-disclosure agreement.

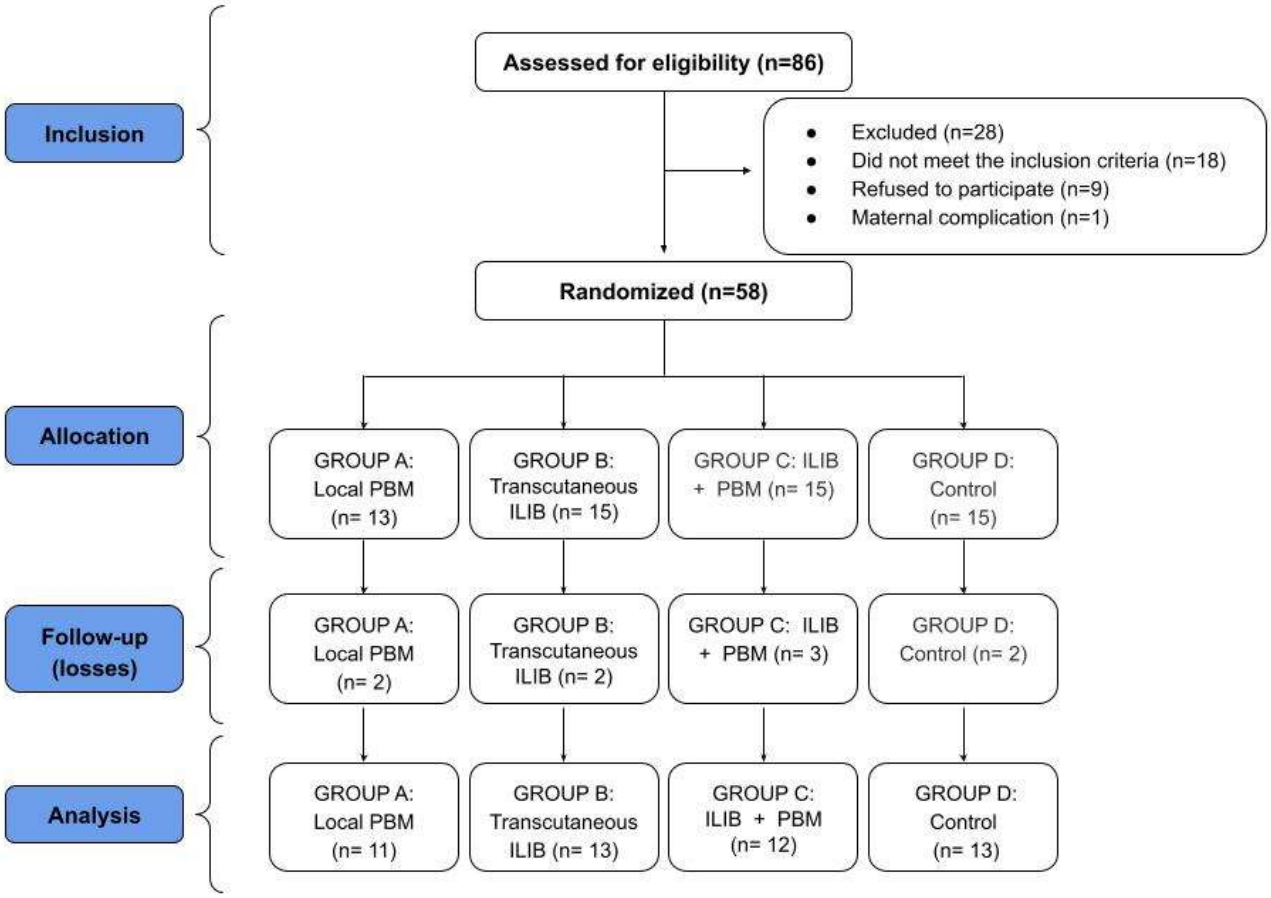
The RCT was registered in the Brazilian Registry of Clinical Trials database (ReBEC), under number RBR-2bzty9v, published on 12/19/2023.

RESULTS

The results of this pilot study are expected and aimed to evaluate the feasibility of the pre-defined protocol for the intervention, adjust the data collection instrument, estimate recruitment, acceptability, and possible reformulations of the intervention.

A total of 59 postpartum women started the pilot study after obtaining consent, with 34 (58.6%) from Institution A and 25 (41.4%) from Institution B; one postpartum woman required care during the approach, before allocation, and was unable to continue in the study. There were a total of 13 patients in Group A, and 15 in each of Groups B, C, and D, respectively. The study flowchart according to CONSORT[20] with the follow-up of participants at each stage of the study is described in Figure 1.

Figure 1 - Explanatory flowchart of the study according to the CONSORT tool. Londrina, Paraná, Brazil, 2025



Source: Authors, 2025

The postpartum women were on average 27.4 (±6.7) years old, 31 (53.4%) self-identified as white, 27 (46.5%) as brown/black, and 43 (74.2%) postpartum women had a partner at the time of the approach.

Regarding education, 57 (98.3%) had at least 8 years of schooling, 24 (41.4%) were homemakers, and 34 (58.6%) were employed. Table 1 presents the obstetric and perinatal

variables among the analyzed groups, highlighting the similarity between them at the beginning of the study. Regarding demographic, obstetric, and perinatal variables, the groups were homogeneous.

Table 1 - Frequency and proportion of obstetric and perinatal variables among the groups. Londrina, PR, Brazil, 2025

Variables	**Groups**					***p*** **- value**
	Total	**Group A**	**Group B**	**Group C**	**Group D**	
Maternal age (years) Median	27.0	24.0	27.0	30.0	32.0	0.343 [a]
P25−P75	21.0 - 33.0	19.0 - 30.0	21.0 - 31.0	23.0 - 33.5	21.0 - 35.0	
Marital status, n (%) No partner	15 (25.9)	4 (30.8)	5 (33.3)	2 (13.3)	4 (26.7)	0.649 [b]
With partner	43 (74.1)	9 (69.2)	10 (66.7)	13 (86.7)	11 (73.3)	
Education (years), n (%) <8	1 (1.7)	1 (7.7)	0	0	0	0.224 [b]
≥ 8	57 (98.3)	12 (92.3)	15 (100.0)	15 (100.0)	15 (100.0)	
Household income (MW), n (%) ≤ 2	34 (58.6)	11 (84.6)	6 (40.0)	6 (40.0)	11 (73.3)	0.029 [b]
>2	24 (41.4)	2 (15.4)	9 (60.0)	9 (60.0)	4 (26.7)	
Maternal occupation, n (%) Paid work	34 (58.6)	6 (46.2)	7 (46.7)	9 (60.0)	12 (80.0)	0.208 [b]
From home	24 (41.4)	7 (53.8)	8 (53.3)	6 (40.0)	3 (20.0)	
Previous pregnancy (ies), n (%)	37 (63.8)	7 (53.8)	11 (73.3)	10 (66.7)	9 (60.0)	0.798 [b]
Number of prenatal consultations, n (%) <6	3 (5.2)	1 (7.7)	0	0	2 (13.3)	0.300 [b]
≥6	55 (94.8)	12 (92.3)	15 (100.0)	15 (100.0)	13 (86.7)	
Route of delivery, n (%) Cesarean	29 (50.0)	7 (53.8)	8 (53.3)	6 (40.0)	8 (53.3)	0.909 [b]
Vaginal	29 (50.0)	6 (46.2)	7 (46.7)	9 (60.0)	7 (46.7)	
Received guidance on BF during prenatal care, n (%)	14 (24.1)	2 (15.4)	2 (13.3)	7 (46.7)	3 (20.0)	0.155 [b]
Did nipple preparation during prenatal care, n (%)	17 (29.3)	2 (15.4)	4 (26.7)	6 (40.0)	5 (33.3)	0.574 [b]
Previous breastfeeding, n (%)	30 (51.7)	6 (46.2)	9 (60.0)	8 (53.3)	7 (46.7)	0.937 [b]
Nipple pain in previous breastfeeding, n (%)	27 (46.6)	5 (38.5)	7 (46.7)	8 (53.3)	7 (46.7)	0.861 [b]

Nipple injury in previous breastfeeding, n (%)	28 (48.3)	5 (38.5)	8 (53.3)	8 (53.3)	7 (46.7)	0.827 [b]
Gestational age, n (%)						
37w to 38w 6d	21 (36.2)	4 (30.8)	6 (40.0)	5 (33.3)	6 (40.0)	0.948 [b]
39w to 4w 6d	37 (63.8)	9 (69.2)	9 (60.0)	10 (66.7)	9 (60.0)	
Apgar ≥7 in the 5th minute, n (%)	58 (100.0)	13 (100.0)	15 (100.0)	15 (100.0)	15 (100.0)	[c]
Birth weight (grams)						
Average	3.303.4	3.372.1	3,143.1	3.212.9	3.494.8	0.153 [d]
Standard deviation	461.4	513.6	503.7	350.4	428.9	
Skin-to-skin contact was established within the first hour of life, n (%)	37 (63.8)	8 (61.5)	11 (73.3)	10 (66.7)	8 (53.3)	0.735 [b]
BF in the first hour of life, n (%)	23 (39.7)	4 (30.8)	4 (26.7)	7 (46.7)	8 (53.3)	0.418 [b]
LATCH scale note						
Median	1.0	1.0	1.0	2.0	1.0	0.508 [a]
P25−P75	1.0 - 2.0	1.0 - 2.0	1.0 - 2.0	1.0 - 2.0	1.0 - 1.5	
Presence of nipple lesion, n (%)	24 (41.4)	8 (61.5)	9 (60.0)	9 (60.0)	9 (60.0)	1.000 [b]
Presence of pain, n (%)	35 (60.3)	7 (53.8)	10 (66.7)	8 (53.3)	9 (60.0)	0.935 [b]
Rating of pain intensity at the moment of baby's latch, n (%)						
None	23 (39.7)	5 (38.5)	6 (40.0)	6 (40.0)	6 (40.0)	0.377 [b]
Light	12 (20.7)	1 (7.7)	5 (33.3)	3 (20.0)	3 (20.0)	
Moderate	12 (20.7)	2 (15.4)	4 (26.7)	4 (26.7)	2 (13.3)	
Intense	11 (19)	5 (38.5)	0	2 (13.3)	4 (26.7)	

Source: Authors, 2025

BF: Breastfeeding; SD: Standard deviation; Group A (n=13): PBM; Group B (n=15): ILIB; Group C (n=15): PBM + ILIB; Group D (n=15): Control; P25: 25th percentile; P75: 75th percentile; MW: Minimum wages; [a]Kruskal-Wallis test; [b]Fisher's exact test; *c*Estimate not generated due to the presence of zeros in the Apgar <7 categories ; [d] One -way analysis of variance (ANOVA).

The presence of nipple pain was constant throughout, peaking at M3, where 75.9% of patients reported some type of pain, demonstrating the relevance of the topic and the need for future research. In the first 24 hours after birth, 41.4% of patients already presented with nipple lesions, which was extremely important for maintaining and adjusting the red laser treatment due to its properties in healing and improving inflammation of lesions.

In the fourth month (M4), 55.1% of postpartum women reported nipple pain and 32.7% presented with lesions at the time of telephone contact. Regarding the rate of exclusive breastfeeding, from the seventh to the thirtieth day postpartum there was a 21.2% decrease in exclusive breastfeeding.

Table 2 presents the possible variables to be analyzed as outcomes in the RCT. Regarding the variables of interest, it was necessary to adjust the discrete variable VAS (Visual Analogue Scale) so that we could calculate the average pain in the RCT, which was not possible in this pilot study.

Table 2 - Frequency and proportion of outcome variables among the groups to be analyzed in the RCT. Londrina, Paraná, Brazil, 2025

Variables	Groups					*p* - value
	Total	Group A	Group B	Group C	Group D	
M1 (n=58)						
Presence of pain, n (%)	8 (13.8)	4 (30.8)	2 (13.3)	0	2 (13.3)	0.113[a]
Rating of pain intensity at the moment of baby's latch, n (%)						
None	50 (86.2)	9 (69.2)	13 (86.7)	15 (100.0)	13 (86.7)	0.113[a]
Light	0	0	0	0	0	
Moderate	8 (13.8)	4 (30.8)	2 (13.3)	0	2 (13.3)	
Intense	0	0	0	0	0	
Pain improvement after the interventions, n (%)	35 (60.3)	8 (61.5)	7 (46.7)	4 (73.3)	6 (40.0)	0.534[a]
M2 (n=55)						
Presence of pain, n (%)	39 (70.9)	8 (72.7)	9 (60.0)	12 (85.7)	10 (66.7)	0.507[a]
Rating of pain intensity at the moment of baby's latch, n (%)						
None	16 (29.1)	3 (27.3)	6 (40)	2 (14.3)	5 (31.2)	0.408[a]
Light	16 (29.1)	1 (9.1)	4 (26.7)	7 (50.0)	4 (26.7)	
Moderate	17 (30.9)	5 (45.5)	5 (33.3)	3 (21.4)	4 (26.7)	
Intense	6 (10.9)	2 (18.2)	0	2 (14.3)	2 (13.3)	
M3 (n=58)						
Presence of pain, n (%)	44 (75.9)	8 (61.5)	9 (60.0)	13 (86.7)	14 (93.3)	0.073[a]
Rating of pain intensity at the moment of baby's latch, n (%)						
None	14 (24.1)	5 (38.5)	6 (40.0)	2 (13.3)	1 (6.7)	0.063[a]
Light	13 (22.4)	1 (7.7)	4 (26.7)	7 (46.7)	4 (26.7)	
Moderate	16 (27.6)	2 (15.4)	4 (26.7)	7 (46.7)	3 (20.0)	
Intense	15 (25.9)	5 (38.5)	1 (6.7)	2 (13.3)	7 (46.7)	
Presence of nipple lesion, n (%)	18 (31.0)	3 (23.1)	8 (53.3)	4 (26.7)	3 (20.0)	0.227[a]
M4 (n=49)						
Presence of pain, n (%)	27 (55.1)	8 (72.7)	6 (46.2)	6 (50.0)	7 (53.8)	0.637[a]
Rating of pain intensity at the moment of baby's latch, n (%)						
None	22 (44.9)	3 (27.3)	7 (53.8)	6 (50.0)	6 (46.2)	0.254[a]
Light	6 (12.2)	0	3 (23.1)	2 (16.7)	1 (7.7)	
Moderate	12 (24.5)	3 (27.3)	3 (23.1)	3 (25.0)	3 (25.1)	
Intense	9 (18.4)	5 (45.5)	0	1 (8.3)	3 (23.3)	

Presence of nipple lesion, n (%)	16 (32.7)	7 (63.6)	2 (15.4)	4 (33.3)	3 (23.1)	0.080[a]
EBF, n (%)	40 (81.6)	10 (90.9)	10 (76.9)	10 (83.3)	10 (76.9)	0.853[a]
M5 (n=48)						
EBF, n (%)	29 (60.4)	7 (58.3)	7 (58.3)	7 (63.6)	8 (61.5)	1.000[a]

Source: Authors, 2025
Group A: PBM; Group B: ILIB; Group C: PBM + ILIB; Group D: Control.
Fisher 's exact test .

Regarding the feasibility of the study, several items were verified and adjusted in the RCT protocol. The first of these related to the acceptability of participation and interventions. When approached, 13.4% of the women refused to participate in the research, even after a thorough explanation and offer of laser treatment and assistance in managing BF.

A 20% loss to follow-up was observed throughout the monitoring period, particularly during telephone contact, resulting in a final sample of 48 postpartum women in the 5th month (M5). To address this, we adjusted the protocol, stipulating that patients would be contacted at least three times via WhatsApp, and if no response was received, three phone calls would be attempted.

Regarding the sample size estimate, we justify, due to losses to follow-up in this pilot study, the 25% increase in the sample size calculation performed for the larger-scale RCT; therefore, our sample will consist of 300 postpartum women.

We standardized and unified the guidelines related to BF, and in the training of the data collection support staff, we calibrated the instrument so that everyone used the same language and approach with the patients, in order to reduce potential biases and facilitate adherence to the research.

There was a need to change the protocol regarding the dosimetry used for the red laser. The company supplying the device has a protocol that recommends the use of 6J of red laser for nipple lesions, but, based on other protocols and the researchers' experience, we maintained 4J[24,30]. However, some patients reported discomfort during the laser treatment, referring to a sensation of warmth and shock-like pain. We contacted the company, which maintained its protocol guidelines. The devices were then sent for preventive maintenance and were deemed suitable for use. Considering the discomfort reported by some women, we changed the protocol to apply 2J of red laser to the center of the nipple and/or lesion, with a 1cm distance in case of discomfort.

DISCUSSION

The findings of this pilot study indicate that the proposed design is methodologically and operationally feasible, contributing to an increased likelihood of success in conducting a larger-scale RCT. The experience gained from recruitment, intervention application, and participant follow-up allowed for the identification of key aspects for refining the final protocol and data collection instruments, especially in this specific healthcare context.

Studies highlight that pilot trials are fundamental to evaluating aspects such as recruitment, adherence, intervention logistics and adequacy of outcomes before the implementation of definitive RCTs, reducing methodological risks and waste of resources in larger studies[19].

Regarding the acceptability of participation, evidence suggests that the timing of the invitation, the clarity of the information provided, and the way in which the potential benefits and burdens of the study are presented directly influence women's decision to participate in clinical trials, particularly in the postpartum period, characterized by greater physical and emotional vulnerability. Elements such as the time commitment required and the duration of follow-up can be perceived as burdensome, while understanding the potential benefits of the research tends to favor adherence[31]. In this sense, the recruitment rate observed in this pilot study reinforces the feasibility of expanding the sample in a future RCT, provided that sensitive outreach strategies and clear communication are maintained.

National and international literature recognizes nipple pain in the first days of breastfeeding as an important predictive factor for the development of nipple lesions and for the early interruption of exclusive breastfeeding[7,10,27]. Although inadequate breastfeeding management is frequently cited as a central cause of nipple pain and trauma[9,10], many studies do not control variables from the beginning of breastfeeding nor use standardized measurement instruments, which limits the elucidation of the causal relationship between pain, injury, and breastfeeding outcomes[7,10,32]. The present pilot study addresses this scenario by proposing an early intervention, integrated into breastfeeding management, during a critical period for the establishment of exclusive breastfeeding.

Low-level laser biopsy (LLB) has been investigated internationally for its effects on tissue regeneration, modulation of the inflammatory process, and analgesia, establishing itself as a non-invasive technology with relatively low cost and potential clinical applicability[17]. Previous randomized clinical trials have demonstrated positive effects of LLB in the treatment of pain and established nipple injury, in interventions similar to those employed in this study [16-18] . However, relevant gaps remain regarding the standardization of application parameters

and the evaluation of the combined use of local LLB and ILIB in the immediate postpartum period, early on.

In this pilot study, the rate of exclusive breastfeeding (EBF) fell from 81.6% to 60.4% between the tenth and thirtieth day of the baby's life, which reinforces the findings of another study in which moderate/high intensity pain increased the risk of early EBF interruption (before 30 days of the baby's life) by 77% when compared to patients who reported mild pain [6]. This data reinforces the clinical relevance of therapeutic strategies aimed at early pain control, with potential impact on maintaining breastfeeding.

The absence of statistically significant differences between the groups regarding clinical outcomes should be interpreted in light of the pilot study design, whose main objective was to evaluate the feasibility of the protocol, not the efficacy of the intervention. The small sample size limits the statistical power to detect therapeutic effects, an aspect that will be adequately addressed in the larger-scale clinical trial, with sample size calculation based on the data obtained in this study.

Regarding reports of discomfort during PBM application, only one study[17] identified that women who received laser treatment reported a tingling sensation; the other studies did not evaluate this outcome. We therefore reinforce the adjustment in dosimetry for the larger-scale study.

Among the limitations, the small sample size, the short follow-up period, and the fact that the study was conducted in a single healthcare setting stand out, factors that may limit the generalizability of the findings. Furthermore, although blinding strategies were adopted, the nature of the intervention may have influenced the participants' perceptions. Even so, such limitations are inherent to pilot studies and do not compromise their main contribution, which is to provide evidence on the feasibility, acceptability, and operationalization of a future RCT.

Thus, the standardization of the PBM protocol tested in this pilot study represents a relevant contribution to the planning of a definitive RCT, with the potential to generate robust evidence to support nursing practice in the care of lactating women, both nationally and internationally.

CONCLUSION

This pilot study addressed the objective of evaluating the feasibility of a randomized clinical trial on the effects of photobiomodulation in the early treatment of nipple pain and injury resulting from breastfeeding. The results demonstrated that the proposed design is feasible from a methodological and operational standpoint, evidenced by satisfactory

recruitment, acceptability of the intervention, and the possibility of implementation in the context of rooming-in. The data obtained provided important input for refining the protocol and data collection instrument, defining the sample size calculation, and organizing the logistics of a larger-scale clinical trial.

It is concluded that conducting a large-scale randomized clinical trial is feasible and scientifically justified, with the potential to generate robust evidence on the role of photobiomodulation in the early management of nipple pain and injury, contributing to the improvement of nursing care for breastfeeding women, reducing maternal suffering resulting from pain and injury, preventing early weaning, and increasing breastfeeding rates.

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Availability of data and material
Access to the dataset may be obtained by requesting it from the corresponding author.

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